

PME

PHARMACEUTICAL MARKET EUROPE

ASCO Quality Care Symposium p20

Celebrating the 2020 PMEAs! p24

Unlocking the potential of precision medicine

Janssen's drive to provide personalised cancer care





OPEN HEALTH

A family of global expert practices, working in partnership to drive positive change in healthcare communications & market access.

Medical Communications | Patient & Brand Communications | Value, Informatics & Evidence

Get in touch to learn more about OPEN Health and what we could do for you.

www.openhealthgroup.com



Keep up to date with the latest developments in the UK and global healthcare marketplace – sign up to daily or weekly news alerts and fortnightly or monthly bulletins on specific topics at www.pmlive.com/register

THE TEAM

Editorial:

Group Managing editor Iona Everson
Reporter Lucy Parsons

Studio:

Executive director Karl Equi
Middleweight graphic designer Helen Penfold

Sales:

Business director Tara Lovegrove

EDITORIAL ADVISORY BOARD

Philip Atkinson

Founder of Hive-Logic, Lifescience Transformation

Uday Bose

Corporate vice president, head of global marketing oncology, Boehringer Ingelheim

Dr Luc Hermans

VP commercial planning and operations Europe, Asia, Middle East, Gilead Sciences

Stefan Janssens

President EMEA, Cegedim Dendrite

John Morris

Partner, KPMG

Paul Pay

Chief business development officer, Norgine

Mark Rothera

Chief executive officer, Orchard Therapeutics

Ian Talmage

Senior vice president, global marketing, general medicine, Bayer Pharmaceuticals

PUBLISHED BY

PMGroup

Mansard House, Church Road,
Little Bookham, Surrey, KT23 3JG, UK

Tel: +44 (0)1372 414200

Fax: +44 (0)1372 414201

CONTACT US

General enquiries: info@pmlive.com

Editorial: editor@pmlive.com

Advertising: sales@pmlive.com

Subscriptions: subscriptions@pmlive.com

Views expressed by the contributors do not necessarily represent those of the publisher, editor or staff.

© 2020 PMGroup

All rights reserved. No part of this publication may be copied, reproduced, transmitted, photocopied, recorded or stored on any retrieval system without the prior written consent of the publishers.

The magazine is also available at the following subscription rates: £120 UK, £180 Europe, £210 RoW



Help is finally on the horizon

The breaking news in early December that Pfizer/BioNTech's COVID-19 vaccine had been approved in the UK, the first country in the world to do so, is a huge cause for celebration. Watching the delighted faces of the television presenters as they announced the news reflected the sheer relief that swept through the nation with the realisation that, after months of desperate hope and the huge cost of living with the virus, help is finally on the horizon.

Even with this incredibly encouraging news, we cannot afford to let down our guard in this last stretch of the unprotected fight against the coronavirus. Christmas is just around the corner and everyone longs to celebrate and put the enormous struggles of this year behind us, even if only for a few hours spent with friends and family. But the battle wages on regardless, with some of the highest infection rates being reported in countries around the world at the time of going to press. So we need to make one final push to stay safe, protect our loved ones and not let COVID fatigue influence our behaviour.

PMGroup has just celebrated hosting the 20th annual PMEAs, where we continued to recognise the achievements in pharmaceutical marketing excellence. While the event took place virtually this year due to the COVID-19 pandemic and social distancing restrictions, the turnout was impressive, with over 1,000 views of the livestream and over 150 tweets posted to the social media wall and 1,300 impressions. Turn to page 24 to read more about the exciting livestream event!

On behalf of the whole team at PMGroup I would like to wish all our readers a happy festive season!



Iona

Iona Everson
Group Managing Editor

COMMUNIQUE

Awards 2021

for Medical Affairs and Healthcare Communications



2021 awards launching soon!

Register your interest now at www.pmlive.com/communique2021
For sponsorship opportunities please contact sales@pmlive.com

Sponsors

SAY.



Edelman

We are looking forward to holding a live event in 2021 and hope to see you there!

DECEMBER 2020

NEWS & COLUMNS

6-7 NEWS

Sanofi's quadrivalent flu vaccine
Supemtek scores EU approval; MSD launches
antibiotic combo Recarbrio in UK

8-11 CORONAVIRUS NEWS

Pfizer/BioNTech's COVID-19 vaccine approved in UK;
WHO director-general says urgent support
is needed for COVAX facility

12 DARWIN'S MEDICINE

Chaperone leadership – an insightful
parallel between bosses and biology

13 POLICY AND PUBLIC HEALTH

An open letter to the incoming President of the
United States on COVID-19 messaging priorities

14 PERFECT PARTNERS

What are the key components for
a successful partnership?

15 LAUNCH LEADERS' BLOG

What should launch leaders be measuring?

28-29 RESEARCH NEWS



**8 THE UK IS FIRST IN THE WORLD TO APPROVE
PFIZER/BIONTECH'S COVID-19 VACCINE**



**9 WHO DIRECTOR-GENERAL SAYS URGENT
SUPPORT IS NEEDED FOR COVAX FACILITY**



**20 DATA FROM THE ASCO
QUALITY CARE SYMPOSIUM**

FEATURES

16-17 JANSSEN'S JOAQUÍN CASARIEGO GARCÍA-LUBÉN

Unlocking the potential of precision
medicine in oncology and Janssen's drive
to provide personalised cancer care

18-19 CELL AND GENE THERAPY

Thanks to advances in technology
and new commercial viability, C&G
therapy is finally coming of age

20-21 DATA FROM THE ASCO QUALITY CARE SYMPOSIUM

The cost-effectiveness of biosimilar
treatment options in cancer care

22-23 ADVANCES IN THE TREATMENT AND PREVENTION OF CARDIOVASCULAR DISEASE

Cardiovascular outcome trials of omega-3 fatty
acids offer hope of an evolution in treatment

26-27 BREXIT: TOO LITTLE, TOO LATE?

What businesses need to know about
post-Brexit immigration



**24
CELEBRATING THE 2020 PMEAs!**



**16 JANSSEN'S JOAQUÍN
CASARIEGO GARCÍA-LUBÉN**

COMMUNIQUÉ MARKETING & COMMS

24-25 CELEBRATING THE 2020 PMEAs!

Continuing to recognise excellence in improving
patient outcomes, the Awards were presented
live online to an excited virtual audience

34-35 SUCCESSFUL PRODUCT COMMERCIALISATION

What can we learn from the rare disease setting?

36-38 PUTTING THEORY INTO PRACTICE

Ideas about new product adoption
are dangerously out of date

40-41 THREE WAYS AI WILL CHANGE HEALTHCARE IN THE NEXT DECADE

AI will continue to take centre stage in global
healthcare initiatives

45 HEALTHCARE COMMS

Envision Pharma Group acquires Two Labs;
Lucid Group gains new UK office space

46 PEOPLE

Q&A with Shairose Ebrahim

CAREERS & RECRUITMENT

42-44 APPOINTMENTS

Changes at Vertex, VectivBio and Novavax

47 PHARMA MARKETING JOBS

Jobs in pharma marketing, sales
and communications



**26
BREXIT: TOO LITTLE,
TOO LATE?**



**34
PRODUCT
COMMERCIALISATION**



**36
PUTTING THEORY
INTO PRACTICE**



**46
Q&A WITH SHAIROSE
EBRAHIM**

NEWS

Lilly links up with Precision BioSciences in genome editing deal

Eli Lilly has shifted its focus to genome editing following a new research collaboration deal agreed with US-based specialist Precision BioSciences, fronting an initial \$100m for access to its novel ARCUS platform.

Lilly and Precision will collaborate on the research and development of in vivo therapies for gene disorders, with an initial focus on Duchenne muscular dystrophy and two further undisclosed gene targets.

Precision's ARCUS genome editing platform could deliver 'safer, more specific gene edits' through the use of a naturally occurring gene editing enzyme known as endonuclease I-Cre1, according to the company.

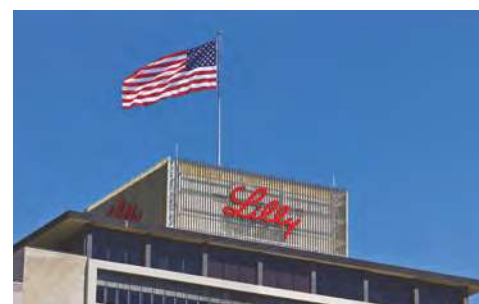
By using this technology, Precision can re-engineer the enzyme's editing abilities to 'knock-in, knock-out and repair' the targeted cells.

"We look forward to working with Lilly to leverage our deep understanding of in vivo gene editing and experience with ARCUS to develop new therapies, including a potentially transformative treatment for Duchenne muscular dystrophy," said Derek Jantz, chief scientific officer and co-founder of Precision BioSciences.

Under the terms of the deal, Lilly will pay Precision \$100m upfront and also make an equity investment totalling \$35m in Precision's common stock.

In addition, Precision is eligible to receive up to \$420m in potential development and commercialisation milestones per product, with tiered royalties on top of that if Lilly successfully commercialises a therapy from the collaboration.

While Precision will lead preclinical research and IND-enabling activities, Lilly will assume responsibility for clinical development and commercialisation.



Sanofi's quadrivalent flu vaccine Supemtek scores EU approval

The European Commission has approved Sanofi's quadrivalent recombinant influenza vaccine Supemtek for the prevention of flu in adults aged 18 years and older.

Sanofi's Supemtek is the now first and only recombinant influenza vaccine to be approved within the European Union.

The French pharma giant developed Supemtek using recombinant technology, which allows an exact match to the key component of the flu strains recommended by the World Health Organization (WHO).

The EU approval is based on data from two phase 3 clinical trials involving over 10,000 participants in total. When evaluated in these trials, Supemtek reduced the risk of flu by an additional 30% in adults aged 50 years and older compared to a standard-dose egg-based quadrivalent influenza vaccine.

Global influenza-associated deaths range from between 290,000 to 650,000 each year, with around ten million influenza-related hospitalisations also reported every year.

Sanofi expects the first European launches of Supemtek for the 2022/2023 flu season and a possible fast-track of doses to be delivered by the 2021/2022 season in certain countries.

Sanofi is also utilising its recombinant technology to develop a COVID-19 vaccine, which will be combined with an adjuvant from GlaxoSmithKline (GSK).



MSD launches antibiotic combo Recarbrio in UK

MSD (also known as Merck & Co) has launched its novel antibiotic combination Recarbrio in the UK.

Earlier this year, the European Commission approved Recarbrio (imipenem/cilastatin/relebactam) for the treatment of infections caused by aerobic Gram-negative organisms in adults with limited treatment options. The regimen combines MSD's imipenem/cilastatin duo with a new beta lactamase inhibitor called relebactam that is designed to restore susceptibility to imipenem in resistant strains.

In a pivotal phase 3 trial of adult patients with infections caused by imipenem-nonsusceptible Gram-negative bacteria, Recarbrio was comparable to the combination of imipenem/cilastatin plus colistin: 71% and 70%, respectively.

Colistin is a drug which was first introduced in the 1950s that has been resurrected to help fight challenging Gram-negative infections. The result was particularly significant, given that colistin is often reserved as a 'last-line' therapeutic for Gram-negative infections, although the drug can have significant side effects including kidney damage.

According to the World Health Organization (WHO), at least 700,000 people die each year worldwide because of drug-resistant infections.

Despite the urgent need for new therapeutics to tackle the growing incidence of antimicrobial resistance (AMR), few pharmaceutical companies are undertaking research in this area.

This is mainly due to the fact that when new antibiotics are launched, they are often held in reserve and used only to treat the most resistant infections.

Earlier this year, the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) raised nearly \$1bn to support clinical research into new antibiotics in a bid to tackle AMR.

The aptly named AMR Action Fund is aiming to bring two to four new antibiotics to patients by 2030. The launch of the fund resulted from a collaboration between 20 biopharmaceutical companies, including MSD, the European Investment Bank (EIB), Wellcome Trust and the WHO.



UCB boosts gene therapy offering with a pair of new deals

Belgium-headquartered UCB has strengthened its gene therapy capabilities with a pair of deals – a collaboration agreement with Lacerta Therapeutics and the acquisition of Handl Therapeutics.

Handl Therapeutics – based in Leuven, Belgium – specialises in adeno-associated virus (AAV) capsid technology and has a focus on developing disease-modifying gene therapies to treat neurodegenerative diseases.

In addition to its own capabilities, Handl has built an international network to access expertise from a number of institutions. This includes platforms licensed from KU Leuven in Belgium, the Centre for Applied Medical Research in Spain, the University of Chile and King's College London in the UK.

UCB did not disclose the financial terms of the acquisition, although it did add in a statement that the Handl team will continue to be based in

Handl and will work closely with UCB's international research team.

The Lacerta deal is focused on developing AAV-based therapies for patients with 'a central nervous system disease with a high unmet need'. Like the Handl acquisition, UCB did not offer the financial details of the Lacerta research collaboration and licensing agreement.

Lacerta is set to lead research and preclinical activities as well as the early manufacturing process development,



with UCB planning to lead IND-enabling studies, manufacturing and clinical development.

The Handl and Lacerta deals build on UCB's previous acquisition of Element Genomics in 2018.



Pierre Fabre's Braftovi scores NICE backing for BRAF+ colorectal cancer

French pharma group Pierre Fabre's Braftovi has been recommended for NHS use by the UK's National Institute for Health and Care Excellence (NICE) to treat BRAF-positive colorectal cancer.

Braftovi (encorafenib) combined with Merck KGaA's EGFR-targeting antibody Erbitux (cetuximab) has been recommended as a second-line treatment for BRAF-positive metastatic colorectal cancer (mCRC).

The positive recommendation is based on results from the phase 3 BEACON CRC study, in which Braftovi/Erbitux significantly improved overall survival (OS) by 40% compared to Erbitux and irinotecan-based chemotherapy, with a median OS of 9.3 months and 5.9 months respectively.

The trial also demonstrated that the treatment combinations was as effective as a triple therapy which also included Mektovi (binimetinib), which meant that additional toxicity from the MEK inhibitor could be avoided without comprising patient benefit.

Pierre Fabre is also looking to prove the Braftovi/Mektovi combination in earlier patient settings – the phase 2 ANCHOR CRC trial is evaluating the drug combo plus Erbitux or another EGFR inhibitor as a chemotherapy-free option for mCRC patients.

Results from this study demonstrated that the three-drug treatment produced a confirmed objective response rate (cORR) of 50%, with tumour-size reduction observed in 85% of patients. In addition, the investigator-measured median progression-free survival (PFS) rate was 4.9 months.

Over 42,000 people in the UK are newly diagnosed with colorectal cancer each year, with approximately 8-12% of patients with mCRC also carrying BRAF mutations.

FDA delays BMS' liso-cel decision, citing COVID-19 travel restrictions

The US Food and Drug Administration (FDA) has delayed a crucial decision for Bristol Myers Squibb's CAR-T therapy liso-cel, a key asset gained in the company's Celgene acquisition.

BMS picked up liso-cel (lisocabtagene maraleucel) following its \$74bn takeover of Celgene last year – the CAR-T therapy is one of the key assets critical to the potential payout of the merger in contingent value rights (CVR).

As part of the merger agreement, BMS agreed on a series of conditional payments to former Celgene shareholders or CVR holders, contingent on the regulatory approval of liso-cel by 31 December 2020, totalling an extra \$6bn.

BMS also agreed similar conditional payments, dependent on approval, for Celgene's multiple sclerosis therapy Zeposia (ozanimod) and another CAR-T therapy, ide-cel (idecabtagene vicleucel).

Zeposia was approved earlier this year, while ide-cel's deadline is coming up in March 2021.

In February, the FDA kick-started a priority review of liso-cel for the treatment of relapsed/refractory large B-cell lymphoma for patients who have received at least two prior therapies.



The CAR-T therapy targets CD19, a protein which is highly expressed on the surface of B cells and remains following the transformation of these cells from normal to malignant.

The FDA biologics licence application (BLA) is based on results from the TRANSCEND NHL-1 study, in which liso-cel achieved a 53% complete response rate and an overall response rate of 73% in the patient population.

However, the FDA has now postponed its decision on liso-cel after it was unable to complete an inspection of a third-party manufacturing facility in the US, which is involved in making a component of the CAR-T therapy.

The agency blamed its inability to conduct the inspection on travel restrictions related to the COVID-19 pandemic and declined to provide a new anticipated action date for the liso-cel decision.

CORONAVIRUS NEWS

Pfizer/BioNTech's COVID-19 vaccine gets first approval from the UK



Pfizer and BioNTech's mRNA-based COVID-19 vaccine has been granted authorisation for emergency use in the UK, making it the first nation to approve the novel vaccine.

The vaccine's path through conceptualisation, development and approval has advanced at an unprecedented rate, taking only ten months.

Typically, in non-pandemic situations, it takes years for a potential vaccine to move from the development stages toward authorisation, with the current COVID-19 vaccine timelines reflecting the urgency involved in finding an effective vaccine.

Following approval from the UK's Medicines & Healthcare Products Regulatory Agency (MHRA), the Pfizer/BioNTech vaccine will be available from next week, said Health Secretary Matt Hancock.

The approval closely follows final analysis of the vaccine, BNT162b2, which found that it has an efficacy rate of 95% in participants without prior SARS-CoV-2 infection (first primary objective) and also in participants with and without prior SARS-CoV-2 infection (second primary objective).

The company added that the efficacy rate was consistent across age, gender, race and ethnicity, with the observed efficacy in adults over 65 years of age coming in at over 94%.

The UK has already signed a supply deal for 40 million doses of BNT162b2, with the first of these set to be delivered 'immediately'.

BNT162b2 is being manufactured in Belgium, among other locations, although this particular Pfizer manufacturing site is 'critical to distribution in the UK'.

The vaccine will be rolled-out to priority groups first, with care home residents, health and care staff and the elderly slated to become the first to be offered the shot.

"The vaccine will be made available across the UK from next week. The NHS has decades of experience in delivering large-scale vaccination programmes and will begin putting its extensive preparations into action to provide care and support to all those eligible

for vaccination," commented a Department of Health and Social Care spokesperson.

According to the BBC, approximately 50 hospitals are prepared to administer the vaccine, while vaccination centres are also currently getting ready to roll-out BNT162b2.

BNT162b2 has a recommended storage temperature of minus 70°C (minus 94°F), which is well below the typical vaccine storage temperature of +2°C to +8°C. This means it will likely be easier to administer the vaccine in a hospital setting, rather in the community.

Pfizer/BioNTech have developed novel temperature-controlled shipping containers, which they say can maintain this temperature for 'extended periods of time'. The companies added, however, that once the vaccine vial has thawed, the vial can also be stored for up to five days at typical refrigerated conditions.

A US Food and Drug Administration (FDA) expert panel is due to meet on 10 December to discuss BNT162b2, and Pfizer/BioNTech has also submitted the vaccine to the European Medicines Agency (EMA) for emergency approval.

"Today's emergency use authorisation in the UK marks a historic moment in the fight against COVID-19. This authorisation is a goal we have been working toward since we first declared that science will win, and we applaud the MHRA for their ability to conduct a careful assessment and take timely action to help protect the people of the UK," said Albert Bourla, chairman and chief executive officer of Pfizer.



WHO director-general says urgent support is needed for COVAX facility

The World Health Organization's (WHO) director-general Tedros Adhanom Ghebreyesus has said that \$4.3bn is urgently needed to support its COVID-19 vaccine access facility COVAX.

COVAX is the vaccines pillar of the WHO's ACT Accelerator – a collaborative initiative co-led by the WHO which aims to accelerate development, production and equitable access to COVID-19 tests, treatments and vaccines.

The COVAX facility is designed to bolster procurement of promising COVID-19 vaccines to ensure the 'best possible prices, volumes and timing for all countries'.

In opening remarks made at a virtual briefing in Geneva, Ghebreyesus added that 187 countries are now participating in the COVAX facility.

This includes 94 higher-income economies who have officially joined the financing mechanism.

However, he also said that 'fundamental change' is needed

to support the full potential of the ACT Accelerator, adding that \$4.3bn is urgently required to aid mass procurement and delivery of vaccines, tests and treatments for COVID-19.

"This isn't charity, it's the fastest and smartest way to end the pandemic and drive the global economic recovery," said Ghebreyesus.

A further \$23.8bn will also be required next year to support the ACT Accelerator, Ghebreyesus added in his remarks.



AZ's COVID-19 vaccine demonstrates efficacy rate of up to 90%

AstraZeneca (AZ) has announced that its Oxford University-partnered COVID-19 vaccine candidate AZD1222 has an average efficacy of 70%, according to an interim analysis of trials in the UK and Brazil.

The efficacy rate comes from a combined analysis of two dosing regimens of AZD1222. One dosing regimen demonstrated a vaccine efficacy rate of 90%, when the shot was given as a half dose and followed by a full dose at least one month apart.

A second dosing regimen, however, showed 62% efficacy when given as two full doses at least one month apart.

The interim analysis was based on 131 COVID-19 cases among participants who either received the AZD1222 vaccine or a comparator meningococcal conjugate vaccine.

Although the current AZ results look less promising in comparison to the efficacy rates observed for Pfizer/BioNTech and Moderna's candidate, AZD1222 has other benefits – including a low cost and easy storage requirements.

The vaccine can be stored, transported and handled at normal refrigerated conditions for at least six months, while Pfizer/BioNTech and Moderna's vaccines need to be stored at far lower temperatures.

According to the BBC, AZ's vaccine is also priced much lower, coming in at around £3 while Pfizer/BioNTech's is reportedly priced at around £15 and Moderna's around £25.



Moderna COVID-19 vaccine is 94.1% effective, updated data finds

Moderna is seeking regulatory approval in the US and the EU for its COVID-19 vaccine candidate after posting an updated primary efficacy analysis for the vaccine of 94.1%.

In November, Moderna announced initial data from an interim analysis of its phase 3 COVE study which suggested that its COVID-19 vaccine, mRNA-1273, is 94.5% effective.

The preliminary data was based on analysis of 95 confirmed COVID-19 cases within the study – 90 of which occurred in the placebo group and five within the vaccinated arm.

The updated data analysis is based on 196 cases, of which 185 cases of COVID-19 were observed in the placebo group versus 11 cases in the mRNA-1273 group, reflecting a point estimate vaccine efficacy of 94.1%.

In addition, an analysis of severe cases of COVID-19 within the study found 30 severe cases – all of these cases occurred in the placebo group, with none observed in the mRNA-1273 vaccinated group.

"This positive primary analysis confirms the ability of our vaccine to prevent COVID-19 disease with 94.1% efficacy and importantly, the ability to prevent severe COVID-19 disease," said Stéphane Bancel, chief executive officer of Moderna.

Following the new, positive data analysis, Moderna also announced that it has submitted an emergency use authorisation (EUA) application to the US Food and Drug Administration (FDA) for mRNA-1273.

An FDA panel of outside experts – the Vaccines and Related Biological Products Advisory Committee (VRBPAC) – is due to review the safety and efficacy data for mRNA-1273 on 17 December, Moderna added in a statement.

The company is also set to apply for a Conditional Marketing Authorisation (CMA) application with the European Medicines Agency (EMA), priming itself to score regulatory approval for the vaccine on both sides of the Atlantic.

CORONAVIRUS NEWS

FDA set to publish reviews of data relating to COVID-19 vaccine EUAs

The US Food and Drug Administration (FDA) has announced that it will publicly post reviews of data relating to emergency use authorisations (EUA) of COVID-19 vaccines.

In a statement, FDA commissioner Stephen Hahn revealed the transparency plans, adding that the agency's drug and biological products centre will publish its reviews 'to the extent appropriate and permitted by law'.

"Let me be clear on a crucial point – the issuance of an EUA is based on data and science. For an EUA to be authorised, FDA's career scientists conduct a rigorous evaluation of currently available scientific evidence about a medical product," said Hahn.

In October, the FDA released new guidelines detailing how it will grant EUAs for COVID-19 vaccines, which included a new advisory stipulating that data from phase 3 studies should include a median follow-up duration of at least two months.

A number of companies have released efficacy data for their COVID-19 vaccines, including Pfizer/BioNTech, Moderna and AstraZeneca.

The FDA has scheduled a meetings of its Vaccines and Related Biological Products Advisory Committee (VRBPAC) to discuss both Pfizer/BioNTech's and Moderna's COVID-19 vaccine candidates – taking place on 10 December and 17 December, respectively.

Although the FDA is not bound to follow advice given by members of the VRBPAC regarding the EUA applications, the agency tends to follow the recommendations of the expert panel.

"The FDA recognises that transparency and dialogue are critical for the public to have confidence in COVID-19 vaccines. I want to assure the American people that the FDA's process and evaluation of the data for a potential COVID-19 vaccine will be as open and transparent as possible," added Hahn.



Lilly's repurposed COVID-19 medication baricitinib gets FDA emergency approval

Eli Lilly and Incyte's arthritis treatment baricitinib has been repurposed as a COVID-19 treatment, scoring an emergency use authorisation (EUA) from the US Food and Drug Administration (FDA) in combination with Gilead's antiviral remdesivir.

The EUA covers baricitinib in combination with remdesivir for the treatment of hospitalised adults and paediatric patients two years or older with COVID-19 who require supplemental oxygen, invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO).

The approval is based on data from the ACTT-2 study – sponsored by the US National Institute of Allergy and Infectious Diseases (NIAID) – which evaluated baricitinib plus remdesivir in hospitalised COVID-19 patients, with or without oxygen requirements.

Results from this trial demonstrated that the combo treatment caused a significant reduction in the median time to recovery from eight to seven days, compared to remdesivir alone.

Patients treated with the baricitinib/remdesivir regimen were also more likely to have



a better clinical status at day 15 compared to remdesivir monotherapy.

In addition, the mortality rate at day 29 was 4.7% for the baricitinib/remdesivir treatment group compared to 7.1% for those who only received remdesivir – a relative reduction of 35%.

Baricitinib is already marketed by Lilly as Olumiant, for the treatment of adults with moderate to severe rheumatoid arthritis in the US.

Joint COVID-19 trial begins testing drugs from Amgen, UCB and Takeda

The COVID-19 R&D Alliance has enrolled the first patient in a trial testing therapeutic candidates from Amgen, UCB and Takeda.

The COMMUNITY trial is testing a number of drugs from members of the COVID-19 R&D Alliance, a cooperative of over 20 pharma and life sciences companies working together in the fight against the novel coronavirus.

As part of the alliance, members are sharing clinical trial data and real-world evidence, as well as crowd-sourcing early-stage candidates to identify mechanisms or treatments that could be effective against COVID-19.

The initial therapies set to be tested within the COMMUNITY trial are Amgen's psoriasis med Otezla (apremilast), UCB's investigational myasthenia gravis treatment zilucoplan and Takeda's hereditary angioedema drug Takhzyro (lanadelumab).

These candidates have been selected based on their potential to suppress or control the immune response and resulting inflammation observed in patients with severe COVID-19.



Amgen's Otezla has already entered the trial, while Takeda and UCB's candidates are expected to enter within the coming weeks.

The COMMUNITY trial is testing therapeutic candidates in hospitalised COVID-19 patients, which includes patients who may require either ongoing medical care, supplemental oxygen, non-invasive ventilation, high-flow oxygen devices or invasive mechanical ventilation.

It is enrolling hospitalised intensive care unit (ICU) as well as non-ICU patients with the aim of gaining a broader understanding of the use of therapeutic interventions in hospitalised COVID-19 patients facing a range of symptoms.

EU secures 405 million doses of CureVac's COVID-19 vaccine

The European Commission (EC) has announced a new supply agreement with German biopharmaceutical company CureVac for 405 million doses of its mRNA-based COVID-19 vaccine candidate.

In a statement, EC president Ursula von der Leyen said that "if the vaccine has proven safe and effective against COVID-19, every member state will receive the vaccine at the same time, on a pro-rata basis, and under the same conditions".

According to Reuters, the deal includes access to an initial 225 million doses of CureVac's vaccine, with

the EC eligible to purchase a further 180 million.

On 3 November, CureVac announced that early data for its vaccine candidate, CVnCoV, suggested that the shot triggered an immune response in participants, including strong binding and neutralising antibody responses.

The vaccine also demonstrated early indications of functional T cells, confirming activation of cellular immune response, according to CureVac.

CureVac's candidate, like Pfizer/BioNTech and Moderna's respective investigational vaccines, uses mRNA technology, a relatively new research area.



Moderna signs COVID-19 supply deals with UK and EU

The European Commission (EC) has secured up to 160 million doses of Moderna's COVID-19 vaccine candidate mRNA-1273 after the vaccine hit the mark in a large-scale phase 3 study earlier this month.

Moderna's mRNA-based COVID-19 vaccine is the latest vaccine to be secured following a series of deals made between the EC and vaccine developers.

Previous EU deals include an agreement for potential vaccines from AstraZeneca, Pfizer/BioNTech, Sanofi/GlaxoSmithKline, Johnson & Johnson and CureVac.

The EC is also in discussions with Novavax for a potential supply deal for its COVID-19 vaccine candidate NVX-CoV2373, which is expected to begin late-stage testing by the end of November.

"While restrictive measures can slow down the spread of the virus in this very difficult situation, we all know that only a safe and effective vaccine will provide a lasting, sustainable solution to this pandemic," said EC president Ursula von der Leyen.

Moderna has also announced an amended supply agreement with the UK for an additional two million doses of its COVID-19 vaccine candidate on top of the already agreed upon five million doses.

Following the agreement for an additional supply of Moderna's mRNA-1273, the UK has now secured seven million doses of the vaccine – enough for around 3.5 million people.

"Every week, we are getting more positive news about the range of vaccines in development, and thanks to the work of our taskforce the UK has pre-ordered hundreds of millions of doses from those companies most advanced in their work," said Health and Social Care Secretary Matt Hancock.

"With a wide range of vaccine candidates in our portfolio, we stand ready to deploy a vaccine should they receive approval from our medicines regulator," he added.



J&J advances COVID-19 vaccine into second phase 3 trial

Johnson & Johnson (J&J) has launched a second phase 3 trial of a single-dose regimen of its COVID-19 vaccine candidate, JNJ-78436735.

The ENSEMBLE trial is set to enrol up to 60,000 participants worldwide, while another study, ENSEMBLE 2, will evaluate a two-dose regimen of the vaccine in up to 30,000 participants.

The initiation of the parallel studies – ENSEMBLE and ENSEMBLE 2 – comes on the heels of positive interim results of J&J's ongoing phase 1/2a clinical study of the investigational vaccine.

Interim analysis from this early-stage study, which is evaluating both a single-dose and a two-dose vaccination regimen, showed that a single dose of JNJ-78436735 induced a 'robust' immune response and was also generally well-tolerated among vaccinated participants.

The ENSEMBLE 2 study will enrol participants in the UK, the US, France, Germany, Spain, Belgium, South Africa, Colombia and the Philippines.

The UK-based trial will be conducted in collaboration with the National Institute for Health Research (NIHR) and is expected to recruit 6,000 participants.

The trial is being conducted in the UK as part of a deal agreed in August, which included an initial supply agreement for 30 million doses of J&J's vaccine. As part of this deal, the UK also agreed to co-fund the phase 3 ENSEMBLE 2 trial.

The ENSEMBLE study, on the other hand, is being initiated in collaboration with the US Biomedical Advanced Research and Development Authority (BARDA) and the National Institute of Allergy and Infectious Diseases (NIAID).



BRIAN D SMITH

DARWIN'S MEDICINE

CHAPERONE LEADERSHIP



An insightful parallel between bosses and biology

The more I research how life sciences companies work, the more I see the parallels between businesses and biology. This week, as I crunched data for a new piece of research on leadership, another link emerged. It is both academically interesting and practically useful, so let me do my usual thing of rambling into the science on the way to something you can use.

Leadership guff

There's a huge amount of guff written about leadership. Whenever I see one of those 'leadership is....' memes on LinkedIn, I can be pretty certain that what is going to follow is going to be platitudinous drivel with no evidence behind it. Even in the more substantial academic literature, it's hard to pin down what leadership is or to identify what great leadership is. There are two reasons for that. First, we talk about leadership as if it were the same in any business. While I'm prepared to accept a few shared basics, the idea that leading Novartis is the same as leading McDonalds seems preposterous. Second, much writing focuses on personality and who leaders are. I've found leaders to be so different that I can't accept that there is a 'leader personality'. Reading books about leadership leaves one thinking that the whole field has fallen for the myth of the hero leader. I think that that's just not correct.

Leadership is a verb

My dissatisfaction with the leadership guff has pushed my work towards focusing on what leaders, and leadership teams, do in the exceptional context of the life sciences industry. There have been lots of useful findings and if you want the full story, let me nudge you towards '*Leadership in the Life Sciences*' on Amazon and the accompanying video on YouTube.

A big, central finding was that, in our business, two of the commonly held models of leadership don't really hold true. We tend not to have hero leaders like Steve Jobs. Truth is, our business and science are too difficult for anyone to manage in such an autocratic way. And nor does the opposite idea that our leaders are 'servants' hold up to empirical study. The complexity of the life sciences, the inherent uncertainty and the risks of getting it wrong mean that we do need decisive leaders.



Decisive facilitators

By speaking to lots of industry leaders, I found that their leadership habits were best described as 'decisive facilitators'. They find ways to draw sense from complexity and then act as the nucleation point for that sense to crystallise into a decision. That's the big picture anyway. Of course, what's really interesting is the cluster of capabilities they develop and employ to enable them to be 'decisive facilitators'. I don't have space here to describe all of them, but they include the capabilities to focus on the sources of uncertainty and reduce it, to encourage focus on corporate, not departmental, goals and to dovetail critical activities that live in different organisational silos.

Dynamic leadership

The purpose of good science is, in part, to see connections between things. In this case a connection emerged that these capabilities were all invisible outside the organisation. They acted to shape and integrate other capabilities, the outcomes of which could be seen in what the company did. In the jargon, these are known as dynamic capabilities, first written about by David J Teece. But it was at that point in the research when I realised that leaders' capabilities were of the dynamic variety, that I once again saw the connection between business and biology.

Chaperone leadership

In my work, the analogues of genes are organisational routines and they work together to express capabilities, the analogue of proteins. The molecular biologists among my readers will be familiar with chaperone proteins, which help other proteins fold in the right way to perform their function. At the same time, they prevent proteins from aggregating into non-functional units. Can you see the parallels? The capabilities that leaders perform don't do anything of direct use, their role is to help other functional capabilities to work correctly and not to get tangled up into a dysfunctional mess. The analogy is really quite elegant. It is also practically useful. Thinking of leadership as a set of chaperone capabilities that act on other, more visibly useful, capabilities helps us in three ways. It reminds us that it's what leaders do, not who they are, that matters. It reminds us that they have a kind of catalytic role, rather than having to be a direct part of the business process. And it reminds us that effective business is always the result of coordination rather than due to some single, heroic act in any one function. Not a bad result for a single analogy.

Professor Brian D Smith works at SDA Bocconi and the University of Hertfordshire. He is a world-recognised authority on the evolution of the life sciences industry and welcomes questions at brian.smith@pragmedic.com

ROHIT KHANNA

POLICY AND PUBLIC HEALTH

DEAR JOE



An open letter to the incoming President of the United States on COVID-19 messaging priorities

Dear Joe,

Congratulations on winning the recent US Presidential Election. Now the work begins. You have tremendous challenges on the domestic front, with foreign policy and with an economy that is staggering. Your country is divided. Schools are closing. People are dying.

But the health of your citizens and a single-minded focus on the healthcare system is the only way out.

You are no stranger to the importance of individual health. You suffer from asthma and have undergone two surgeries for intracranial aneurysms and a pulmonary embolism. So, you know that if you have your health, nothing else matters. And if you don't have your health, nothing else matters. You also most certainly know about the gravity of a strong US healthcare system since you were part of the administration that crafted the Affordable Care Act in 2010. The importance of protecting pre-existing conditions and expanding access to affordable health insurance. You have spoken about a new 'public option' and tax credits to help working class families along with the elimination of surprise medical billing. You have promised to reverse the US administration's withdrawal from the World Health Organization. Your goals are high. And your aim is far. Bravo.

But COVID-19 is the problem. It is here today. And it is not going anywhere soon. How you deal with it is the singular answer to how everything else goes in 2021.

While PPE procurement may seem like a conversation from a different time, reports suggest that this is still a problem. Ensuring that healthcare and frontline workers can safely do their jobs is paramount to dealing with the virus in the here and now.

Vaccines are coming. Preparing the supply chain and understanding the logistics of getting these vaccines to the people is a gargantuan task. You have selected amazing people for your taskforce. But you must also use the collective experience of other countries that have rolled out complex, large-scale public health vaccination programmes.

Vaccines are great. Vaccinations are better. The sad truth is that many Americans have expressed a distrust in science and in the development of these vaccines. Experts have stated that, in order for the economy and the workplace to return to normal, at least 70% of society needs to get vaccinated in order for herd immunity to take effect. Having enough doses to make



this happen does not appear to be an issue based on long-term manufacturing projections that we have been given. But after a full year of anti-science rhetoric and deception in your country, the messaging and education campaign will be more important than the logistics and supply chain discussions. Take my word for it.

And here's a suggestion for the key messaging elements of your campaign to the American people: Trust and Two.

In order to establish trust in the vaccines, your administration must put epidemiologists and doctors at the forefront to share information and data with the general public. The Food and Drug Administration (FDA) and Centers for Disease Control (CDC) must be part of this campaign, after being sidelined for the past year, or used exclusively as vehicles to misinform and confuse. You must have independent scientists and form review committees to validate the information that is shared with the American public. And you must have a plan to work with local leaders in communities of colour and with visible minorities who, for too long, have been on the fringes of healthcare communication and who have become understandably leery.

Two. This key element of the messaging campaign should not be overlooked. Pfizer's vaccine requires two shots, three weeks

apart. Moderna's vaccine requires two shots, four weeks apart. And AstraZeneca's vaccine is being studied in a protocol where two shots are given one month apart. You see why 'two' is important? Two shots. Not one. An individual gets immunity with two shots and only with two shots. Research has shown that other immunisation programmes are plagued by patients who initiate but do not complete a vaccine series.

This could be the biggest hidden issue with the COVID-19 vaccines and it is not being forcefully messaged or communicated. Call it compliance. Or adherence. Or whatever you wish to call it. The key is that 'two' will be the most important number of 2021. You have been dealt an exceedingly difficult hand, with the outgoing administration effectively relinquishing any action on controlling COVID-19, which has allowed the infection to run rampant to the tune of one million cases per week.

Good luck. The world is rooting for you and your administration.

Rohit Khanna is the Managing Director of Catalytic Health, a healthcare communication, advertising & strategy agency. He can be reached at: rohit@catalytichealth.com

MIKE DIXON

PERFECT PARTNERS



What are the key components for a successful partnership and how can that be achieved?

Christmas is nearly upon us; a festival of joy and hope, something we certainly need in abundance this year. So, with that air of positivity, let's talk about something we have seen significantly more of in 2020 that the HCA has recently been discussing and dissecting – partnerships. In response to COVID-19 the pharmaceutical sector, and indeed the whole healthcare system, has seen a proliferation of partnerships, many of which we would never have thought possible at the end of 2019. But they have happened and many have delivered some amazing outcomes, not least the realistic prospective of starting 2021 with a viable vaccine. The general consensus is that the appetite for partnerships has increased and will now continue to do so, irrespective of COVID-19. To capitalise on this increased appetite, what are the key components for a successful partnership and how can that be achieved?

Why become partners?

What we are really looking to achieve with a partnership is synergy. Whatever our goal or purpose, a partnership would hope to achieve more than could be achieved by any one person, and hopefully more than if each worked alone. A partner may provide additional skills, knowledge or access, add resource or just create a greater voice. In identifying a partner, it is therefore important not just to consider those organisations that are like-minded. If you agree on the common purpose, diverse thinking can itself be a benefit of partnership. Every partnership will be based on different needs and it is important to be clear and transparent on what those needs are before identifying potential partners.

Start right

How the partnership is started and set up is fundamental to its eventual success. Setting good governance from the outset ensures all parties are clear on their roles, responsibilities and how everybody will work with each other. In the inevitable rush to get started, the importance of documenting and agreeing on the detail of the process should not be sacrificed.

Trust is essential in a partnership, so honesty and transparency from the start is essential. The risks and challenges also need to be outlined and discussed so all parties are clear on what these are and how they are avoided or managed.



In pharma, we have codes of practice that help clearly outline how partnerships should be set up, but we should consider these as the minimum requirements and also consider what else we need to incorporate to help ensure success.

The goal remains the focus

If you are aligned with the overall purpose, the best mindset when entering a partnership is not to think about what you are going to get out of it, but rather to focus on what you can offer to help achieve that goal.

One of the challenges that can occur in a partnership is when it is felt one party is inappropriately 'taking the glory', perhaps in the media, which can cause animosity. Once again, establishing upfront how the partnership is always presented, who undertakes the external communications, and when and how they happen, will all help to eliminate this or provide a point of reference if slippage occurs. Fundamentally, the best premise is to ensure that whoever or however the work of the partnership is communicated, the goal remains the sole focus, not the sponsors.

Managing perception

In healthcare in particular, concerns about perception, often with respect to inappropriate influence, are common. These can sometimes derail what might be potentially incredibly fruitful partnerships. Partnerships should be transparent, and the role of each partner should

stand up to scrutiny. Lack of transparency only opens up the chance for claims of 'conspiracy' whether it exists or not, as we have seen recently with government contracts. If there are perception concerns about, for example, a pharma company working with a charity, don't avoid or hide the partnership. Explain it, how it is set up and how the partnership is not inappropriately influencing opinion, but actually adding value to help improve patient health or well-being.

The results can be amazing

We don't have to look far to see the amazing things partnerships achieve. Everything from developing vaccines in months rather than years, CEOs' partnering in open letters reaffirming safety before speed, 20 biopharmaceutical companies creating the AMR Action Fund to bring new antibiotics to patients, industry working with health commissioners to reach hard to engage communities with health messages, or the many corporates from across different sectors partnering with charities to provide food for families who can't afford it at Christmas.

As we end this challenging year, let's consider how partnerships could help support our success in 2021. Happy Christmas!

Mike Dixon is CEO of the Healthcare Communications Association and a communications consultant

STEPHANIE HALL

LAUNCH LEADERS' BLOG



WHAT SHOULD LAUNCH LEADERS BE MEASURING?

Challenging a few norms in our industry so we don't become fixated on the wrong type of metrics

This time I'd like to explore what launch leaders should (ideally) be measuring at different phases of their launch – pre-, peri- and post-launch.

I'd like to challenge a few norms in our industry as we can sometimes become fixated on the wrong type of metrics: what's the peak year sales figure? What market and class share can we expect? What's the likely uptake vs previous launches in our company or in the class?

When working with global or local launch leaders, I've come across two distinct 'personas':

1. The strategic and numerical experts

run a tight project management ship, are immersed in the analysis, derive strategy from the numbers they see and will set a fully quantified set of KPIs adapted to different phases of the launch. Are you one of these people? If so, you are in high demand! But don't forget the qualitative, intuitive insights that can come from real-life observation, interactions and 'gut feelings', based on healthcare and patient-centricity.

2. The number-phobic launch leaders

who delegate analytics, forecasting and measurement to finance, business analysis, competitor intelligence and sales force colleagues. These launch leaders are much more comfortable immersed in the patient experience journey, insight generation, branding, team dynamics and thought leader interactions. Are you one of these people? If so, you're in high demand too! Ideally launch leaders should combine

these two profiles but often launch leaders come from either a quantitative or a qualitative background, which informs their experience and confidence.

So, the questions that a launch leader needs to consider are: what matters at each key stage of my launch? What information will help me make better strategic and operational decisions as the launch progresses? Which KPIs do my senior management need to see? Which KPIs are truly important from a patient, prescriber, payer, competitive and internal team perspective? Are we truly engaging and changing the knowledge, attitudes and behaviours of target customers in order to improve patient outcomes?

In my experience, some of the most important KPIs for the pre-launch phase are:

- Tracking to the critical launch path timeline – ie speed to market for regulatory, pricing/access, supply and commercial operations, and mapped vs the competition



- Probability of success for hitting clinical trial primary endpoints and showing an improvement or differentiating benefit from alternative treatments
- Scientific thought leader engagement with the launch, active input to the clinical programme and strategy, active readiness with media and peer-to-peer activity, indicators of proactivity from thought leaders as 'extended' members of the launch team
- Pricing, formulary and percentage open access to key territories or patient populations within a geography
- Prescriber understanding of the mechanism of action, published clinical studies and degree of unmet need, along with motivation to act in the future
- Engagement and support of the patient advocacy community and media
- Internal launch team belief in the success of the launch, senior management support for the launch.

In the peri-launch phase, the focus is on implementation, communication and coordination on a daily and weekly basis. If you are in a global or regional team, my strong recommendation is to back off and let the local teams deliver the launch and engage with their local customers! I know this is easier said than done. Some local launch teams create a 'global request triage manager' to process and respond to multiple requests for a variety of information across different functions. But not all teams have the resources to do this. If your company has business analysts to manage your market

research, performance analysis and reporting and launch KPIs, they are an invaluable part of your launch team, helping to identify the issues that need decisions or management attention.

In the post-launch phase, this is the time to identify learnings, 'fast failures', share best practices with the next countries about to launch and, of course, to recognise the heroic work of the members of the launch team. In this post-launch phase, it's worth tracking:

- The highest performing launch tactics and how to measure their operational effectiveness
- The competitive response – strategically and operationally to the launch
- Who the early 'hot spot' prescribers and patients initiated in the first instance are
- Any lesser performing tactics, channels, content, messages – 'course correct' fast
- Payer, formulary and pricing/value discussions with how best to demonstrate the value of the new product
- How the media – medical and general – is covering the launch, disease area, access, policy
- Internal organisational learnings – processes that don't quite work or don't work fast enough, new capabilities needed for success
- Who the highest performing members of the launch team are – across territories and functions and ensuring their great work is shared and recognised.

Stephanie Hall is MD of the award-winning brand planning healthcare consultancy Uptake Strategies

Unlocking the potential of precision medicine in oncology

Joaquín Casariego García-Lubén talks to PME about how Janssen is driven by the premise of providing personalised treatment solutions in cancer care

Precision medicine is a term we are all familiar with in the industry, however its true meaning should not be underestimated.

Although its scientific basis is complex and is founded on an understanding that has taken many decades for the research community to uncover, it comes down to one very simple premise: that every patient is unique and requires bespoke medical care. This is particularly true in oncology, where we are relentlessly undertaking research to help us uncover potential therapies which will target genes that have mutated or been altered. By focusing on the genetic make-up of the tumour itself when considering treatment pathways, we have the potential to see positive benefits in the clinical setting.

Developing transformational treatments

Finding solutions to the challenges we face in oncology, such as improving our understanding of the route for malignant tumour progression and early development, as well as meeting the needs of severely underserved patient populations, are my biggest driving ambitions.

For me, it's a very personal challenge. Devastatingly, my father passed away this year due to cancer during the peak of the coronavirus pandemic in Spain. This tragedy has further strengthened my resolve to not rest until we, together as a community, can create a radically improved future for all oncology patients, their families and friends. It is for people like my father, the hundreds of cancer patients I treated as a physician, and indeed my family, that I am so dedicated to my work every single day, both as a clinician and as a researcher. I am very much aware of my part in developing transformational and precise treatments that can improve people's lives. To me, this means providing patients with the invaluable gift of more quality time: not just adding years to life, but also life to years.

Patient-centred research

Ultimately, I believe that precision medicine requires doing the right things, such as daring to innovate in more patient-centred research – and doing things right – by conducting research

under the highest scientific, operational and ethical standards, while taking advantage of new technologies at our disposal. In this endeavour to eradicate or intercept cancer, it is our duty to account for distinct differences in people's '-omics' spectrum, but also importantly in their clinical, psychosocial and professional environments, while also considering unique lifestyle-related factors. All of which interact in one way or another, in every patient, linking subpopulations with similar features and so, prognosis and outcomes.

'Precision medicine comes down to one very simple premise: every patient is unique and requires bespoke medical care'

Through my work at Janssen I am privileged to be part of a company that is driven by the premise of providing personalised treatment solutions in cancer care. Across our solid tumours portfolio, we are confident that our approach to precision medicine will deliver significant societal value, by optimising patient care through improving disease prevention, diagnosis and treatment. As I see it, precision medicine is truly an evolution where we are dedicated to moving away from a disease-focused model, so that we can translate technological advances into more patient-centred benefits.

Powering precision medicine

Biomarkers are well known in the oncology space and as a company we are determinedly pioneering research in areas where patients currently face poor clinical outcomes, such as those living with urothelial carcinoma (UC), the most common type of bladder cancer. I am particularly proud of our achievements in this area, where we were the very first company to receive FDA approval for a fibroblast growth factor receptor (FGFR) inhibitor in advanced and metastatic bladder cancer harbouring an FGFR alteration, addressing the considerable unmet need for patients living with this disease. Not only are we exploring this

in bladder cancer, but we are also investigating a multitude of solid tumour types that bear these genetic aberrations so that a wider range of patients could potentially benefit from this research.

Targeted therapies

Furthermore, by following a similar trajectory in the treatment of non-small cell lung cancer (NSCLC), where we are studying specific alterations in the epidermal growth factor receptor (EGFR), we endeavour to provide options to a heavily underserved patient population. Our teams of clinical researchers are unrelenting in their efforts to deliver data to support the treatment of patients who have NSCLC expressing exon 20 insertion mutations in the EGFR gene, who have extremely limited options currently, while also developing treatments to bring practice changing results. In addition, DNA repair defects (DRD) such as BRCA-1/2 or ATM mutations present in advanced- and late-stage prostate cancer represent a key focus for Janssen in complementing the continuum of targeted therapies now available to prostate cancer patients, including PARP inhibitors.

It's my firm belief that advances in all these research areas may provide important outcomes for patients living with these deadly diseases, and help to address one of the most pressing health challenges that exists: achieving long-duration and high-quality cancer survivorship.

Tailored solutions for patients

The patients of today are certainly more empowered and better-informed than ever before. I see examples of this every single day, and at Janssen we are devoted to ensuring that patients inform our every step, from providing input into the design of our clinical trials, right through to our disease area strategies. An important element in ensuring treatments reach the right patients, at the right time and for the right outcome, when biomarkers play a critical role in patient outcomes, is through using a companion diagnostic. I am excited to see first-hand how, at Janssen, we are working to shape the personalised healthcare spectrum through accurate testing in the clinical setting.

‘At Janssen we are confident that our approach to precision medicine will deliver significant societal value, by optimising patient care through improving disease prevention, diagnosis and treatment’



The right test, performed at the right time, not only benefits patients directly but also helps to support healthcare systems by allowing medications to be used in the most appropriate patient populations and in an efficient way, from a resource perspective.

Biomarker testing

That's why, in collaboration with our strategic industry partners, we are pursuing biomarker testing to accurately identify patients whose tumours harbour FGFR alterations, ensuring they receive appropriate treatments tailored to their needs. This, in turn, will help to guide treatment decisions in the clinical setting. We are following a similar approach in lung cancer through an ongoing partnership to pursue a molecular diagnostic strategy for our early-stage investigational EGFR-MET bispecific antibody, which is being studied in the treatment of NSCLC. Similarly, DRD testing in late stage prostate cancer is needed to identify patients who could potentially benefit from PARP inhibition. Through use of these diagnostics, we can limit inefficient use of healthcare resources and direct these back to where they truly matter – patient outcomes.

I am constantly impressed by the tireless endeavours of our biomarker scientists who are also working to create tests that detect the presence of androgen receptor (AR) abnormalities for people living with prostate cancer. These

tests are designed to detect multiple biomarker changes simultaneously, and efforts are ongoing to understand the changes that occur in circulating tumour cells (CTCs) as a result. This ongoing research will undoubtedly help us to better understand the development of prostate cancer at the molecular level, so that we can move towards more personalised treatments in this space, as well as in bladder and lung cancers.

Pushing the boundaries

Janssen's precision medicine research, supplemented by new technologies such as Artificial Intelligence (AI), is pushing the boundaries of what we previously thought possible. We are working to make this beneficial for the patients of the future, by combining with big data collected from patients with a long-duration disease course. This is exciting for a number of reasons, not least the potential to reformulate our understanding of the impact of different diagnostics and treatment approaches in clinical practice. More specifically, through our ORACULUM studies, we are using AI to analyse patient-level data that is collected through electronic health records across numerous countries in Europe, the Middle East and Africa. This will give us the opportunity to inform the wider scientific community on new hypotheses for future trials. I firmly believe that, with the help of

like-minded strategic partners and groundbreaking technological advances such as these, we are making huge strides on our combined journey towards changing what a cancer diagnosis means for the patients of today and tomorrow.

Cross-industry partnerships

With the evolving focus on precision medicine comes a great deal of change for the pharmaceutical industry, and vitally hinges on resilient, cross-industry partnerships. I strongly believe in the power of collaboration and our alliances take many forms, but our goal is always the same: to advance scientific research which has the prospects to deliver solutions that provide value to patients, physicians, payers and society as a whole. Through this combined, robust approach I am optimistic that, as an industry, we will revolutionise the way we treat cancer and pave the way for the precision medicine of the future.

I look forward to a time when our ambitions to make cancer a manageable condition can become a reality, both for patients like my father and for their families – because time has a wonderful way of showing us what really matters.

Joaquín Casariego García-Lubén is EMEA Therapeutic Area Lead Oncology, The Janssen Pharmaceutical Companies of Johnson & Johnson

After years of potential, cell and gene therapy is ready for the pharmaceutical mainstream

Thanks to advances in technology and new commercial viability, cell and gene therapy is finally coming of age

By Mark Brewer



Seen as the future of pharma for many years, cell and gene therapy (C&GT) is finally coming of age – advances in technology and new commercial viability mean we are closer than ever to that future becoming reality. The result is greater levels of investment in the companies that are leading the way forward, along with an environment that is ripe for M&A consolidation, with larger pharma companies eager to prevent start-up innovators from gaining an unassailable head start in such an important field.

Firstly, it is important to understand exactly what cell and gene therapy is, and why, given its potential has long been known, it is only now becoming the centre of attention for the main pharmaceutical players. Often lumped together as terms, the key difference between cell therapy and gene therapy is that the former utilises cells from a donor or the patient themselves to treat a disease through their modification and insertion (or re-insertion) into the blood stream. By contrast, gene therapy involves modifying, copying or replacing a gene. Recent innovative techniques that can reach genes without causing significant side effects have triggered a surge in activity in the area.

The reason both therapies are linked together so regularly is due to their crossover: both involve targeting specific genetic characteristics. Cell therapy often strays into gene therapy territory when it is decided that an easier method to treat cells would be to extract them from the body and rework their genetics.

Such complex solutions were, understandably, seen as too advanced, risky, or frankly not commercially viable enough. But with continued innovation – much of it coming from biotech companies – we have now reached the stage where products once on the periphery of pharmaceutical research are being sanctioned with FDA approval, with the organisation expecting to approve between 10-20 C&GT products a year by 2025.

M&A activity surging

With large pharmaceutical companies reluctant to miss out on such an important advance in medicine, M&A activity in the space has increased exponentially. In 2014-15, M&A deal values in this sector were \$5bn, and in 2018-19, this surged 980% to a combined two-year total of \$49bn. The cell therapy, gene therapy and tissue engineering sector raised \$2.9bn in venture capital in 2018 – twice the 2017 amount.

‘Products that were once on the periphery of pharmaceutical research are now gaining FDA approval, with approval of between 10-20 C&GT products a year expected by 2025’

Recent examples of this trend can be seen in Roche’s December 2019 \$4.8bn takeover of Spark Therapeutics, one of the first US gene therapy firms to succeed in obtaining FDA approval – in this case for a project that can treat inherited vision loss. Another example is Biogen’s \$800m acquisition of Nightstar’s late-stage gene therapy assets for retinal disease – NSR-REP1 and NSR-RPGR. Both deals represent well-capitalised pharma giants paying large sums for completed, or nearly completed, final products, giving the buyer an almost guaranteed product to start manufacturing, branding and distributing immediately. Such deals often benefit all parties involved – sellers may well have been struggling under the costs to pursue trials and approvals (even for extremely promising candidates) and would have faced extreme financial pressure in trying to bring a treatment to market.

Pharma’s next wave of innovation, yet challenges remain

C&GT has innovated at such a rapid pace that much of this appetite for M&A is also led by a hangover of big pharma being left behind in the sphere of monoclonal antibody technology. Then, pharma firms did not react in time and lost ground to advancing smaller firms. Now, these companies are aiming to give themselves ample opportunity to acquire, partner and strengthen their hand in the C&GT space.

Indeed, with treatments already at approval stage, market revenue is close at hand. With the nature of C&GT being highly tailored and often one-off, it represents a new form of revenue generation that can command high prices for each treatment, rather than the gradual revenue obtained from conventional drug sales.

Such a model also presents the flourishing sector with challenges. High prices can cross into financially unviable territory, with a prime example being the innovative treatment Zolgensma. The one-off therapy, which delivers a new, working SMN gene to the motor neurone cells in the body to target motor neurone disease, is FDA approved and developed by Avexis, but it won’t see widespread availability due to a price tag of \$2.1m per treatment.

Projects that require such tailored solutions are harder to manufacture than traditional medication, and another challenge arises in the form of medical providers’ payment preferences. Traditionally, hospitals are more comfortable with paying for constant, easily affordable medication; C&GT presents them with a high upfront cost, albeit one they rarely have to repeat on the same patient.

However, continued innovation shows progress can be made in solving these problems. In addition, the continued success of C&GT may prompt reworked financial models as it becomes more established in the industry.

The argument for continued investment

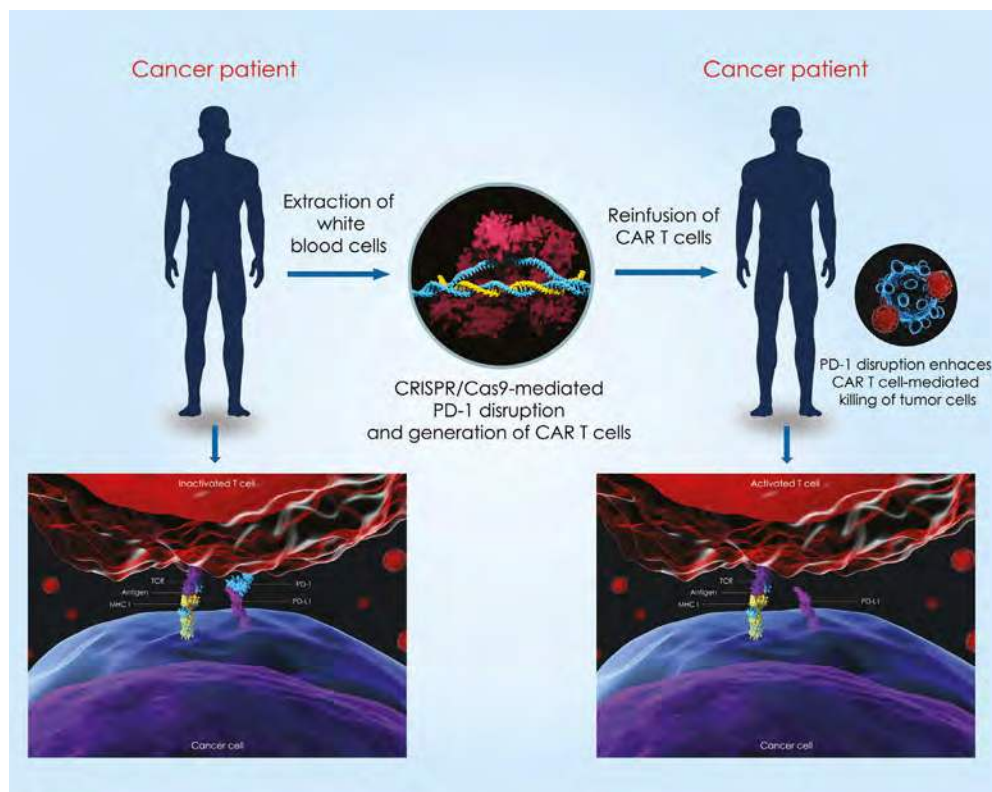
C&GT is a high potential and maturing sector, and is an already crowded environment, playing host to numerous start-ups and now, through M&A, recognised big pharma firms. Much like the rush to find a COVID-19 vaccine that dominates headlines worldwide, not every company involved will be able to succeed. But finnCap's finnLife watch list of 50 leading AIM-listed biotech companies demonstrates that there is room for numerous companies to contribute to, and profit from, C&GT. Examining three entirely different approaches to CAR-T therapy, it is possible to see just how much space there is for this exciting sector, therefore displaying the case for continued investment.

Innovative CAR-T therapy demonstrates the depth of C&GT potential

CAR-T therapy in its existing form is a relatively new and specialised approach at treating cancer. It takes T cells from a patient's bloodstream and genetically modifies them in a laboratory. These T cells are then injected back into the bloodstream with the aim of targeting and killing cancer cells. While it has been shown to be an effective treatment, there are risks and side effects. One is the two-step autologous process (the slow time it takes for cell expansion – sometimes as long as two weeks) while another is cytokine release syndrome (CRS), which occurs when cytokine molecules are inadvertently released, but too quickly to target just the tumours and instead target healthy cells.

The next generation of CAR-T treatments shows that there is space for a multitude of start-ups to be active in the C&GT space as they all help find varied solutions to these problems without negating the effectiveness of CAR-T.

One example is Horizon Delivery, a company that is developing its CYAD-02 project, which will help transport T cells more effectively to the tumour via the use of SMARTvector products. The product underwent its first phase 1 trial test in January 2020 with a patient who was suffering from acute myeloid leukaemia. Horizon Delivery is also an industry leader in CRISPR (Clustered Regularly Interspaced Short Palindromic Repeats) screenings, meaning they can identify key genes or genetic sequences that draw out specific functions of a cell type from thousands of potential variants.



In a cancer context, this means they can route out and exclusively eliminate problematic cells that may have shown signs they'd resist a future cancer treatment.

Another example is Maxcyte, a global cell-based therapies and life sciences company that is developing its CARMA process, where a patient's peripheral blood mononuclear cells (PBMCs) are removed and modified. The modified cells can then be used to target an array of different cancers. Currently the company is conducting a phase 1 trial for advanced ovarian cancer in a dose escalation trial that will treat four separate cohorts – the fourth of which was administered in March 2020.

Another example which shows the versatility of new CAR-T innovation is provided by Oxford Biomedica, a gene and cell therapy company specialising in the development of gene-based

medicines. Rather than a contained project or platform, its contribution to CAR-T is through a contract manufacturing development organisation. Collaborating with pharma companies, Oxford Biomedica uses its infrastructure to produce other companies' licensed products, including Novartis' Kymriah treatment (alongside other undisclosed CAR-T-related products).

With fast-moving innovation finally allowing multiple C&GT treatments to gain regulatory approval, along with a huge pipeline of upcoming therapies and an influx of funding and M&A activity, investing in C&GT no longer entails taking a bet on potential – the future is finally here.

Mark Brewer is Research Director, Life Sciences at finnCap



THE EUROPEAN PHARMACEUTICAL STRATEGY – IT'S OUT, SO WHAT?

The European Commission has published its long-awaited Pharmaceutical Strategy outlining its priorities for the coming years. As anticipated, the focus is on patient access to affordable treatments and boosting the competitiveness of the European pharmaceutical sector. But what's the big deal? In this piece, Jenni Kortelainen explores the possible impacts of the Commission's eagerness to overhaul EU pharmaceutical legislation.

Read Jenni's blog on the the PMHub to find out more.

hanover

**PharmaTimes Award
Winners 2019:**
International Challenge

**EMEA Sabre Award
Winners 2019:**
Medical Technology

**PRWeek Award
Winners 2019:**
Issues and Reputation
Management

Growing evidence supports the important role of biosimilars in healthcare

New data released at the ASCO Quality Care Symposium continues to underscore the cost-effectiveness of biosimilar treatment options in cancer care

By Edward Li



Access to healthcare, including affordable medicines, remains a top concern across the US. As we advance solutions, new data released at the American Society of Clinical Oncology (ASCO) Quality Care Symposium supports biosimilars as lower-cost, effective treatment options.

In recent years, complex biologic medicines have changed the way we respond to and treat some of the most challenging diseases, including cancer. However, biologics are often challenging to develop and costly to produce. In 2019, four of the top five prescription expenditures in the US were biologics and accounted for approximately \$46 billion in expenditures. As the US population

continues to age and face rising rates of chronic disease, these medicines will become more commonplace and the associated costs will likely continue to rise.

Biosimilars – FDA-approved treatments that match their reference medicine in terms of quality, safety and efficacy – have an important role in creating sustainability for overburdened health systems through increased competition. As more biosimilars enter the US market, patients treated with biologic medicines will have access to a broader set of more affordable treatment options. An estimated 1.2 million US patients could gain access to biologics by 2025 as the result of increasing biosimilar availability.

High cost biologics can impact patient access

To better understand the relationship among biologics, biosimilars and patient access, the field of oncology offers an example of how the cost of care can impact treatment decisions, specifically when it comes to the supportive care agents such as the myeloid growth factors Zarxio (filgrastim-sndz) and Neupogen (filgrastim).

After receiving chemotherapy, some patients may experience neutropenia, a temporary reduction in their white blood cell counts as a result of myelosuppressive chemotherapy. If a patient with neutropenia develops a fever greater than 100.3°F/37.9°C, this is febrile neutropenia (FN) which is considered a medical emergency, as it can indicate a life-threatening infection. Accordingly, treating febrile neutropenia requires more costly interventions, which may include hospitalisation and the use of intravenous antibiotics. Still, these patients are at a significant risk; based on a retrospective analysis of hospital discharge data, the inpatient case fatality rate associated with febrile neutropenia within breast cancer patients was 5.6%. The fatality rate was higher for patients with lung cancer and non-Hodgkin Lymphoma, at 15.7% and 9.4%, respectively.

Myeloid growth factors such as Zarxio and Neupogen are FDA-approved to prevent febrile neutropenia, and the National Comprehensive Cancer Network (NCCN) provides primary and secondary prophylaxis strategies. In primary prophylaxis, patients are administered a myeloid



'An estimated 1.2 million US patients could gain access to biologics by 2025 as the result of increasing biosimilar availability'

ASCO Quality Care Symposium

growth factor with the first cycle of chemotherapy to prevent FN. Secondary prophylaxis is a 'watch and wait' approach, where prophylaxis is given only after a patient develops FN or a significant neutropenic event after a previous cycle.

With primary prophylaxis, more episodes of FN are prevented compared to secondary prophylaxis. Thus, health systems experience fewer hospitalisations, less need for IV antibiotics and fewer costs associated with these interventions. Further, patients can maintain a timely chemotherapy regimen, preventing potentially harmful delays in administration. However, this is associated with more drug-related costs in the form of providing myeloid growth factors to more patients and within earlier cycles of their chemotherapy. When a patient receives a chemotherapy regimen at high risk ($\geq 20\%$ risk of FN), then the costs associated with myeloid growth factor prophylaxis is offset by reductions in the costs of hospitalisation and treatment of FN. When patients receive an intermediate-risk regimen (10-20% risk of FN), the secondary prophylaxis strategy is commonly employed due to the traditionally high cost of myeloid growth factors.

Biosimilars could offer a solution

Data presented at the ASCO Quality Care Symposium expands the pool of evidence demonstrating biosimilars as lower-cost, effective treatment options for life-changing medicines,

such as G-CSF. The study, conducted by Sandoz, shows that using biosimilar Zarxio (filgrastim-sndz) as primary prophylaxis after the first cycle of adjuvant docetaxel chemotherapy (an intermediate-risk regimen) in the treatment of early stage breast cancer is cost-effective based on a willingness to pay (WTP) threshold of \$50,000 per quality adjusted life year (QALY).

'In 2019, four of the top five prescription expenditures in the US were biologics and accounted for approximately \$46 billion in expenditures'

Due to the lower cost of myeloid growth factors after the introduction of biosimilars, the incrementally higher costs of providing primary prophylaxis vs secondary prophylaxis using Zarxio in patients receiving intermediate-risk regimens now falls under the threshold of what society would deem to be worth the outcomes of reduced FN events, reduced mortality and increased quality of life.

These findings align with the recent NCCN recommendations for FN prevention, which have expanded to those receiving intermediate-risk regimens (in addition to those at high risk) as a response to the potential higher risk of COVID-19

complications among cancer patients. It also builds on previous studies demonstrating the cost-effectiveness of Zarxio as primary prophylaxis within patients with lung cancer and lymphoma who are also receiving intermediate-risk regimens.

Ongoing support for biosimilars is imperative

Biosimilars are typically discounted by 20-40% from the price of a reference biologic prior to biosimilar market entry and, in turn, have the potential to reduce average patient out-of-pocket costs by 17%. This can help expand options for chronically ill patients and allow greater use of biologic medicines by providing more affordable access to individuals who, in the past, have either forgone treatment or settled for less effective medicines.

As the ASCO data demonstrates, and with the trend of increased spending on specialty medicines expected to grow, biosimilars play an important role in offering significant savings, providing some relief to the overburdened healthcare system. We must continue to support a clinical, legal, regulatory and market environment that helps realise the full access and savings potential that biosimilar medicines can provide.

Edward Li is Director, Health Economics and Outcomes Research at Sandoz

Treatment and prevention of cardiovascular disease

The potential of next generation omega-3 fatty acids



In 2019 approximately 17.3 million people died globally due to cardiovascular disease.

Treatment of cardiovascular disease and its complications continues to pose a substantial burden on healthcare systems around the world. The annual cost of cardiovascular disease in 2019 was officially estimated at \$351bn in the US and €210bn a year in Europe.

Diabetes is a major public health problem which affects more than 415 million people worldwide with an estimated increase to 642 million by 2040. For individuals with diabetes, cardiovascular disease is the leading cause of morbidity and mortality. In the US alone there is an estimated \$37.3bn in cardiovascular-related spending per year associated with diabetes.

Against this backdrop, the ability to treat both type 2 diabetes by improving blood glucose control and substantially improve cardiovascular outcomes in both diabetics and non-diabetics represents an important opportunity to address two major public health needs with a single compound.



Many advances in the treatment and prevention of cardiovascular disease have been made over the past few decades including type 2 diabetes treatments, LDL cholesterol management with statins, blood pressure-lowering medications, antiplatelet agents and other treatments. However, tackling residual cardiovascular risk remains as a substantial public health challenge across the world.

It is becoming more common for individuals to have multiple risk factors leading to an increased risk of cardiovascular disease. Therefore, a large unmet need remains for the development of new therapeutics that will tackle these various risk factors.

'The annual cost of cardiovascular disease in 2019 was officially estimated at \$351bn in the US and €210bn a year in Europe'

Recent progress in primary and secondary prevention of cardiovascular events provides hope that new therapies targeting various modifiable cardiovascular risk factors including high triglycerides, inflammation and hyperglycaemia will produce additional benefits to current prevention strategies.

In this context, the recent resurgence in omega-3 fatty acid research and the clinical data that has been produced provide an avenue for the development of such multifaceted therapies. The next generation of omega-3 fatty acids may have the potential to address several facets of cardiovascular risk simultaneously

by significantly improving on what has been achieved to date.

Cardiovascular disease treatment and prevention

One strategy that had been trialled repeatedly to address cardiovascular risk is omega-3 fatty acid treatment. After a number of recently failed cardiovascular outcome trials of omega-3 fatty acid mixtures, including the recent STRENGTH study, the REDUCE-IT trial (Reduction of Cardiovascular Events with Icosapent Ethyl-Intervention Trial) with a highly purified omega-3 fatty acid signalled a promising development in cardiovascular disease treatment and prevention.

REDUCE-IT demonstrated that a specific omega-3 fatty acid, eicosapentaenoic acid (EPA), significantly reduces the risk of ischaemic events, including death from cardiovascular causes, in patients with high triglycerides despite statin use. REDUCE-IT showed that in the enrolled population of 8,179 high-risk patients, treatment with highly purified EPA significantly reduced first cardiovascular events by 25% and total (first plus subsequent) cardiovascular events by 32%.

These findings represented a potentially notable advance in cardiovascular disease prevention, after the advent of statins approximately thirty years ago. EPA treatment was adopted into all major treatment guidelines in both the US and Europe, even though this was before regulatory approval for icosapent ethyl has been gained in Europe.

By contrast, the recent STRENGTH trial (Statin Residual Risk Reduction with Epanova in High Cardiovascular Risk Patients with Hypertriglyceridemia) 'was terminated early due to interim analysis revealing low probability for benefit with omega-3 CA', as reported by the American College of Cardiology on 15 November 2020.



STRENGTH was a cardiovascular outcome trial of a therapy containing an omega-3 mixture of EPA and DHA (Docosahexaenoic acid).

The different outcomes between the REDUCE-IT and STRENGTH studies highlighted that not all omega-3 treatments are equal and focused the attention of researchers on high-purity EPA-axis treatment.

Changes in the omega 3 space

Since the publication of the REDUCE-IT results, a change in omega-3 fatty acid research and drug development has taken place, focusing on EPA and its metabolites and derivatives. After the accumulation of evidence regarding the actions of EPA, the utility of this therapeutic approach is evident and has brought this field of research back into the spotlight.

Afimmune, a company with a focus on the discovery and development of bioactive lipids, is working to bring novel next generation derivatives of EPA and its metabolites to patients. High purity EPA treatment has opened the door to a largely untapped therapeutic class. Epeleuton is the company's first next generation synthetic omega-3 compound to enter phase 2 clinical trials. It appears to not only replicate the effects of EPA more potently and at a lower dose but also treats type 2 diabetes by improving glycaemic control. This is a novel additional property as EPA has not demonstrated any improvements in glycaemic control.

Epeleuton is a synthetic high-purity EPA-derived second-generation omega-3 fatty acid

with a therapeutic profile that is distinct from other omega-3 fatty acids. In a phase 2a study, it decreased triglycerides, improved glycaemic control and improved markers of inflammation.

The data indicates that this next generation derivative of EPA has potential for cardiovascular risk reduction by simultaneously targeting high triglycerides, type 2 diabetes, inflammation and other risk factors.

'A phase 2b multinational trial of epeleuton is currently underway in the US and Europe, with results expected before the end of 2021'

The speed of translation of the learnings from REDUCE-IT to further drug discovery and development shows a renewed interest in this space. Epeleuton is currently being studied in a phase 2b multinational trial in the US and Europe, with results expected before the end of 2021.

Beyond the efficacy results, EPA and its next generation derivatives show a good safety and tolerability profile compared to many of the current treatment options for cardiometabolic diseases.

The established and advantageous safety profile of this therapeutic class is suited to long-term treatment that could not only alleviate some of the substantial burden experienced by patients but will also encourage further research in this field.

Improving cardiometabolic disease treatment

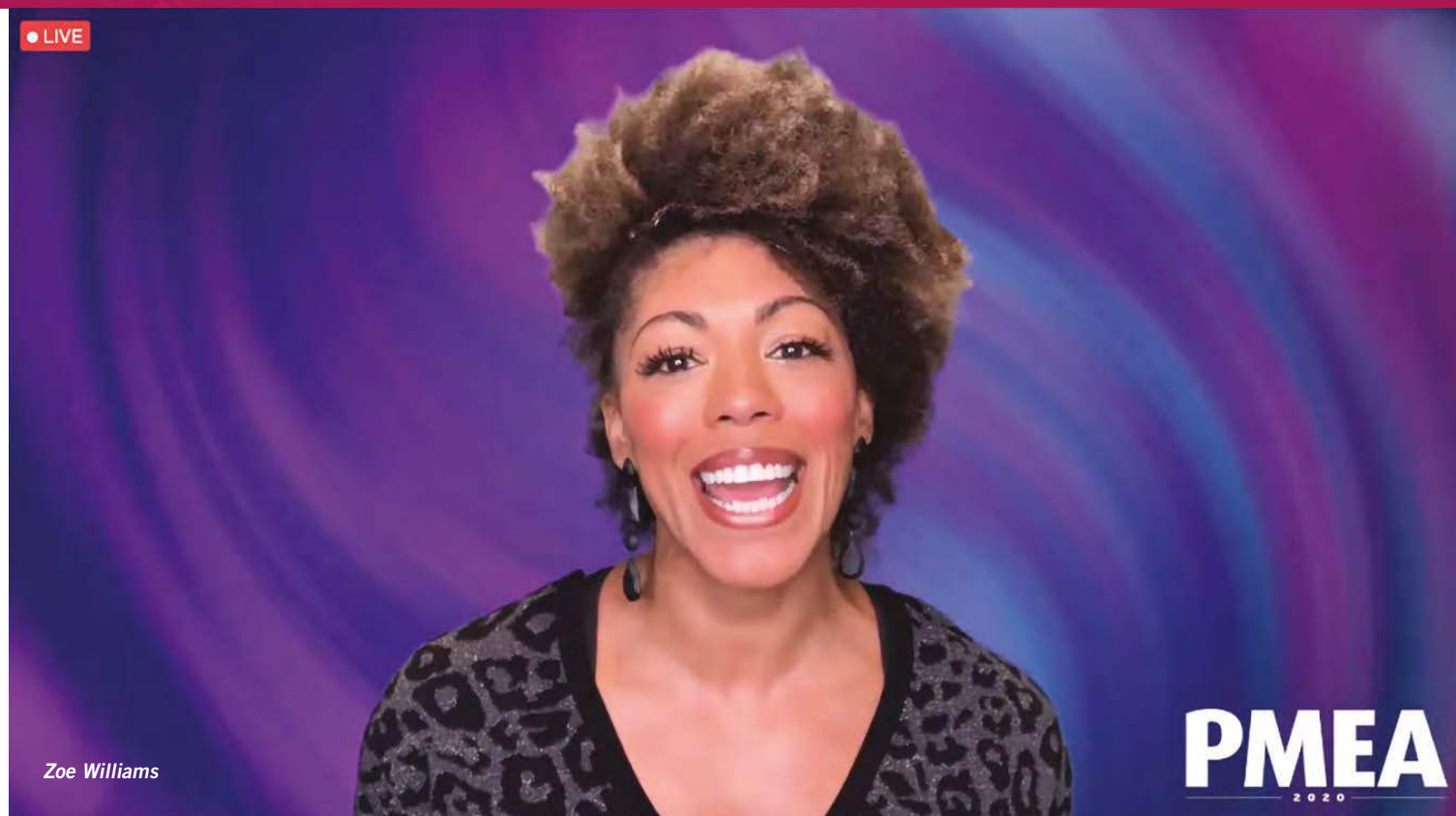
Current cardiovascular risk strategies often require multiple treatments to address individual risk factors. Treatment of hypertriglyceridaemia, hyperglycaemia and inflammation have been individually shown to effectively reduce cardiovascular risk and the rate of ischaemic events.

While there is established and accumulating evidence that multiple strategies may delay the progression of atherosclerosis and reduce the incidence of ischaemic events, this comes with an added pill burden to patients and in many cases potentially problematic polypharmacy, itself a growing problem. Each treatment comes with its own individual safety concerns and considerations, and the often burdensome combinations present additional concerns.

The next generation omega-3 fatty acids currently in development have the potential to treat these multiple risk factors simultaneously, advancing on the established effects of EPA. The omega-3 story has just started with EPA which has laid the foundations for the platform. The next generation compounds will build on this evidence base to provide greater efficacy and expanded therapeutic benefits with treatments that are safe, convenient for patients and ultimately improve their quality of life. This is an exciting time in cardiovascular research and innovation.

Moayed Hamza is Medical Director of Afimmune Ltd

● LIVE



Zoe Williams

PMEA 2020: continuing to recognise excellence in improving patient outcomes

The 20th annual PMEAs took place virtually this year due to COVID-19

The 20th annual PMEAs continued to recognise the achievements in pharmaceutical marketing excellence, taking place virtually for the first time this year due to the COVID-19 pandemic and social distancing restrictions.

The annual PMEAs continued to bring in a high number of entries, with a wide range of companies entering across the different categories.

While the event took place virtually this year, rather than at its usual venue at the Royal Lancaster London Hotel, the turnout was impressive, with over 1,000 views of the

livestream and over 150 tweets posted to the social media wall and 1,300 impressions.

Those watching the awards ceremony live could see their social media posts on the live social media wall by using the #PMEA20 hashtag.

For the first ever virtual PMEAs, television presenter and personality Zoe Williams hosted the online ceremony.

Debbie Tuesley, events director at PMGroup said: "In a truly unprecedented year it was remarkable to see the positive response that the livestream awards garnered. Despite the many obstacles posed by the COVID-19 pandemic, we

have been proud to ensure that the very best work within the healthcare environment can continue to be recognised through the PMEA programme."

A brand-new category was introduced for 2020 – the Agility Award in Pharma Market Excellence. This award recognised pharma brand teams that have successfully changed their strategic and operational approach due to the global COVID-19 pandemic to continue to supply, support and engage with healthcare professionals and patients.

Taking home this award was Accord Healthcare's Agility Ensures Medicines Supply During COVID-19 initiative with support from Alexa Forbes Consulting.



PMEA judges



PMEA sponsors



The judges commented: "Accord's reaction to the COVID-19 pandemic and their quick thinking was extremely forward thinking. The challenges were well documented, and their plan was executed impressively, with an impressive scale-up which resulted in extra doses of medicines before export bans came into place. This pre-emptive thinking was bold and worthwhile."

Paul Tredwell, VP Specialist Brands at Accord Healthcare said: "We are delighted to accept this award on behalf of the whole team at Accord. Our proactive and collaborative approach with our global partners, suppliers and our employees is what allowed us to really respond to the pandemic with agility and efficiency."

"I want to give a huge shout-out to the creative talents of Swordfish Advertising, who pulled our efforts together to effectively showcase this award and again thank you to Alexa Forbes Consulting for supporting us with this award submission. It was a truly collaborative effort," he added.

For PMEA Company of the Year, three companies were in the running to receive this prestigious award – AstraZeneca, MSD UK and Takeda UK & Ireland.

Coming out on top in this category was AstraZeneca – an impressive, first-time achievement for the company!

AstraZeneca also took home the following awards: Excellence in Innovation, Excellence in Collaboration and Partnerships and Excellence in Capability Development (supported by Uptake Strategies and EY).

The judges commented: "We were incredibly impressed by AstraZeneca; the performance of the business in the last few years is truly inspiring. They provided a strong articulation of strategy delivered with energy and enthusiasm by a very senior team, demonstrating that innovation is now central to everything they do."

They added: "While the company is obviously driven by the science, its values mean it goes above and beyond to make sure it delivers significant outcomes to patients irrespective of

hard commercial return. The company's response to COVID-19 was swift and effective. And finally, the company also takes its environmental responsibilities very seriously. All in all, the judges felt that AstraZeneca is a company they'd like to work with/for!"

Meanwhile, for PMEA Support Agency of the Year, Makara Health beat the competition to take home this award.

Overall, it was a very successful night for Makara Health, with the company also winning awards in the Excellence in Patient Education and Support and Excellence in Rare Diseases and Orphan Drugs categories.

Although the ceremony looked different this year, PMEA 2020 remained a successful event thanks to the impressive entries and hard work and dedication of all those involved in the programme.

The full results from PMEA 2020 are available at pmlive.com/awards/pmea/awards_archive

A special results brochure for PMEA 2020 is also available for download at pmlive.com/pmearesults.pdf





The Brexit clock is counting down and time is running out

What businesses need to know about post-Brexit immigration

By Jackie Penlington



With only weeks now until the Brexit transition period ends on 31 December 2020, businesses are running out of time to prepare for the immigration changes ahead.

Virtually all UK employers are likely to be affected, and life sciences businesses particularly so, given that international mobility and collaboration are key features of the sector.

Consider future business trips

Pharma businesses will be used to their European colleagues coming across to the UK and British nationals travelling to Europe – for example, to collaborate on projects for short periods. From January 2021, when EEA nationals are entering the UK as business visitors, they will only be able to undertake limited activities, such as attending meetings or conferences. Additional activities are permitted within science and research, such as sharing knowledge/advising on an international project being led from the UK, provided the visitor is not carrying out research in the UK. If individuals will be undertaking an internship or working in the UK, they will need to obtain prior immigration permission.

Conversely, businesses should consider the visitor rules in each respective European country for UK national employees taking business trips from January 2021.

Frontier workers

Pharma businesses may also have individuals who are resident in a European country but who frequently travel to the UK to work. It may be possible for these individuals to apply for a frontier worker permit to enable them to continue to work in this way.

'The impact on the life sciences sector will be keenly felt and employers should take action to ensure they are ready for what is ahead'

These significant changes are just around the corner now. The impact on the life sciences sector will be keenly felt and employers should take action to ensure they are ready for what is ahead. Below you will find checklists and more detailed information on the upcoming changes.

What does the end of free movement for European nationals mean for UK employers?

Currently, UK employers can recruit a European national in exactly the same way as a UK national.

European nationals can enter the UK on the basis of their current EEA passport or ID card – it involves no immigration application or visa fees.

The key change is that this free movement for EEA nationals (and their family members) will end at 11pm on 31 December 2020. There will be different immigration rules applicable to European nationals depending on whether that individual first arrived in the UK before or after 11pm on 31 December 2020. It will therefore be important for employers to know when the person first entered the UK.

European nationals and family members who enter the UK before 11pm on 31 December 2020

In most cases, these individuals will need to apply for pre-settled or settled status under the EU Settlement Scheme (the 'Scheme') in order to continue to live and work in the UK long term. This involves an online application and there are no visa fees. The deadline for applications is 30 June 2021.

Only those with Irish citizenship or with indefinite leave to remain are exempt from applying under the Scheme. It is important to note that individuals who have already obtained a Permanent Residence document still need to apply for settled status.



If individuals fail to apply by the deadline, it is likely that the individual will no longer have the right to live and work in the UK after 30 June 2021. It is also likely to be a criminal offence for a UK employer to continue employing them in the UK. To avoid key members of staff being left without the right to work in the UK, it is important that employers take a proactive approach now.

Settled status

Those who have been 'continuously resident' in the UK for at least five years should be eligible for settled status under the Scheme. 'Continuously resident' means that the individual has been present in the UK for at least six months in every 12-month period. If the person is absent from the UK for longer than six months in any 12-month period, this will usually break continuity, except in limited circumstances. If continuity of residence is broken, it is unlikely that the individual will be eligible for settled status.

Pre-settled status

If the individual has been in the UK for less than five years, they should be granted pre-settled status. Pre-settled status is granted for five years and, importantly, it seems that this cannot be extended. It is therefore vital for individuals to safeguard their continuous residence so that they are able to apply for settled status after five years in the UK. As above, in order to be able to apply for settled status they must not spend more than six months in any 12-month period outside of the UK. In addition, if an individual is absent from the UK for a continuous period of more than two years, their pre-settled status will lapse altogether.

If an individual obtains pre-settled status, employers should therefore consider the implications of the length of any international secondments or regular business travel or overseas working on that person's future eligibility to apply for settled status.

Top tips for employers – EU Settlement Scheme

- If not already done, carry out an audit to identify who is affected by Brexit and needs to make an application under the EU Scheme
- Encourage your European workforce to apply under the Scheme before 30 June 2021 – the gov.uk website has an employer toolkit to assist with this
- Make a note to check in May/June 2021 that everyone who needs to has applied or will be applying under the Scheme by the deadline of 30 June 2021
- Make a note of the expiry dates of employees' pre-settled status and follow up before the expiry date to ensure that they have now obtained settled status

- Take care when offering international secondments, allowing remote working overseas or regular business travel for employees holding pre-settled status. If they spend too long outside the UK, they may find themselves having to leave the UK after five years.

European nationals and family members arriving in the UK after 11pm on 31 December 2020

Generally, these individuals will not be able to apply under the Scheme (although in certain circumstances family members may be able to apply). In order to live and work in the UK, they will need to apply under the new Immigration Rules in force from January 2021. In most cases, employers will need to sponsor European nationals under the new Skilled Worker route and employers will need a sponsor licence in order to do so.

In essence, those holding a European passport will no longer have any advantage when applying for UK immigration. EEA nationals and their family members arriving for the first time to live and work in the UK will, from 1 January 2021, be treated in exactly the same way as non-EEA nationals under the UK's immigration rules.

'From January 2021, EEA nationals entering the UK as business visitors will only be able to undertake limited activities, such as attending meetings or conferences'

The majority of roles in the life sciences sector undertaken by non-UK nationals are highly or medium skilled. This means that pharma businesses will have the option of sponsoring individuals for these roles in the UK, provided the minimum salary threshold is met and the person meets the English language requirements. Employers will, however, need to contend with the significant costs of sponsorship – Home Office's fees alone are usually around £10,000 to sponsor one individual for five years. If the worker is bringing three dependants with them, these fees swiftly rise to over £20,000.

Businesses will also need to engage with the longer lead-in times for individuals to apply and enter the UK. While at present European workers travel to the UK as soon as they are needed, the sponsorship system will entail several weeks or even months for the submission and approval of

visa applications. Even longer will be required if the company does not already have a sponsor licence.

Top tips for employers – preparing for the new immigration system

- If the business does not yet hold a sponsor licence, we strongly recommend it considers applying for one now. Before doing so, it is important to take advice on the onerous sponsor obligations and HR processes that must be in place.
- Employers that already have a sponsor licence should ensure they are compliant with their sponsor obligations so that they are ready for any Home Office audit. This is particularly relevant this year when many changes may have taken place, such as updated working hours or salaries for sponsored workers or changes to the business itself, all of which may need reporting to the Home Office. Sponsors' licences can be (and often are) revoked for non-compliance. You may wish to consider an immigration audit.
- Ensure you are up-to-date with the latest immigration rules and sponsorship guidance as significant changes come into effect on 1 December 2020.
- Review your recruitment strategies and factor in additional costs for sponsorship into recruitment budgets.
- Ensure you are carrying out right to work checks correctly in relation to all employees – failure to do so could lead to civil penalties and sponsor compliance action being taken. Right to work checks are likely to be an issue in relation to European nationals too next year. We recommend from 1 January 2021 you ask EEA nationals when they first arrived in the UK to see if this was before or after 31 December 2020. If they arrived before 1 January 2021, you should encourage them to provide details of their pre-settled or settled status if they have already applied or remind them to apply by 30 June 2021. If they arrived after 31 December 2020, you will need to see evidence of their right to work in the UK and it is likely you will need to sponsor them.
- The offer letter and employment contract for all employees should clearly state that employment is conditional on the person having the right to work and the employee providing satisfactory evidence of that right to work.

Jackie Penlington is Managing Associate, Stevens & Bolton LLP

RESEARCH NEWS

Life sciences hub set to be developed in the West Midlands

Birmingham Health Innovation Campus will create 10,000 new jobs

A new life sciences hub is set to be developed in the West Midlands and will become the only science park in the region dedicated to translational health and life sciences research.

The Birmingham Health Innovation Campus will sit at the centre of an established cluster of health excellence led by Birmingham Health Partners (BHP) – a strategic alliance between the University of Birmingham and two co-located NHS Foundation Trusts (University Hospitals Birmingham and Birmingham Women's and Children's).

The development of the campus is set to be delivered via a long-term collaboration between the University of Birmingham and Bruntwood Scitech, a property provider for the science and technology sector.

The campus will provide up to 657,000 square feet of lab, office and incubation space, providing co-location opportunities for health and life sciences businesses at all clinical or commercial stages.

"With access to Birmingham's world-class genomics laboratories, health data programmes, healthcare technology development teams, clinical trials leadership and academic expertise, this campus will become the ideal place for innovative health and life sciences businesses to thrive," said Tim Jones, University of Birmingham provost and vice-principal.

"This ambitious new development will leverage the existing integrated BHP ecosystem to drive innovation and economic growth – all centred on a shared mission to transform the health of all citizens, in Birmingham and beyond, by accelerating the development and adoption of healthcare innovations," he added.

The campus has already received development funding from Birmingham City Council and the Greater Birmingham and Solihull Local Enterprise Partnership. It has also been designated a Life Science Opportunity Zone by the Department for Business, Energy and Industrial Strategy.

According to the University of Birmingham, the campus will aid the development of a new high-growth life sciences cluster for the city and region. By 2030, the campus will have received £210m in investment, creating around 10,000 new jobs and delivering over £400m GVA to the local economy, the university added.

"Life sciences is an incredibly exciting and important sector that we have been quietly growing in the West Midlands over the last few years. Now with this announcement we are cementing our ambition to be one of the global leaders in this sector," commented Andy Street, the Mayor of the West Midlands.

UCB acquires new campus for UK operations in Surrey

Site was acquired from Eli Lilly

Biopharmaceutical company UCB has acquired a new campus for its UK operations located in Windlesham, Surrey.

The campus will support the company's research and development, early manufacturing and commercialisation of medicines in the UK.

With the acquisition of the Windlesham site expected to be completed in November 2020, the company added that the investment reflects UCB's commitment to keep the UK as one of its three global hubs for research and development.

Including the acquisition of the new campus, UCB's projected investment in the UK is set to top £1bn over five years. The transition to the new facility in Surrey will support over 650 high-value jobs in scientific research, translational medicine, clinical development, early manufacturing and commercial roles.

UCB acquired the 47-acre campus from Eli Lilly – following the completion of the acquisition, the site will be refurbished prior to UCB relocating from its current UK headquarters in Slough, Berkshire.

The company has a network of collaborations with UK universities, charities and other companies to aid in its endeavours to advance scientific research in the UK.

"We have a strong track record of discovering medicines in the UK which go on to make a difference to the lives of patients worldwide," said Jean-Christophe Tellier, chief executive officer at UCB.

"I am delighted to have signed an agreement to secure this new campus for our UK hub, from which our scientists will be able to continue to develop their extensive collaborations with some of the most innovative universities, bio-techs and medical research charities, bringing even greater benefit for patients.

"This new UK site will not only support our ambitions for future drug discovery, it will also be well-placed to enable us to achieve our 2030 global sustainability goals, and it provides an environment which supports the physical and mental well-being of our people, which is essential in helping us thrive," he added.

"It's fantastic to see that UCB has reaffirmed its commitment to the UK's world-leading life sciences sector, and I welcome the role this facility will play in creating hundreds of high-value jobs in the years to come," commented Nadhim Zahawi, Business and Industry Minister.



Life sciences industry in Northern Ireland is 'flourishing'

Life sciences activity contributes an annual GVA of over £1.1bn

A report by the Fraser of Allander Institute, commissioned and supported by the Association of the British Pharmaceutical Industry (ABPI) has identified the growing importance of the life sciences sector in Northern Ireland.

According to the research, the life sciences sector has seen major growth in Northern Ireland over the last few years, with employment in both pharmaceuticals and medicines manufacturing climbing by 6% since the last record in 2015. Wider life sciences employment also increased by 12% in the same period.

The report characterised life sciences to include all pharmaceutical industry, medicines manufacturing and healthcare activity across Northern Ireland.

In addition, life sciences activity contributes an annual gross value added (GVA) of over £1.1bn in Northern Ireland, mainly driven by the pharmaceutical industry which employs 13,900 people and generates a GVA of £910m.

The life sciences sector is also now the joint second-biggest spender on research and development in Northern Ireland alongside the machine industry, investing £74m in 2018 according to the latest NISRA data. According to the ABPI, companies are attracted to Northern Ireland for a number of reasons including skills availability and excellent infrastructure.

On top of that, Ulster University and Queen's University Belfast rank among the top ten in the UK for bioscience research, ensuring a continued supply of high-skilled scientists required for the pharmaceutical and life sciences industries to advance medical science.



"Science will help us beat this pandemic and good-quality jobs will help us deal with its economic fallout. Northern Ireland's thriving life sciences sector provides both," said Colette Goldrick, director of ABPI Northern Ireland.

"Public and private enterprises are already having a positive impact on the lives of people across the country and today's report shows there is a solid foundation for growth in the future. The message is clear: our sector is flourishing," she added.

Highest quarter for investment in UK biotech recorded this year

Over £1bn raised between June and August 2020

Data from the BioIndustry Association (BIA) and Clarivate reveals that UK biotech companies raised over £1bn between June and August 2020.

The equity finance investment during this period is the highest quarter for investments in the sector on record, the BIA added.

By October this year, £1.9bn had been raised for the UK biotech sector, meaning that it is on target to be the best year ever recorded.

In particular, the report shows that £119m, was raised through the year's first initial public offering, as well as £282m raised through venture capital (VC), including a return to pre-COVID-19 levels of seed and early VC deals.

A further £601m was raised through other public financings on both London and New York exchanges as biotech shares continue to perform across the Atlantic.

During this quarter, some notable investments in companies included Freeline Therapeutics, which topped investments with a £119m IPO on the NASDAQ. Also, NodThera – which is developing anti-inflammatory therapeutics – raised £41m in a series B venture capital deal.

"During the pandemic, UK biotech has shown its strategic value and received great interest from UK based investors, with many investing in the sector for the first time," said Steve Bates, chief executive of the BIA.

"This could be transformative for patients and the economy, and for shareholders, when combined with the global money we already attract – large pharma, US and Chinese venture capitalists are already aware of the vast opportunities UK biotech presents," he added.

"Biotech companies are well positioned to deliver the clinical advances patients need. Not only have companies across the globe banked record sums this year but, in the first three quarters of this year, specialist biotech investors have raised more than \$16bn in new funds to support biotech in the coming years," commented Mike Ward, global head of thought leadership, DRG, a part of Clarivate.



PME

PHARMACEUTICAL MARKET EUROPE

PME is Europe's leading magazine for decision-makers in the pharmaceutical industry, tracking the trends and issues that affect the pharmaceutical marketplace throughout Europe.

PME is a monthly print and digital title written by experienced journalists and high-profile pharma and healthcare experts. The magazine provides insights and offers solutions to the issues that keep industry leaders awake at night.

From the latest developments in cancer treatments and the strategies behind them to new marketing and commercialisation models and the regulations that underpin the fabric of the sector - PME's got it covered.

PME is a trusted source for decision-makers and influencers in pharma and healthcare and offers practical and accessible content to the pharmaceutical industry.

Visit pmlive.com/pme to view the latest edition and apply for a subscription in print or digital format!

Check out
our new look
digital edition!



COMMUNIQUÉ MARKETING & COMMS

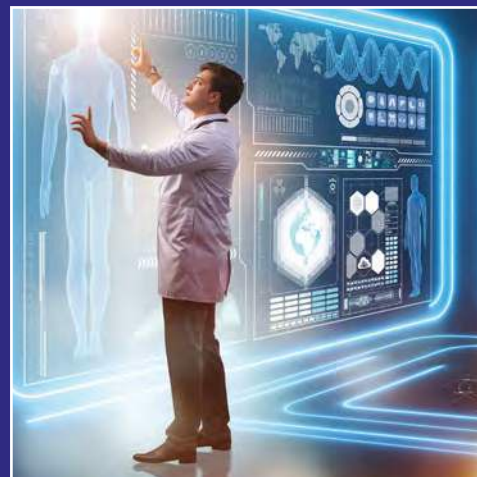
DECEMBER HIGHLIGHTS



34-35
**SUCCESSFUL PRODUCT
COMMERCIALISATION:**
What can we learn from
the rare disease setting?



36-38
**PUTTING THEORY
INTO PRACTICE**
Ideas about new product
adoption are dangerously
out of date



40-41
**THREE WAYS AI WILL CHANGE
HEALTHCARE IN THE NEXT DECADE**
AI will continue to take
centre stage in global
healthcare initiatives

APPOINTMENTS ON PAGES 42-44

Changes at Vertex, VectivBio and Novavax

HEALTHCARE COMMS NEWS ON PAGE 45

TOP STORY: Envision Pharma Group acquires Two Labs

Rebranding in an evolving world

By Graeme Duncan

‘Our company vision is to improve the lives of patients by enhancing the critical medicines they depend on, broadening patient access and improving health outcomes around the world’



In our industry, a corporate brand can often be perceived as a stand-alone concept, a recognisable colour scheme or a company logo, but an organisation’s brand is, in fact, its identity: its values, its personality and its people. That’s why at ADVANZ PHARMA we have been committed to transforming our brand over the past two years to closely align with our revitalised company vision. It is only through the resilience and entrepreneurial spirit of our people, and the intrinsic guidance of our corporate personality that we can reach this vision: to improve the lives of patients by enhancing the critical medicines they depend on, broadening patient access and improving health outcomes around the world.

In 2018, we made the decision to transform our corporate identity and redefine our company, through our determination to innovate and grow within the niche established medicines sector. This decision meant going beyond our past achievements to refocus and re-evaluate our position in the market, while meeting the needs of increasingly complex global healthcare systems. We have made significant inroads to this plan and, as a result, I would describe the past 24 months for the company as being truly transformative in what we have achieved. This has included structural and physical changes to the organisation, ranging from shifts in our senior leadership team, right through to the look and feel of our office spaces across the globe. This has helped to ensure that all employees feel they are part of the journey and have the same vision for growth, while becoming a truly dynamic, progressive company in the process.

A time for investment

One of the many benefits of the rebranding and refinancing of the company is that it has allowed us to shift the focus of the business so that we can invest more extensively in our pipeline, both organic and inorganic. We have been able to reset our strategic compass to move towards a more complex, added-value portfolio, while keeping the base established products business as the foundation of our work through the creation of two distinct business units, the first being our global established products unit and the other a strategic growth unit, where we can focus our efforts on commercialising more complex medicines in the European hospitals market.

‘The need to continue evolving and growing will be at the forefront of our minds and strategy as we move forwards’

This includes advancements in some of our key therapy areas that we believe will be of great value to patients, particularly in the anti-infectives space which has had limited investment in recent years, despite the ever-increasing health burden of antimicrobial resistance globally. Further to this, our expansion in endocrinology will, I believe, be of notable significance as we focus on a more patient-focused treatment experience with the launch of one of our key pipeline assets in the new year. Simultaneously, we are consistently searching for products that fit our brand and portfolio so that we can continue to expand and provide clear value to patients and healthcare providers.

It goes without saying that partnerships are a fundamental part of that portfolio expansion, which is why another key area of investment has been in mergers and acquisitions. Through our strategic dedication to growth in the past two years, we are now well placed as a ‘go to’ partner within an ever-expanding collaboration network. We’ve made monumental strides in increasing our European presence through the acquisition of Correvio Pharma in May this year, which immediately strengthened our position as a trusted partner when commercialising hospital medicines in Europe. Acquiring Correvio was a truly landmark step in our journey of rebranding and restrategising the company, bringing stability, capability and, above all, a robust foundation to continue on our growth trajectory. It also brings a highly experienced team, with significant commercial and medical knowledge, as well as established relationships with healthcare professionals across Europe – something we are very much looking to build upon.

A shift in culture

Our rebrand undeniably infiltrated all aspects of our company, not least our company values, vision and people. In becoming ADVANZ PHARMA, we were able to create a new, fast-paced culture where we are constantly challenging and championing one another. There is a true collegiate, entrepreneurial spirit within the company which inspires everyone to transcend the boundaries of what we can achieve in line with our corporate goals. The injection of vibrant, diverse talent from people of all walks of life, and at all levels, has been incredibly refreshing to see and we look forward to recruiting more ambitious minds as we look ahead to 2021.

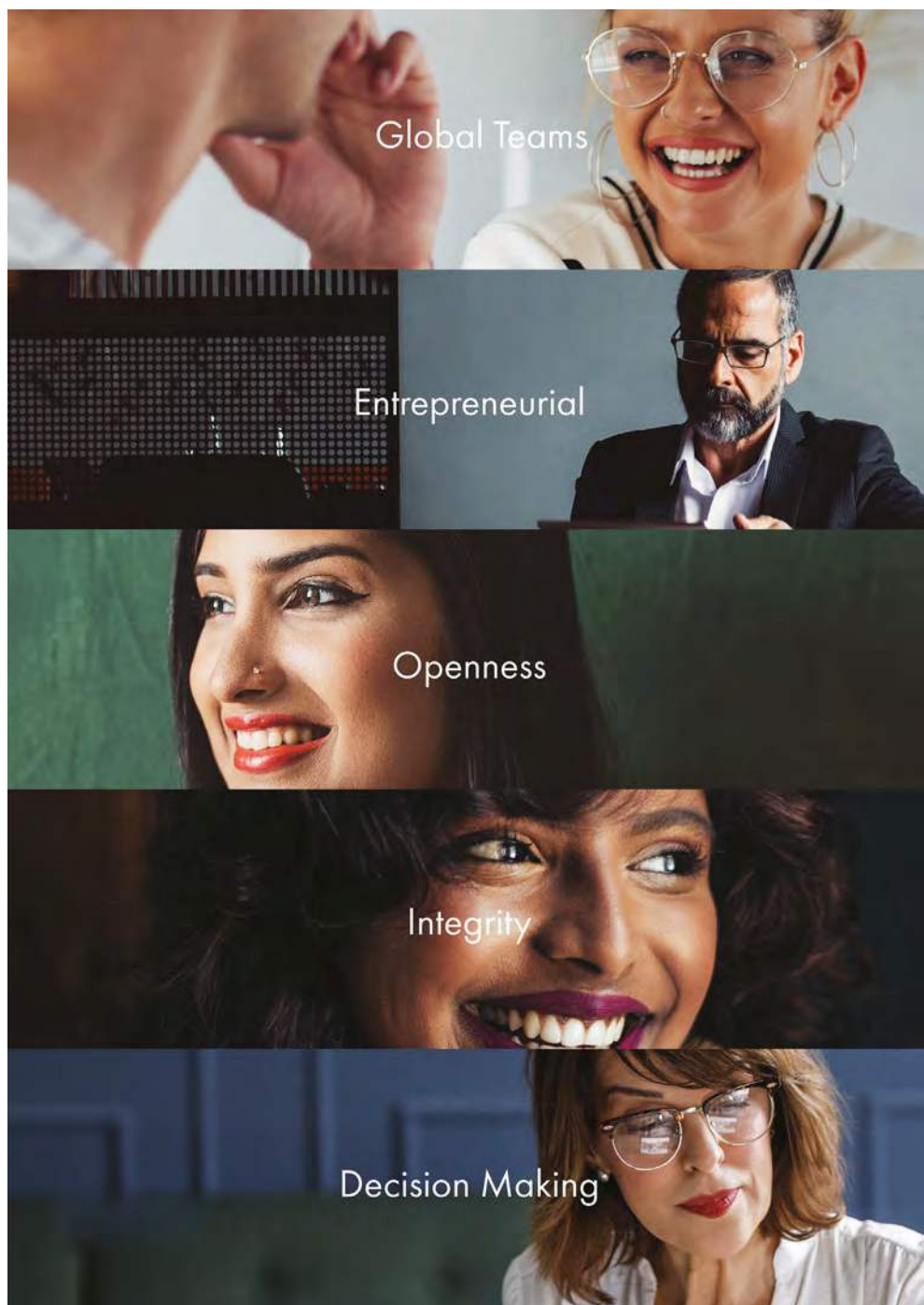
At a time of such monumental change for the industry and, in fact, the world, this year has also provided us with a stark new perspective on the vital importance of supporting our employees across the globe, from our staff in Mumbai to employees in our Sweden offices, to ensure they can work as safely and as comfortably as possible. This has meant a transition in our policies, to provide flexible working patterns and an efficient transition to remote working at the beginning of the year. Through our recognition of the unimaginable struggles that many have sadly faced this year, we have revitalised our commitment to corporate social responsibility in support of those who are less fortunate than ourselves. One example of this was our 24-hour dance-a-thon where our employees around the world, beginning on the east coast of Australia and ending in the Asia Pacific region, danced around-the-clock to raise tens of thousands of pounds for The British Red Cross Global Coronavirus Fund, an activity which I believe encapsulates the spirit of our people.

The next phase for growth

This year has given us all time to reflect on our priorities, both from a personal perspective and a business standpoint; however as a company, we are unwavering in our ambition and determination to grow and strengthen the strong foundations we have laid in the past two years. Since the rebrand, I am proud to say that, to date, we have set out exactly what we wanted to achieve. We have stabilised the company in such a way that we can create new, lasting partnerships, where we can continue to invest significantly in products and portfolio expansion. Our lean operating model combined with regulatory, quality and supply-chain capabilities across almost 100 countries means we are also able to acquire and integrate new products and companies quickly and efficiently.

'We are consistently searching for products that fit our brand and portfolio so that we can continue to expand and provide clear value to patients and healthcare providers'

In the process, we have determinedly established our reputation in the established products industry, becoming an esteemed partner of choice within a competitive global network. The solidification of our long-lived niche-established medicines business unit with our newly formed strategic growth business unit places us in a strong position to continue the supply of our 180+ molecules to specialised patient populations around the world, while simultaneously focusing on commercialising more complex medicines. The strides we have made in both of these areas would not have been possible without the dedication and steadfast resilience of our employees around the world, many of whom are part of our freshly acquired talent pool. Overall, as a company



and as a team of 550+ staff, our goals for patients and for healthcare providers remain unchanged, but the need to continue evolving and growing will be at the forefront of our minds and strategy as we move forwards.

While we are still in the midst of the ongoing challenges of the pandemic, we are looking ahead to 2021 with plans to re-energise and shift the lens to portfolio expansion and the launch of promising pipeline assets. With our brand identity firmly in place, next year will be an opportunity to refine our strategy to ensure we remain on track to reach the corporate targets that we set out two years ago.

When reflecting on our move to restructure and rebrand the business in 2018, I am extremely proud to see how far we have come

as a company in two short years. It was a bold decision to begin a new chapter and implement a vast array of changes to a company in such a small time frame, however we have already seen that we can withstand the most challenging of circumstances and not only survive but thrive. Transforming our corporate brand and becoming ADVANZ PHARMA was a landmark milestone in the company's history and we look forward to building upon the successes, learning from the challenges and, ultimately, leading our employees into the next chapter of growth for the organisation.

Graeme Duncan is CEO of ADVANZ PHARMA

Successful product commercialisation: what can we learn from the rare disease setting?

Achieving launch success in an increasingly challenging commercial environment

By Amanda Henkel



The pharmaceutical industry is constantly evaluating opportunities to accelerate product life cycles and bring efficiencies to drug discovery, development and commercialisation.

However, in addition to these internal drivers to improve agility, several external trends are also emerging. First and foremost, companies are under pressure to reduce drug prices and demonstrate greater value from their therapies, with an increased emphasis on value-based outcomes and real-world evidence. Consequently, products are launching into an increasingly challenging commercial environment that is experiencing unprecedented influence from patients, regulatory authorities, healthcare policymakers and payers.

This trend is not surprising – in part driven by the pressures facing healthcare budgets through the rising incidence of chronic diseases, as well as the advent of cell and gene therapies and novel medicines for rare diseases. The Boston Consulting Group has projected that the orphan drug market will grow almost 11% annually to approximately \$240bn by 2024, nearly double the growth projected for all drugs. Furthermore, orphan drugs are anticipated to account for 55% of the EU pipeline's cumulative value in 2022.

Rare diseases: setting the gold standard for successful product launches

A recent Deloitte Insights white paper found that three product characteristics are strongly associated with strong launch performance: priority review and specialty or orphan drug status – all of which are typically associated with drugs targeting rare diseases. Of course, these are not the only characteristics that define a strong performance, so what else is it that differentiates these launches and sets them up for success?

In the field of rare diseases, it's common to come across statements that emphasise how launching a rare disease medicine demands a different launch model from that of traditional drugs. There's no doubt that drug launches targeting rare diseases have distinct characteristics from those of more mainstream drugs, but in some ways their chance of success is more assured (since they target diseases that typically have limited treatment options). Furthermore, a priority review designation by the FDA or EMA signals to the market an expectation that the drug will provide an improvement over currently available treatment.

'It is projected that the orphan drug market will grow almost 11% annually to approximately \$240bn by 2024'

However, a rare disease product launch faces its own set of challenges – with increased competition and pricing pressures, regulators demanding more evidence of therapeutic value, and patients themselves driving treatment decisions and impacting success through globally connected communities. Despite these challenges, rare disease products are increasingly setting the gold standard for launch success – so are there any lessons we can learn (from these frequently smaller pharmaceutical companies) or any best practices that we can carry over to more mainstream drug launches?

Establishing a successful launch strategy

While each rare disease launch is different, several similarities are shared – a key element being a

truly patient-centric, cross-functional approach. One that genuinely puts patients at the heart of all communications by addressing their needs. As with all products, a holistic, long-term launch strategy is required, with life cycle management and scenario planning. However, during our work with pharmaceutical companies launching products in rare diseases, one key characteristic stands out. Collaboration – a cross-functional approach to launch execution that allows all stakeholders to input, not only through the sharing of insights and development of collaborative tools, but through a true alignment and consistency of messages across audiences and regions.

A deep understanding and alignment to patient needs

As with any drug launch, a comprehensive understanding of the patient and physician's journey and ecosystem is required. Journey maps are essential to build understanding of the challenges and opportunities facing the patient or prescriber throughout a disease course. These maps not only help us understand the practical aspects, but they provide insights into the needs and emotions each stakeholder experiences – allowing us to identify treatment decision drivers and pain points. Furthermore, a thorough mapping of the ecosystem allows us to form a detailed picture of the different stakeholders involved (including the role of patient advisory groups [PAGs], caregivers, primary care physicians, specialist physicians, nurses, payers and policymakers), as well as the influencers of these stakeholders. A full understanding of all stakeholders and their individual journeys also ensures interactions can be tailored to meet their needs at each touchpoint.

Putting theory into practice

Ideas about new product adoption are dangerously out of date

By Matthieu Le-Clerc Chalvet and Professor Brian D Smith

It is a truism that the life sciences industry – pharma, medtech and its related sectors – are driven by innovation. Without innovative new products, our industry sinks into the pit of commoditisation. And without the adoption of those new products, patients' needs remain unmet and healthcare professionals lack the tools to advance their practice. And yet we know that many innovative new products fail to be fully adopted and that many older, suboptimal products remain in everyday use. This is clearly an important issue for our industry and one of the topics we are researching in our research group at the University of Hertfordshire, which specialises in the evolution of the life sciences industry. Our findings challenge the accepted wisdom about new product uptake that most medical marketers take for granted and have important implications for practice.

All good research begins with the question: 'What do we think we know already?' In the case of new product adoption, the field is dominated by Rogers' Diffusion of Innovation (DoI) theory, summarised in box 1. Rogers' published his seminal work in 1962 and, even if you have not read it, you are almost certainly marinated in his ideas. Whenever you say 'early adopter' or 'laggard', you are talking Rogers' language. The concept of a Key Opinion Leader, so prevalent in our industry, is derived from Roger's work. He has been hugely, if invisibly, influential in how we launch new medicines and medical technology. His work captures many of the key factors that influence the degree and speed of new product uptake but, as a theory on which to base huge investment and effort, it has its limitations.

Most of the evidence supporting it comes from

consumer markets in which individuals make relatively simple choices. Even though most medical marketers are taught it, there is very little empirical evidence to support DoI theory in pharmaceutical, medical technology and related markets.

The second theory that tries to explain uptake is far less well-known by marketers, although it is well accepted by academics. Communities of Practice (CoP) theory, first suggested by Lave and Wenger in 1991, looks at new product adoption as a group effort and is summarised in box 2.

'Many innovative new products fail to be fully adopted and many older, suboptimal products remain in everyday use'

Although they have not embedded themselves into marketing thinking as deeply as has Rogers, the work of Lave and Wenger lies beneath concepts such as 'gatekeepers', 'champions' and 'influencers'. Their influence is therefore especially strong in models of adoption of complex, high-involvement products that require significant changes in practice or in the organisation. CoP theory has the obvious strength that it addresses group decision-making much better than DoI theory. However, although it has been used to explain the adoption of new clinical procedures, like its older predecessor theory, there has been little empirical application to the question of new product uptake in pharmaceuticals or medical technology.



Our painstaking review of the literature on new product uptake, especially in the life sciences, was the necessary foundation to our research. It told us that, although there are two well-established schools of academic thinking and that DoI in particular is often applied in practice, we have relatively little scientific evidence to support either of these ideas in the particular context of pharmaceuticals, medical technology and related markets. We simply don't know which, if either, of these theories, is correct. It was this gap in our knowledge, important to both the industry and to society in general, that our research set out to fill.

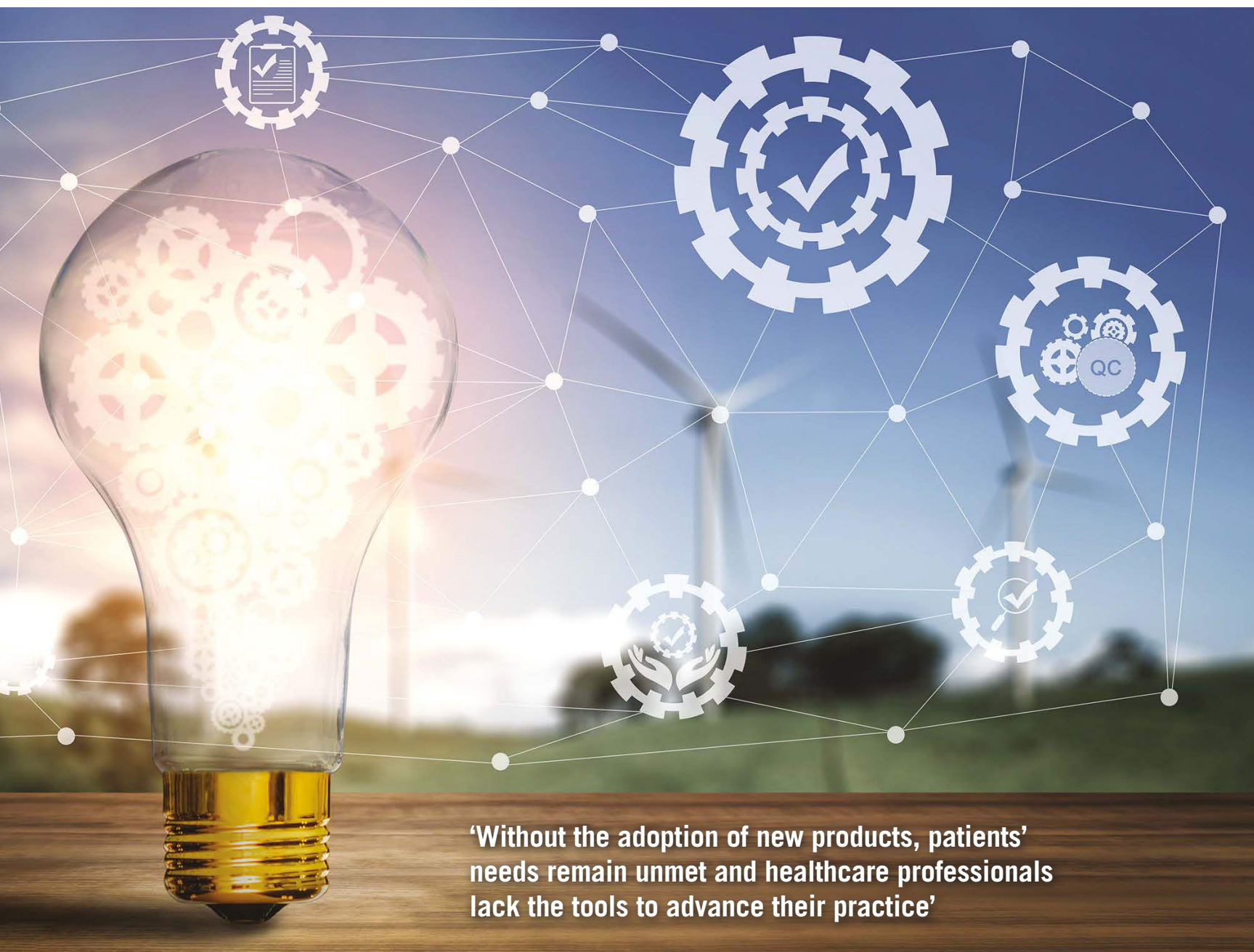
Exploring the gap

To explore this gap, we decided to study the uptake of five different innovative medical technologies across multiple secondary care centres. Our research was both quantitative and qualitative. Our aim was not simply to look for correlations between factors but to get deep into

Box 1: Diffusion of Innovation theory

Diffusion of Innovation theory explains the rate of uptake of new products in terms of variables including:

- The adopters' appetite for innovation, which varies between individuals
- Access to information about the product
- The influence that more innovative, earlier adopters have on less innovative users
- Characteristics of the product, such as its cost, efficacy and ease of use
- How easy it is to try out the product and how compatible it is with current practice.



‘Without the adoption of new products, patients’ needs remain unmet and healthcare professionals lack the tools to advance their practice’

the causative explanations for why new product adoption varied between products and between customers. As we examined both kinds of data, the question at the back of our minds was: ‘Does DoI or CoP best explain what we see in the real world or is it something else entirely?’ The research was detailed, laborious, has taken four years so far and it is not yet complete. Our findings, although preliminary and not yet published in the management literature, can be summarised in three important discoveries.

Firstly, both Rogers and Lave and Wenger were on to something. Unsurprisingly for such great minds, both schools of thought captured much of the complexity of the new product uptake phenomenon. All of the ideas summarised in boxes 1 and 2 were, to some extent, correct. But both theories were also inadequate. DoI highlights important factors such as ease of trial and product complexity but tends to place too much emphasis on the role of the individual. CoP balances this with a good

understanding of group dynamics in decision-making but perhaps understates the changing level of the decision over time. It also completely ignores the product’s characteristics. The reality is that both sets of scholars are looking at the same problem but from different perspectives. They are seeing different sides of the same coin. In practice, this means that if you are an adherent of either theory (and most marketers are implicit disciples of Rogers), then you understand only half the story of new product adoption.

Second, both CoP and DoI describe important and specific factors that influence new product uptake but in both cases, if they are to be of any practical use, these factors need to be tailored to the specific case of medical markets. For example, DoI sees adoption as being modified by the appetite of adopters for innovation, that distinguishes ‘early adopters’ from ‘laggards’. This is true, but in medical markets, where patient well-being is the goal, this individual trait is tempered by risk

aversion. Equally, CoP sees adoption as being a function of the intensity of interaction between the members. This is certainly true but in life sciences this factor is strongly moderated by the complex interplay of the various professions working together in healthcare institutions. In other words, we found that both CoP and DoI provided good tools for understanding and manipulating the adoption of innovative new products but those tools are like adjustable spanners: they work best only when fitted to the details of the situation and don’t work when used without adjustment. In practice, if you throw around the ideas of either DoI or CoP as bits of jargon, without really understanding them, you will not be able to manage or improve the adoption of your new product.

Our third and, we think, most significant finding was also connected to how the two theories of new product adoption apply to the practice of product launch and life cycle management in pharmaceuticals and medical technology.



Both theories consider new product adoption as happening at one level. In a medical context, for example, they see adoption as occurring in the clinical unit, such as an operating department or a cardiology lab. This is the truth, of course, but not the whole truth because, in practice, there are two other, simultaneous and interacting levels of adoption. Firstly, the adoption of the idea to fund for the new product or technology. This takes place in a separate decision stream, such as national health technology assessment bodies and local formularies. Secondly, the adoption of the idea to refer the patient for treatment in this innovative way. This adoption process often takes place in a separate clinical sphere, such as when one healthcare professional, for example in primary care, must choose to refer to another, for example in secondary care. This means that, in many cases, managing and manipulating new product adoption involves thinking about how DoI and CoP factors play out at three parallel but connected levels at once. If your product launch or marketing strategy considers only one, you are unlikely to succeed.

Putting theory into practice

Our research is the first of its kind to explore new product adoption in the life sciences in this rigorous, theory-based but practice-oriented way.

‘To address unmet patient needs means to simultaneously manage the three dimensions of professionals, payers and patient referral’

As academic researchers, we will be judged on how our findings contribute to the next generation of textbooks. But perhaps more important, and certainly more immediate, is the contribution we think this work makes to the everyday practice of pharmaceutical and medical technology marketers trying to accelerate their adoption of life-saving and enhancing products. We think there are three key lessons for marketers to learn from our research.

Firstly, stop thinking simplistically in terms of DoI. The concepts of innovators, early adopters, etc are useful but they are crude approximations to reality. Augment and improve your thinking by incorporating the ideas of Lave and Wenger, whose work is very relevant to the complex, cross-functional working of today’s health systems.

Secondly, don’t use the ideas of CoP or DoI without translating them into the specific context of medical markets. Both schools of thought developed their ideas in non-medical markets. This means that they have to be translated to allow, for example, for risk aversion and the complex interplay within multidisciplinary clinical teams.

Finally, broaden your thinking about how the adoption of new products works in pharmaceutical and medical technology markets. To address unmet patient needs means to simultaneously manage the three dimensions of professionals, payers and patient referral. Focusing on only one is a mistake.

As well as being academics, both of the authors of this article work as practitioners in pharmaceuticals and medical technology. We hope and believe that our findings are valuable to our fellow marketing practitioners. But we also think that our peers would do well to remember the words of the great thinker Kurt Lewin: there is nothing so practical as a good theory.

Box 2: Communities of Practice theory

Communities of Practice theory explains the rate of uptake of new products in terms of variables including:

- Who is and who is not in the community of practice that needs to adopt the new product
- The degree to which people within the community of practice interact and influence each others’ practice
- How well established the community of practice is
- The differences of status and influence within the community of practice.

Matthieu LeClerc-Chalvet is CEO of Therapixel and a PhD candidate at the University of Hertfordshire. **Professor Brian D Smith** works at SDA Bocconi and the University of Hertfordshire. He is a world-recognised authority on the evolution of the life sciences industry and welcomes questions at brian.smith@pragmedic.com

Can digital communications boost behaviour change?

By Lorraine Walters and Federico Marchisio

‘Mobile phones and digital comms channels are incredibly powerful tools, influencing decisions and providing support at every stage of the behaviour change process’



Adopting new, healthy behaviours – or breaking old, bad habits – can be hard to sustain, but as both communication and support tools move almost exclusively online, will this shift to digital or mobile platforms make sustained behaviour change easier to achieve?

Mobile phones and digital comms channels are incredibly powerful tools, influencing decisions and providing support at every stage of the behaviour change process. Technology offers unprecedented opportunities to reach, monitor and keep users on track, and it is encouraging to see public health bodies embracing the digital revolution.

Digital health interventions

New NICE guidelines, published in October 2020, highlight goal planning, monitoring and social support as the components to focus on when developing digital health interventions. However, for us, it is personalisation that can make or break behaviour change programmes.

Using a ‘one-size-fits-all’ approach can result in poor uptake or even backlash, such as Cancer Research UK being accused of fat-shaming while trying to raise awareness of the link between obesity and cancer. Technology allows us to customise experiences and tailor messages to a user’s unique needs and interests; as a result, healthcare communication professionals can develop campaigns that resonate at a much deeper level.

Personalisation

How can personalisation permeate every aspect of behaviour change and make each step more effective?

Segmenting audiences and tailoring messages are crucial to cut through the noise and spark a positive response, especially in the age of tribalism and non-stop exposure to visual

stimuli. Digital channels own a disturbing amount of information about us, but this can be used as a force for good, identifying those in need and reaching them with relevant messages, customised to their interests, on the channels where they are most active.

Once we start our behavioural change journey, setting personalised, specific goals makes us accountable, while reaching those goals gives us a sense of achievement. Digital tools encourage and reinforce behaviour change throughout the journey by capturing those goals and allowing us to track them, measure progress and get immediate feedback. By implementing rewards and introducing gamification and social validation, users can be rewarded for their behaviour while also being entertained.

Once goals are set, digital communication allows for relevant and direct engagement, with messages tailored to the individual delivered by text message, apps, wearable devices or the internet.

Support can be provided at steps in the journey when people are most receptive, either when presented with an opportunity to engage in healthy behaviour or when vulnerable to negative behaviour. And with 80% of people in the UK now owning smartphones, individualised support can be accessed at any time.

Repetition helps establish behaviour change and digital push notifications can deliver reminders and reinforcement with the right message at the right time. Digital technologies can also be used to offer support when users are confronted with barriers and setbacks. They increasingly use information about a person to adapt support to that person’s unique and changing needs.

Digital communications also create a sense of community: a feeling that we’re on a journey with others and are not alone. Social networks can positively influence healthy

behaviour by allowing people to create personal profiles and join a community to chat and meet other users, providing both support and information when it’s needed.

Long-term sustainability

While personalised digital tools and communications can certainly kick off and enhance behaviour change, can they sustain it in the long term and can they work in isolation?

Despite the enthusiasm we have for digital tools, we don’t believe we can solely rely on them to drive positive change. The current pandemic and consequent lockdown demonstrated how digital tools can keep us connected, but also exposed their limitations, with mental health issues increasing due to a lack of human contact as well as the ongoing uncertainty.

Some healthy behaviours have been supported by digital; fitness app downloads skyrocketed during the pandemic, but how many were from people who were already active, and how many will be motivated to continue as opportunities to show off the results keep being delayed?

Other behaviours were negatively influenced by digital comms. Disinformation was spread on social media about COVID-19, masks and vaccines, and traditional channels had to be leveraged to publicise consistent, timely communications, such as reminders to wear masks before entering stations and shops.

These examples show why every behaviour change programme should be planned carefully and built around the target audience, leveraging the mix of tools and comms channels that best fit their traits and attitudes. After all, this is personalisation too.

Lorraine Walters is Practice Leader and **Federico Marchisio** is Digital Programme Director, both at Say Communications

Three ways AI will change healthcare in the next decade

Looking forward, there is no doubt that AI will continue to take centre stage in global healthcare initiatives

By Nikolas Kairinos



Although artificial intelligence (AI) has been influencing healthcare for years, 2020 firmly solidified its position as an indispensable part of the industry's ongoing evolution. However, one question still remains: how is the power of this technology helping to stop a global pandemic in its tracks and shield people from its devastating effects?

So far, its performance has been promising. Not only has AI enabled policymakers and frontline health workers to trace and limit the spread of Covid-19, but it has also accelerated the process of developing effective vaccines.

Looking forward, there is no doubt that AI will continue to take centre stage in global healthcare initiatives. Our reliance on artificial intelligence is reflected in the technology's growing dominance in the financial landscape: the global AI in healthcare market size is projected to grow from \$4.9bn in 2020 to reach a whopping \$45.2bn by 2026.

In the UK, the National Health Service (NHS) has demonstrated its commitment to pushing the frontiers of AI by placing it at the heart of its innovation strategy. Indeed, the NHS Long Term Plan includes several commitments to help frontline staff leverage AI in their day-to-day roles.

With this in mind, here are three ways that the technology is set to transform healthcare over the next decade.

Introducing the predictive power of AI

They say that prevention is better than cure. However, healthcare today is still largely geared towards treating illnesses, rather than focusing on preventative measures.

Recent advances in medical research and technology mean that we have become significantly better at diagnosing problems in their early stages and prescribing the right treatment.

However, while the progress has been immense, we are still largely limited to responding to problems once they present themselves.

Wearable technology, for instance, is being used to help diabetes sufferers manage their blood sugar levels in an effort to prevent long-term complications. But what if we could predict with great accuracy if an individual is at risk of contracting a disease, and prevent it from even surfacing?

'In the UK, the NHS has demonstrated its commitment to pushing the frontiers of AI by placing it at the heart of its innovation strategy'

In the decade to come, AI and predictive analytics will help people understand the factors that make them more predisposed to suffering from certain illnesses. Algorithms are specifically designed to extract data from a variety of sources; in this case, AI will be able to leverage information from health records, wearables, genetic tests and socioeconomic factors in order to establish a holistic view of a person's health. It can then create a disease risk profile and suggest personalised interventions that might limit a person's susceptibility to given diseases.

AI-enabled solutions will also enhance patient engagement in their own care, giving them the knowledge that they need to take their health into their own hands. The ability to make proactive changes might ultimately prevent people from having to seek complicated treatment further down the line.

Streamlining the delivery of healthcare

The growing use of big data and AI will also transition us to an era of connected, more efficient care. It is no secret that health services struggle with operational inefficiencies, whether that is a shortage of clinicians or poorly managed patient flow. Tech solutions are desperately needed to streamline operations and reduce costs.

University College Hospital London has created an algorithm to try to combat two of the biggest problems facing the NHS today – wasted resources and prolonged waiting times. By using records from 22,000 appointments, the system was able to identify 90% of those patients who would fail to show up to their appointments. It was estimated that utilising AI in this way could save the NHS a significant £2-3 per appointment.

Improved data collection and analytics will also aid tremendously in the complex logistics of delivering quality health services. The unparalleled ability of AI to sift through huge volumes of data will undoubtedly expose the administrative challenges that are standing in the way of delivering quality healthcare. What's more, such insights will enable hospital administrators to find ways to optimise performance, drive productivity and improve the use of existing resources – thereby ultimately improving the overall standard of hospitals.

Another simple example highlights the potential of AI in this domain. A recent study found that only 3% of NHS histopathology departments actually have enough staff to meet clinical demand. This has a direct and substantial knock-on effect on the ability to deliver a high standard of care, and means that patients suffer delays in receiving appointments and results.

Integrating AI solutions would both speed up and simplify access to information, helping



specialists to optimise their workflow and treat more patients. Automating administrative processes will also relieve practitioners from this heavy burden, making it much easier for them to manage referrals, schedule patient appointments (and predict no-shows), and make preparations for upcoming exams and consultations.

A new way of learning

Importantly, it is not just patients who will benefit from AI in the coming decade. Clinicians, too, will reap the rewards of having on-demand knowledge at their fingertips.

Traditionally, healthcare practitioners have been pressured to remain up-to-date with the latest medical studies and data sets. Thus, they dedicate a lot of time to researching and memorising information, both in early training and in ongoing efforts to maintain their skills. This is a mammoth task, given the speed at which information becomes outdated. For example, PwC has noted that for a skin specialist, there are 11,000 new dermatology articles published every year. Meanwhile, 80% of the data available is unstructured – meaning that it is not contained in an easily accessible database.

Healthcare providers need a new way to find the information they require within the swathes of data available to them.

Over the coming years, AI will play a vital role in helping medical practitioners to stay on top of changing industry trends. Powerful AI algorithms can automatically assimilate all the data that might be helpful in a given context, extract the most relevant information and present it to clinicians in an easily digestible format.

'The size of the global AI in healthcare market is projected to grow from \$4.9bn in 2020 to reach \$45.2bn by 2026'

The advent of natural speech means that doctors will even be able to ask the AI questions verbally and receive accurate responses as though they were seeking help from a mentor. Thanks to machine learning capabilities, AI will also be able to learn from previous interactions and continually adjust to meet the users' learning needs.

Positively, AI-enabled training platforms will enable practitioners to engage in continuous learning that is personal to their own individual requirements and learning style. Even better, they will be able to engage in training at any given time or place: with sophisticated solutions easily accessible from smartphones, tablets and laptops, practitioners will benefit from being able to easily brush up on their knowledge through quick catch-up sessions.

Ultimately, the integration of AI solutions within healthcare will deliver better patient outcomes and enable clinicians to focus on the more human component of their job – delivering primary care to patients. Technology is a key driver in changing the face of healthcare, and it will be exciting to see how AI will complement those working on the front lines to improve global standards of care.

Nikolas Kairinos is the chief executive officer and founder of Soffos, the world's first AI-powered KnowledgeBot, and is also the founder of Fountech.ai



Vertex

NICOLA MASSEY

Vertex has appointed **Nicola Massey** as the senior country manager for UK & Ireland. Massey has extensive experience leading global, European and country teams across multiple therapy areas. During her career, she has also gained expertise in rare diseases in both multinational and medium-sized pharmaceutical

companies. Previously, she served as global franchise head at Shire, where she oversaw the launch of a haematological rare disease medicine across 31 countries. More recently, she held the position of managing director of Colonis Pharmaceuticals, where she established and successfully grew the licensed pharmaceuticals

business, achieving approvals and uptake of a large portfolio of medicines. Prior to joining Vertex, she established her own consultancy, providing UK and European launch strategy development for start-up companies as well as global biopharmaceutical companies planning first-in-class launches in rare conditions.

VectivBio



SARAH HOLLAND

VectivBio has appointed **Sarah Holland** as chief business officer. Most recently, Holland served as global head of licensing at Lonza where she built the new licensing business research and led research and development. Prior to Lonza, she led external science and partnering across the globe for Sanofi R&D. Before that, Holland served at Roche for over a decade.

Novavax



GREGG ALTON

Novavax has appointed **Gregg Alton** to its board as an independent director. Alton brings extensive industry experience to Novavax, including 20 years at Gilead Sciences, where he served in a number of leadership roles. Among these roles at Gilead, he served as the company's interim chief executive officer from January 2019 until March 2019, before and after which he worked as chief patient officer.

Mylan



BILL SZABLEWSKI

Mylan has appointed **Bill Szablewski** head of capital markets for Viatrix, the spin-out company resulting from Mylan's merger with Pfizer's Upjohn generics unit. Szablewski has nearly 15 years of experience in the healthcare industry, most recently serving as assistant treasurer, capital markets at Bristol Myers Squibb (BMS). At BMS, his work supported the successful shareholder vote and debt financing for the Celgene acquisition.

Horizon Therapeutics



KARIN ROSÉN

Horizon Therapeutics has appointed **Karin Rosén** as executive vice president, research and development and chief scientific officer. Rosén has nearly three decades of experience in the life sciences industry and previously served as senior vice president, US medical affairs at GlaxoSmithKline. Prior to GSK, Rosén was senior vice president, US and global medical affairs at Aimmune Therapeutics.

Mission Therapeutics

SUHAIL NURBHAI

Mission Therapeutics has appointed **Suhail Nurbhai** as chief medical officer. Nurbhai has over 25 years' experience in the strategic and operational leadership of all phases of clinical research and development. He joins Mission from VHSquared, where he served as CMO – prior to that, Nurbhai was senior vice president and head of development and medical affairs for Shionogi in Europe.

Gilead Sciences

ANTHONY WELTERS

Gilead Sciences has appointed **Anthony Walters** to the company's board of directors. In 2016, Walters retired as senior adviser to the officer of the CEO of UnitedHealth Group (UHG). During his tenure at UHG, he served as executive vice president and a member of the office of the CEO, and also led the company's public and senior markets group.

VectivBio

ADITYA VENUGOPAL

Also joining VectivBio is **Aditya Venugopal**, who has been appointed vice president of business development at the company. Previously, Venugopal served as an executive director at Intercept Pharmaceuticals, where he held roles leading corporate strategic planning and business development. He also served as an associate director at Navigant Life Science Consulting.

Freeline Therapeutics

MARK BALDRY

Mark Baldry has joined Freeline Therapeutics as chief commercial officer. Baldry is an experienced commercial leader with 30 years' experience working in the biopharmaceutical industry. He joins from Wave Life Sciences where he served as chief commercial officer and prior to that as senior vice president, global marketing and commercial operations at Amicus Therapeutics.

Oryzon Genomics



TORSTEN HOFFMAN

Oryzon Genomics has appointed **Torsten Hoffman** as chief scientific officer. Hoffman has spent over 23 years in pharmaceutical research and development including senior roles at Roche and Zealand Pharma. At Roche, Hoffman was head of discovery chemistry and head of the Roche Postdoc Fellowship Programme. He also served as CSO at Zealand Pharma and CSO of British biotech Silence Therapeutics.

Apaxen



BART WUURMAN

Apaxen has appointed **Bart Wuurman** as its new chief executive officer. Wuurman has over 30 years of experience in drug development, biotech financing, business development and licensing. Prior to joining Apaxen, Wuurman served as the CEO of De Novo Pharmaceuticals, as well as AM-Pharma, Lanthio Pharma and is the current director of Hercules Pharmaceuticals.

Exscientia



GARRY PAIRAUDEAU

Exscientia has appointed **Garry Pairaudeau** as chief technology officer. Pairaudeau joins from AstraZeneca, where he held the position of vice president of hit discovery. During his time at AZ, he championed developments in artificial intelligence and machine learning. Pairaudeau was also part of the team that discovered the cardiovascular drug Brilinta (ticagrelor).

Silence Therapeutics



MARIE WIKSTRÖM LINDHOLM

Silence Therapeutics has appointed **Marie Wikström Lindholm** as senior vice president, molecular design and a member of its executive leadership team. Lindholm joined Silence in 2017, serving as VP head of technology innovation. She has over 13 years' experience with oligonucleotide therapeutics, starting at Danish biopharmaceutical company Santaris Pharma.

Scancell



GILLIES O'BRYAN-TEAR

Scancell has appointed **Gillies O'Bryan-Tear** as chief medical officer. O'Bryan-Tear has over 30 years of experience in the pharmaceutical industry. He has held senior leadership roles in large and small pharma and biotech companies in the US and Europe. Previously, he served as the chief medical officer of Algeta, a Norwegian biotech company developing a radiopharmaceutical for prostate cancer.

Scancell



ROBERT MILLER

Robert Miller has also joined Scancell, taking on the role of medical director. Previously, Miller worked as a managing director at Artemida Pharma. He has provided strategic expertise, medical management and clinical development support for both small and large pharma and biotech companies during his 30-year career in the industry, particularly in the fields of oncology and immuno-oncology.

Tacalyx



KLAUS SCHOLLMEIER

German biotech company Tacalyx has appointed **Klaus Schollmeier** as chairman of its board of directors. Schollmeier has over 30 years of experience in the pharma and biotech companies, with senior leadership experience in R&D, marketing and general management. He also serves on the board of several other European biotech companies includes Anergis Pharma, Affiris Pharma and Eternigen.

Jazz Pharmaceuticals



JENNIFER COOK

Jennifer Cook has been appointed to Jazz Pharmaceuticals' board of directors. Previously, Cook was chief executive officer at GRAIL, an early cancer detection diagnostic company. Prior to that, she worked at Roche/Genentech for 25 years where she held a number of senior management positions. This included holding the position of global head of clinical operations at Roche.

Jazz Pharmaceuticals

MARK SMITH

Jazz Pharmaceuticals has also appointed **Mark Smith** to its board of directors. Smith currently serves as a non-executive director on the boards of Phreesia and Teladoc Health. He also serves on the board of The Commonwealth Fund and the Institute for Health Care Improvement. Smith is also a professor of clinical medicine at the University of California.

AC Immune

JOHANNES ROLF STREFFER

AC Immune has appointed **Johannes Rolf Streffer** as its chief medical officer. He joins AC Immune from UCB Biopharma, where he held the position of vice president, head of translational medicine neuroscience. Prior to this, he was a member of the Alzheimer's disease area leadership team at Johnson & Johnson's pharma division Janssen.

Mereo Biopharma

SUBA KRISHNAN

Mereo Biopharma has appointed **Suba Krishnan** as senior vice president of clinical development. Krishnan has over 20 years' experience in late-stage immuno-oncology drug development, academia and clinical practice. Most recently, she worked at Genmab as the global programme head of immuno-oncology. Prior to Genmab, Krishnan was a senior principal scientist at Merck.

Inventiva

MICHAEL COOREMAN

Inventiva has appointed **Michael Cooreman** as chief medical officer. Cooreman joins Inventiva from Ferring Pharmaceuticals where he served as vice president, science and medicine in charge of global research and development, gastroenterology and hepatology. Cooreman has worked for several companies in the US and been involved in a range of clinical trials.

OPEN Health



ROB BARKER

OPEN Health has named **Rob Barker** as its new chief executive officer. Barker has approximately 30 years of executive leadership experience in the biopharmaceutical industry, having held a number of roles at medical communications and strategy consulting firms. Most recently, he served as the CEO of OPEN Health's Medical Communications practice, which he joined six years ago.

Lucid Group



LAURENCE BANNISTER

Laurence Bannister has joined Lucid Group as its new chief commercial officer. Bannister brings over 20 years of experience in the pharmaceutical and healthcare industry to the role. For the past nine years, he worked at STEM Healthcare and most recently held the role of international president. Prior to that, he completed stints at Mundipharma and Novo Nordisk.

MHP Health



NICK HOILE

MHP Health has appointed **Nick Hoile** as a senior director, who returns to the agency from Publicis Resolute. At Publicis, Hoile served as director of government affairs for close to two years. He was previously at MHP Health for more than five years, reaching the role of director before leaving the company. Hoile started his comms career as a policy officer with the Mental Health Foundation.

Page & Page and Partners



ASMA SHIRAZI

Page & Page and Partners has appointed **Asma Shirazi** as account director. Previously, Shirazi has worked at a number of agencies, including Hive, Havas SO and most recently Sudler where she advised on pharma brands. Earlier in her career, she worked as an intern at Grey Healthcare, where she worked up to the role of senior account executive.

Page & Page and Partners



ISABELLE NICHOLSON-ROSE

Also joining Page & Page and Partners is **Isabelle Nicholson-Rose**, who has been appointed to the role of account executive. Prior to joining Page & Page, Nicholson-Rose worked as a business support administrator at Public Health England, where she provided support within its Coronavirus Response Centre. She also worked as an intern at medcomms agency Lucid Group.

CREATION.co



TOM BOURNE

Health strategy consultancy CREATION.co has appointed **Tom Bourne** as associate director, analytics. Prior to joining CREATION.co, Bourne held analytical roles at both the local and national government levels. Most recently, he worked at Kent County Council as public health intelligence manager, where he oversaw a team of specialist public health analysts supporting local government's tracking of COVID-19 cases.

CREATION.co



VICTORIA DONOUGH

CREATION.co has also welcomed **Victoria Donougher** as associate director of marketing and communications. Donougher is an experienced senior marketing professional with experience in brand strategy, digital propositions and audience development. Previously, she ran her own marketing consultancy business, specialising in strategic and digital marketing, working with global clients.

GCI Health



DAVID BERKOVITCH

GCI Health has appointed **David Berkovitch** as senior director of its London team. Prior to joining GCI Health, Berkovitch spent nearly four years at Zeno 3 Monkeys as head of healthcare. Before his role at Zeno 3 Monkeys, he also held senior roles at Edelman and Fleishman Hillard Fishburn, where he most recently served as director and partner and interim co-head of healthcare.

GCI Health

KAYLEIGH MOORE

The final new starter joining GCI Health, as a senior account director, is **Kayleigh Moore**. Previously, Moore worked at Chandler Chicco Agency, where she held the position of healthcare communications consultant. Prior to that, she worked as a product marketing manager at IQVIA's CODE (Collaboration for Oncology Data in Europe).

GCI Health

FENYA LAZAR

Also joining GCI Health, as an account director, is **Fenya Lazar**. Before joining the team at GCI Health, Lazar worked at Syneos Health Communications for a period of seven years, working in the role of PR consultant. She graduated from the London College of Communication in 2013, earning a bachelor's degree in public relations.

GCI Health

HARRIET MOONEY

GCI Health has also appointed **Harriet Mooney** as an account director. Mooney previously worked at Evoke KYNE as an account director. Prior to that, she worked at integrated corporate communications consultancy madano. Earlier in her career, she worked in a number of roles at Janssen, most recently serving as a therapy area communications specialist.

Page & Page and Partners

EMILY SIDLOW

Emily Sidlow has also joined Page & Page and Partners as a senior account manager. Prior to joining the Page & Page and Partners team, she worked at ApotheCom, also serving in the role of senior account manager. Before that, she worked at InVentiv Health as a medical education consultant. She also completed a stint at Ogilvy, where she worked as an account executive.

Envision Pharma Group acquires Two Labs

The acquisition will enable Envision to reach new clients

Envision Pharma Group has acquired Two Labs, a provider of integrated and customised commercial solutions to the pharma and biotech sectors. The acquisition will allow Envision to extend its reach to new clients in the 'product pre-launch' setting, while also opening up new business opportunities and geographies for Two Labs.

Two Labs, founded in 2003 and headquartered in Ohio, US, has offices and operations across both the US and the UK. It helps pharma companies to develop and execute customised launch strategies for products.

"This exciting combination of Envision and Two Labs creates a compelling and unrivalled proposition in launch excellence partnership globally and in the US," said David Thompson, chief executive officer of Envision.

"We look forward to sharing our joint expertise and leveraging our complementary services across medical affairs and product launch planning to support our clients in their goal of bringing new medicines to market effectively and compliantly, to improve patient outcomes," he added.

"We are delighted to be joining the Envision family and taking Two Labs to the next logical step in its successful journey to date. With Envision's global footprint and Two Labs' market-leading US footprint,



we have a unique opportunity to enrich our client partnerships with more connected services across the launch continuum," said Howard Miller, chief executive officer of Two Labs.

"The cultural fit between our organisations is compelling, and we look forward to a new chapter for Two Labs in partnering with David and the Envision team," he added.

Lucid Group gains new UK office space in Macclesfield

Healthcare comms agency strengthens its footprint in the UK

Lucid Group has expanded its reach in the UK after gaining a new office space in the Tytherington Business Village, located in Macclesfield.

The healthcare communications agency has bolstered its presence after moving into Greenway House to complement its existing team of 20 in Oakfield House, within the same business park.

Most of the office will be taken up by Lucid's Healthcare 21 team and will also be home to a number of people from its medical editorial team, COMET and Bluedog digital team.

The Healthcare 21 has also recently celebrated its first-year anniversary following its acquisition by Lucid Group in September 2019.

The team specialises in scientific strategy, content creation, editorial excellence and digital design.

Within the 60-strong Healthcare 21 team, 40 are now based in Greenway House in a mix of content generating, account management, publishing and digital roles.

"Macclesfield has a rich heritage as a medical communications hub, so we were always going to stay in the area, we just needed more suitable space for our expanding team," said Cliff Wyatt, managing director at Healthcare 21.

"Greenway gives us stylish, professional, open plan offices where we can all be together – better for collaborative, creative working – with great parking facilities and transport links," he added.



"They (Healthcare 21) are one of our longest-standing customers so it's especially rewarding to be helping them expand into new, more spacious accommodation on Tytherington," commented Benn Dickinson, leasing manager from Orbit Developments.

Q&A



What gets you out of bed in the morning?

Aside from my chihuahua Bluey nuzzling me for attention, it's the excitement of what a new day will typically bring. I'm entrepreneurial so I look forward to new ideas and challenges!

What's the best thing about working in healthcare comms?

The work we do can have a huge impact on improving the lives of patients and when I see it in motion, it's not only a humbling experience but it also fills me with pride.

What's the worst thing about working in healthcare comms?

The lack of diversity. I actively promote the women in STEM and BAME agendas. One size does not fit all, and to provide the best insight and drive programmes that truly impact patient health, we need more diversity.

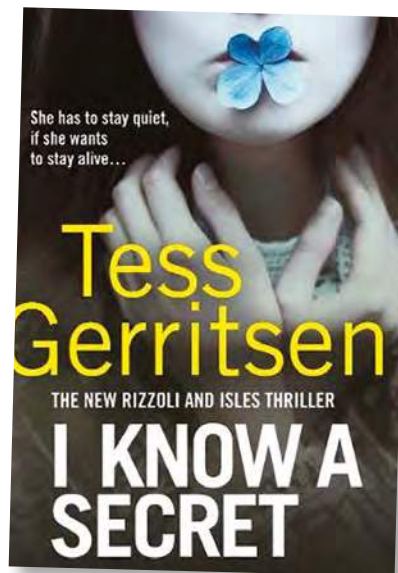


What's your favourite bar or eatery?

I'm a real foodie and enjoy trying different cuisines. My favourite restaurant right now is Darjeeling Express in Soho London. The homestyle Indian food is made with passion by an all-women team of housewives.



SHAIROSE EBRAHIM



Which book/film would you recommend above all others and why?

I love reading crime thrillers and my all-time favourite author is Tess Gerritsen, a retired physician. Her books are not only gripping, they also bring some great medical and science insight into the mix. For a healthcare comms geek like me, it's the ideal combination of fact and fiction!

Which buzzwords/office jargon get on your nerves?

I recently heard the classic 'think outside the box'. I thought to myself: 'Box, what box – I can't even see the box!' My advice to the imc team is always 'say what you mean and mean what you say!'.



Which person, living or dead, do you admire the most and why?

I admire the contributions of those BAME women who succeeded despite the discrimination they faced. Such as Jane Cooke Wright (pictured above) who developed a non-surgical way to fight tumours. Or Dr Patricia Bath, who created an entirely new discipline of ophthalmology focused on public health.

Who is your healthcare comms hero/heroine?

All the people who work in this industry are heroes/heroines. They often need to communicate high science and complex data to different audiences under extremely strict regulations – no easy task!



What has been your career highlight to date?

imc group recently entered into a partnership with Waterland Private Equity – the company I founded 14 years ago has grown year-on-year and caught the interest of investors. Such an amazing feeling!

What's your golden rule/piece of advice for someone starting a career in healthcare comms?

Be passionate about the work. It can be a tough industry to work in but your passion will drive your commitment and ultimately your success!

Shairose Ebrahim is President & CEO of integrated medhealth communication (imc) group

Top job this month



Senior Leader

Home-based, Competitive Salary

A leading medical communications agency is seeking a senior leader to join its team. Applicants should have strong commercial and strategic capabilities as well as an entrepreneurial mindset. Additionally, the successful candidate will have previous medical communications or medical education experience. In this role, the successful candidate will lead and develop the commercial and operational management. Applicants will also be expected to drive commercial and creative strategy and growth, and focus on process and pathway improvement. Contact Lissa on 01344 379027 or email lissa@kaizenlifesciences.com for more information.

December highlights*

Digital Specialist, Healthcare PR London, £60,000 to £65,000

Applicants must have experience in a digital planning and delivery role within a healthcare PR/medcomms setting. Contact Julia on 02073 598244 or email julia.walton@media-contacts.co.uk.

Account Director London, £55,000 to £60,000

The ideal candidate will be an experienced leader with experience working with top pharma clients on local and global campaigns. Contact Julia on 02073 598244 or email julia.walton@media-contacts.co.uk.

Account Director London, £40,000 to £50,000

This is an excellent opportunity for an established senior account manager to take the next step in their career. Contact Naveed on 01932 797998 or email naveed.ali@id-ss.com.

Healthcare Account Director Basingstoke, Competitive Salary

In this role, the successful candidate will support the client services director and have responsibility for a portfolio of client accounts. Contact Stephanie on 01256 631670 or email Stephanie.Marchment@adareinternational.com.

Senior Account Manager, Patient Communications London/South East, Competitive Salary

A growing specialised agency is seeking applicants with previous healthcare marketing/communications agency experience. Contact Anthony on 07968 181759 or email anthony@adeptoconsulting.com.

Senior Consultant, Pharma Marketing London, Competitive Salary

Previous marketing consulting experience is essential for this role and applicants must have excellent project leadership skills. Contact Anthony on 07968 181759 or email anthony@adeptoconsulting.com.

Account Manager London, up to £35,000

A medcomms and digital agency is seeking an account manager with previous experience in a fast-paced agency role. Contact Richard on 02088 662418 or email richard@chemistrysearch.co.uk.

Medical Editor Basingstoke/Home-based, Competitive Salary

The successful candidate will have four-plus years' experience of medical editing, as well as experience in digital production. Contact Stephanie on 01256 631670 or email Stephanie.Marchment@adareinternational.com.

Healthcare Lead Copywriter Basingstoke/Home-based, Competitive Salary

Applicants must have at least three to four years of previous experience as a medical writer in a promotional agency. Contact Stephanie on 01256 631670 or email Stephanie.Marchment@adareinternational.com.

* 100s of live vacancies with more added daily

- Medical communications
- Healthcare PR
- Medical writing
- Healthcare market research
- Pharmaceutical
- Market access
- Medical education
- Healthcare advertising
- Healthcare consultancy

Pharma marketing, sales and communications jobs
jobs.pmlive.com

*Featured jobs were live as of 30/11/20



GREAT STORIES START HERE

We don't create great stories; the stories are already there. They are all around us, in our hospitals, homes, schools and workplaces. Here at Life we uncover hidden truths about brands, we understand them and share them as powerful narratives. And we believe that our craft as storytellers can engage emotions, challenge beliefs and change the behaviour of your audience. If you want your brand's story to be heard, get in touch - juliet@life-healthcare.com

bring your story to



life-healthcare.com