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Thermo Fisher and Pfizer collaborate on NGS-based cancer tests

The companies have announced a collaboration to advance next-generation sequencing-based cancer testing, page 11

Companies showcase innovative biotech at American Association for Cancer Research

Leading companies in the biotechnology sector have showcased their latest innovations at the American Association for Cancer Research (AACR) meeting that was held in Florida, US, between 14-19 April. The three companies below are a selection of those with positive improvements in solid-tumour treatments.

Glycotope announced its glycol-engineered cell lines in a poster. This proprietary platform technology develops antibodies against proteins carrying tumour-specific carbohydrate structures.

Patrik Kehler, chief scientific officer of Glycotope, commented: "Our glyco-engineered cell lines provide the basis for a new generation of therapeutic antibodies with increased tumour specificity and safety for highly potent therapeutic approaches like ADCs, CARs and radiotherapeutics. Glycotope's proprietary platform represents a versatile tool for target validation and screening of glycosylation-dependent protein binding antibodies."

Innovent Biologics develops, manufactures and commercialises medicines for oncology, autoimmune, metabolic and ophthalmology diseases. At AACR, it announced the final analysis results of phase 3 study ORIENT-15, which evaluated sintlimab in combination with chemotherapy for first-line treatment of oesophageal squamous cell carcinoma (OSCC). Data showed that sintilimab with chemotherapy "significantly improved" the median overall survival rate (mOS) with a 33.9% reduction in death.

Dr Hui Zhou, senior vice president of Innovent, stated: "The approval of immunotherapy has significantly improved the clinical benefits of standard treatments in patients with advanced OSCC… In this final analysis, the continued significant mOS benefits have been verified in advanced OSCC patients with an acceptable safety profile over time and further demonstrated that sintilimab as a first-line treatment option will benefit OSCC patients in China."

Transgene designs and develops virus-based immunotherapies for oncology treatments and highlighted its promising preclinical data for its novel oncolytic virus TG6050 at AACR. The data demonstrates the ability of TG6050 to induce strong antitumour responses, leveraging the production of IL-12 and anti-CTLA4 antibody in the tumour.

Hedi Ben Brahim, Transgene's CEO, said, "We have designed TG6050, a novel oncolytic virus encoding the IL-12 and an anti-CTLA4, to generate both innate and adaptive immune responses. These outstanding preclinical findings clearly support the clinical development of TG6050, which has recently started the phase 1 Delivir trial in patients with non-small cell lung cancer. We are confident that by generating similar effects in humans, TG6050 could become a new standard of care in patients with solid tumours."

Future Focus

FDA approves world's first RSV vaccine

The US Food and Drug Administration (FDA) has announced that it has approved the world's first respiratory syncytial virus (RSV) vaccine for use in the US in individuals aged 60 or over.

RSV is a highly contagious virus, which causes infections in the lungs and breathing tract. In older adults, RSV is a common cause of lower respiratory tract disease (LRTD), which can cause pneumonia and bronchiolitis.

Arexvy, affiliated with GSK Biologicals, received approval based on results from the ongoing AReSVi-006 phase 3 randomised, placebo-controlled clinical trial. The vaccine showed statistically significant and clinically meaningful overall efficacy of 82.6% against RSV-LRTD in patients aged 60 or over. Efficacy against severe RSV-LRTD – known as an LRTD episode affecting everyday, normal activity – was 94.1%.

In April 2023, the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) announced a

positive opinion recommending the vaccine for the prevention of LRTD in RSV-positive adults aged 60 or over. A final European decision is expected in the latter half of 2023.

Tony Wood, chief scientific officer at GSK, said: "Today marks a turning point in our effort to reduce the significant burden of RSV. Arexvy is the first approved RSV vaccine for older adults, expanding GSK's industry-leading vaccine portfolio, which protects millions of people from infectious diseases each year. Our focus now is to ensure eligible older adults in the US can access the vaccine as quickly as possible and to progress regulatory review in other countries."

John Kennedy MD, president of the American Medical Group Association (AMGA) commented: "For decades, AMGA and the healthcare community at large have been active in finding ways to increase adult immunisations. As a result, we are pleased that we can now add a respiratory syncytial virus vaccine to providers' options for patient care. With this vaccine, Americans over the age of 60, and particularly those with underlying health conditions like COPD, asthma or congestive heart failure, will have a vaccine to help protect against potentially serious outcomes from RSV."

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Welcome to the June issue of *Pharmafocus*!

This month's issue covers the latest news, from the US Food and Drug Administration approving the world's first RSV vaccine (page 2) and pharmacists in England being given greater prescribing powers to reduce the strain on the NHS (page 5), to the National Institute of Health awarding a grant to gammaCore for its clinical trial for patients with opioid use disorders (page 11) and GSK acquiring Bellus Health in a £1.6bn deal (page 12).

This issue also includes a fascinating Q&A from AstraZeneca that considers the link between climate health and human health, as well as looking at how the pharma industry is involved and what companies can do to reduce their impact (page 14).

CytoReason explores patient heterogeneity and explains why it is so significant for successful drug development (page 16), while Medidata talks to *Pharmafocus* about pharmaceutical regulation, as well as the challenges and possibilities posed by digitalisation (page 18).

Finally, I explore the impact climate change could have on health in general, specifically considering whether this may worsen, or even trigger, future pandemics (page 20).

I hope you enjoy this issue, and keep an eye out for the next issue of *Pharmafocus* released at the end of June!

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Eli Lilly's tirzepatide achieves 15.7% weight loss in adult patients

Eli Lilly has announced that tirzepatide (10mg and 15mg) achieved significant and superior weight loss compared to a placebo over 72 weeks of treatment. This data follows results from the SURMOUNT-2 trial, which met all co-primary and secondary endpoints.

The results showed that those taking tirzepatide lost up to 15.7% (34.4lb or 15.6kg) of body weight for the efficacy estimand. On a 10mg dose patients lost an average 13.4%, while 15mg dose patients demonstrated a loss of 15.7%. Furthermore, 81.6% (10mg) and 86.4% (15mg) of patients taking the drug experienced at least 5% body weight reduction, which was the trial's other co-primary endpoint, compared to only 30.5% of the placebo group.

The drug also met all secondary endpoints in the trial and the safety profile remained consistent to previously reported SURMOUNT and SURPASS trials. These secondary endpoints included reduction in A1C and other cardiometabolic parameters; 41.4% (10mg) and 51.8% (15mg) of patients taking the drug achieved at least 15% body weight reduction compared to only 2.6% of those in the placebo group.

Jeff Emmick MD PhD, senior vice president of product development at Eli Lilly, commented: "Obesity is a difficult-to-manage disease, and it's even more difficult for people living with type 2 diabetes. The degree of mean weight reduction seen in SURMOUNT-2 has not been previously achieved in phase 3 trials for obesity or overweight and type 2 diabetes."

FDA issues update around changes to COVID-19 vaccines' EUAs

The FDA has announced its amendment of the emergency use authorisations (EUAs) for the Moderna and Pfizer-BioNTech COVID-19 bivalent mRNA vaccines in an attempt to simplify the vaccination programme.

These amendments mean that:

- Most people who have previously been vaccinated with a monovalent COVID-19 vaccine and haven't yet had a bivalent dose may now receive one
- Most people who have had one dose of the bivalent vaccine are not currently eligible for another dose; people over 65 who have had one bivalent vaccine dose may receive another at least four months after their initial dose
- Most immunocompromised people who have had one bivalent dose may get another at least two months after their initial dose, with additional doses administered at the discretion of their healthcare providers
- Unvaccinated people may receive a single bivalent vaccine dose
- Children from six months to five years who are unvaccinated may receive a two-dose series of the Moderna bivalent vaccine or a three-dose series of the Pfizer-BioNTech vaccine
- Children from six months to five years who have had one to three monovalent COVID-19 vaccines may receive a bivalent vaccine depending on vaccine history.

Peter Marks MD PhD, director of the FDA's Center for Biologics Evaluation and Research, commented: "At this stage of the pandemic, data support simplifying the use of the authorised mRNA bivalent COVID-19 vaccines and the agency believes that this approach will help encourage further vaccination. Evidence is now available that most of the US population five years of age and older has antibodies to SARS-CoV-2, the virus that causes COVID-19, either from vaccination or infection that can serve as a foundation for the protection provided by the bivalent vaccines. COVID-19 continues to be a very real risk for many people, and we encourage individuals to consider staying current with vaccination, including with a bivalent COVID-19 vaccine. The available data continue to demonstrate that vaccines prevent the most serious outcomes of COVID-19, which are severe illness, hospitalisation and death."

Johnson & Johnson warns of dangers of Benadryl TikTok challenge

Following the death of a 13-year-old boy who took part in an online 'challenge' to take a large amount of the antihistamine, Benadryl (diphenhydramine), manufacturer Johnson & Johnson (J&J) has issued a statement warning of the dangers of overdosing with the drug.

It is reported that the TikTok challenge involves adolescents challenging each other to ingest large amounts of Benadryl aiming to create hallucinations, posting videos of this on TikTok. This trend began gaining popularity in 2020, triggering a statement from the FDA, explaining that overdosing on Benadryl can lead to 'serious heart problems, seizures, coma or even death.'

The FDA has suggested that consumers and parents should store Benadryl, along with other over-the-counter medicines and prescription medicines, out of the reach of children.

According to J&J's Benadryl website: 'The challenge, which involves ingestion of excessive

quantities of diphenhydramine, is a dangerous trend and should be stopped immediately. Benadryl products and other diphenhydramine products should only be used as directed by the label. […] Collaboration and education are critical to putting an end to this dangerous misuse. We are working with TikTok and other social platforms to remove content that showcases this behaviour. We will look to partner across industry and with key stakeholders to address this dangerous behaviour.'

TikTok have stated: "Our deepest sympathies go out to the family. At TikTok, we strictly prohibit and remove content that promotes dangerous behaviour with the safety of our community as a priority. We have never seen this type of content trend on our platform and have blocked searches for years to help discourage copycat behavior. Our team of 40,000 safety professionals works to remove violations of our Community Guidelines and we encourage our community to report any content or accounts they're concerned about."

Liberal states begin stockpiling abortion medications following Texas court ruling

Various liberal US states, including California and Massachusetts, have begun stockpiling abortion medications following Texas judge Matthew Kacsmaryk's attempt to invalidate the long-standing approval of mifepristone, one of the pills used in medication abortions.

Currently, mifepristone remains available, however Democratic governors in Massachusetts and Washington state have secured emergency supplies of the drug, while California's governor has secured a supply of misoprostol.

Massachusetts governor Maura Healey, said: "A judge has made a politically motivated decision to override doctors, patients and medical experts and block access to critical medications. Today, we are collectively saying loud and clear: not on our watch."

The Biden administration lawyers were expecting a decision by 13 April, one day ahead of the lower court's decision taking effect. If the justice department fails to make this decision, the lawyers are expected to take the case to the Supreme Court.

It is still unclear how the justice department or the Supreme Court would rule and how mifepristone would be restricted if the FDA is forced to revoke its approval, however the current uncertainty is worrying for many. More than half of US abortions use mifepristone and misoprostol, so this decision could mark the biggest blow to abortion since the overturning of Roe vs Wade last year.

Erin Hawley stated in the Texas lawsuit that the FDA has put women in harm's way 'by illegally approving dangerous chemical abortion drugs, and imposing its mail-order abortion regime. […] Pregnancy is not an illness, and chemical abortions don't provide a therapeutic benefit.' However, Lawrence Gostin, a professor of global health law at Georgetown University, commented: "If the FDA can't approve this drug [mifepristone], I'm not sure what the FDA can approve. It's been on the market for over two decades, it's got an impeccable health and safety record."

Pharmacists in England given wider prescribing powers to relieve GP pressure

NHS England has announced that pharmacists in England will be given wider prescribing powers to relieve pressure put on GPs. The organisation has said that this will free up 15 million GP appointments over the next two years – around 2% of the total amount of appointments.

Pharmacies will be able to prescribe for seven common illnesses: earache; sore throat; sinusitis; impetigo; shingles; infected insect bites; and uncomplicated urinary tract infections (UTIs) in women. Patients will also be able to self-refer for certain services, such as NHS physiotherapy or podiatry, and attain oral contraception without having to ask a GP first.

£645m has been allocated from the Department of Health to implement the scheme, with £240m going to upgrading the telephony systems and providing training for staff answering calls.

At the end of 2019, the Government's target was to recruit an extra 6,000 GPs to add to the 28,000 full-time GPs currently practising, however figures at the end of March 2023 revealed that there has been a drop to 27,500 full-time GPs.

NHS England chief executive Amanda Pritchard said: "We are already seeing more than half a million patients a week more in GP surgeries than we were pre-pandemic. But we know that we need to go further to expand services and transform the way we provide care… We are also planning to massively expand the number of people who can have high street blood pressure checks to 2.5 million a year, meaning fewer people will be at risk of heart attacks or strokes."

However, Royal College of General Practitioners (RCGP) chair Professor Kamila Hawthorne stated the measures were just "one part of the jigsaw in improving access," and that "the best way to improve access to GP care […] is to increase numbers of fully trained, full-time equivalent GPs through effective recruitment and retention schemes."

Trade union Unite calls for GSK staff walkouts over pay increase disputes

UK-based trade union Unite were pushing for staff walkouts at several GSK manufacturing sites due to disputes regarding pay increases, however to date there have been no updates as to whether GSK have extended another offer.

750 workers who are Unite members voted in favour of strike action after rejecting GSK's pay offer of 6% and a one-off lump sum of £1,300, which Unite called "significantly below inflation rate pay offer."

The strikes are taking place between 2nd May and 26th June 2023 at six locations, including five manufacturing sites – Irvine and Montrose in Scotland and Barnard Castle, Worthing and Ulverston in England – and one R&D facility in Ware, England.

GSK and Unite faced the same issue last year, when GSK offered a 2.75% pay increase, which was labelled "derisory" by workers. Strike action was avoided then, however, after employees accepted a 10.5% pay rise in May 2022.

A spokesperson for GSK told Endpoints News: "We recognise that for many of our people, this past year has seen their cost of living rise rapidly and believe the offer we have made to our UK manufacturing colleagues covered by collective bargaining agreements is fair and reasonable."

Unite national officer Tony Devlin stated in a release: 'Strike action will inevitably result in widespread disruption across GSK's operations, but the company has brought this dispute on itself. It has had every opportunity to make a pay offer that meets member expectations, but it has failed to do so. GSK has effectively stuck two fingers up to its workforce by walking away from the pay negotiations.'

AbbVie shares results from phase 3 trial for atogepant migraine treatment

AbbVie has shared positive results from its phase 3 ELEVATE study, which assessed atogepant for the preventative treatment of episodic migraines in patients who have previously had two to four unsuccessful classes of oral preventive medications.

The study results demonstrated that adult patients treated with the atogepant 60mg dose once daily experienced a decrease of 4.2 days in their mean monthly migraine days (MMDs) across the 12-week treatment period compared to the placebo group.

All primary and secondary endpoints were met and the drug demonstrated a statistically significant reduction in MMDs compared to the placebo group. The full data was expected to be presented during the Emerging Science session on 25 April 2023 at the 2023 American Academy of Neurology (AAN) Annual Meeting in Boston, US.

Dawn Carlson, vice president of neuroscience development at AbbVie, commented: "We understand that people living with migraine endure a chronic neurological disease and we are dedicated to providing them the best chance to live a life with less frequent migraines. The data presented at AAN underscores the important role of atogepant, not only as a treatment option for people living with episodic migraine but also for those whose previous treatments failed to help reduce the impact of migraine on their lives."

Professor Patricia Pozo-Rosich MD PhD, head of Neurology Section, Vall d'Hebron Hospital and Institute of Research, Spain, added: "For those living with migraine, the path towards effective treatment can be a long and complex journey. The ELEVATE trial demonstrates atogepant as a once-daily oral treatment that can significantly reduce monthly migraine days across a lifelong disorder, allowing people to experience relief in their daily lives, including those who have previously been failed by other preventive migraine treatments."

AstraZeneca and Ionis share positive results from phase 3 trial for eplontersen

AstraZeneca and Ionis have announced positive results from their phase 3 NEURO-TTRansform trial in patients with hereditary transthyretin-mediated amyloid polyneuropathy (ATTRv-PN), showing that the companies' drug eplontersen met all primary and secondary endpoints at 66 weeks compared to an external placebo group.

At the 66-week point, patients treated with eplontersen showed consistent and sustained benefits on the three co-primary endpoints, which were serum transthyretin (TTR) concentration, neuropathy impairment and quality of life (QoL).

Full results were reported at the Emerging Science Session at the American Academy of Neurology (AAN) 2023 Annual Meeting in Boston, US, and the companies are now seeking approval for the drug in the US, having already had a new drug application accepted by the US Food and Drug Administration (FDA).

Sami Khella MD, chief of the Department of Neurology at Penn Presbyterian Medical Center, professor of Clinical Neurology at the Perelman School of Medicine at the University of Pennsylvania School of Medicine and a principal investigator on the NEURO-TTRansform trial, commented: "In the past, patients with hereditary transthyretin amyloid polyneuropathy usually deteriorated given the limited available treatments. This new study shows eplontersen can halt progression of neuropathy and improve quality of life at 66 weeks when compared to placebo. Today's important results demonstrate that eplontersen has a consistent and sustained treatment effect and reinforces its potential as an important medicine for the thousands of patients living with this debilitating and fatal disease."

Mene Pangalos, executive vice president of BioPharmaceuticals R&D at AstraZeneca, added: "Without treatment, hereditary transthyretin-mediated amyloid polyneuropathy is a relentlessly progressive disease. These results show that eplontersen sustains reduced transthyretin levels and improves neuropathy progression and quality of life consistently across a substantial number of patients. We are confident in eplontersen's potential to be a much-needed and differentiated treatment option for patients living with all types of this devastating disease, which can also lead to heart failure."

Eli Lilly shares positive results from phase 3 study of donanemab for early Alzheimer's disease

Eli Lilly has announced positive results from the TRAILBLAZER-ALZ 2 phase 3 trial assessing donanemab's ability to slow cognitive and functional decline in people with early symptomatic Alzheimer's disease.

The drug met its primary endpoint of change from baseline until 18 months on the integrated Alzheimer's Disease Rating Scale (iADRS), measuring cognition and activities of daily living such as managing finances, driving, engaging in hobbies and conversing about current events. Additionally, all secondary endpoints of cognitive and functional decline were also met and showed highly statistically significant clinical benefits.

Lilly is now expected to progress with global regulatory submissions as soon as possible, with plans to make a submission to the US Food and Drug Administration (FDA) by the end of the quarter (Q2 2023).

Analysis of the trial data showed that 47% of participants on the drug showed no decline on the Clinical Dementia Rating-Sum of Boxes (CDR-SB) at one year, compared to 29% on the placebo; 52% of participants completed their treatment in one year, while 72% completed in 18 months as a result of achieving plaque clearance; those treated with donanemab experienced 40% less decline in ability to perform daily activities at 18 months; and participants on donanemab also experienced at 39% lower risk of progressing to the next stage of disease compared to those in the placebo group.

Daniel Skovronsky MD PhD, Lilly's chief scientific and medical officer and president of Lilly Research Laboratories, commented: "Over the last 20 years, Lilly scientists have blazed new trails in the fight against Alzheimer's disease by elucidating basic mechanisms of AD pathology and discovering imaging and blood biomarker tools to track the pathology. We are extremely pleased that donanemab yielded positive clinical results with compelling statistical significance for people with Alzheimer's disease in this trial. This is the first phase 3 trial of any investigational medicine for Alzheimer's disease to deliver 35% slowing of clinical and functional decline."

GSK announces positive data from phase 3 trial for new UTI antibiotic

GSK has shared positive data from its phase 3 trial for gepotidacin as a new oral antibiotic for the treatment of uncomplicated urinary tract infections (uUTIs) in female adults and adolescents.

The drug is in late stage development in GSK's infectious diseases portfolio and the positive data from the EAGLE-2 and EAGLE-3 phase 3 trials have been stopped early for efficacy following a recommendation from the Independent Data Monitoring Committee (IDMC) in November 2022.

The trial data was presented at the European Congress of Clinical Microbiology and Infectious Diseases (ECCMID) in Copenhagen, Denmark, although full results are expected to be submitted for publication in a peer-reviewed journal later in 2023.

In both phase 3 trials, the drug demonstrated non-inferiority to nitrofurantoin, an existing treatment for uUTIs. In the EAGLE-3 trial, gepotidacin demonstrated statistically significant superiority compared to nitrofurantoin. Both results are based on a primary efficacy endpoint of therapeutic success, in the form of an eradication of bacteria at the Test-of-Cure visit 10-13 days after the beginning of the treatment.

The safety and tolerability profile of gepotidacin remained consistent with information from previous trials.

Chris Corsico, senior vice president of Development at GSK, commented: "Despite uUTIs being one of the most common infections in women and mounting concern about rising resistance rates to existing treatments, there has been no new class of antibiotics for over 20 years. We believe that gepotidacin, if approved, will offer a much-needed additional oral treatment option for patients at risk of treatment failure associated with resistance or recurrence of uUTI. We are committed to working with global regulators to bring this new antibiotic to patients as quickly as possible."

Dr Florian Martin Erich Wagenlehner, principal investigator for the EAGLE-2 phase 3 trial, added: "These results are a significant step forward in an area that has seen very little innovation for decades. Gepotidacin is the first antibiotic to meet contemporary regulatory criteria, which set a high threshold for the efficacy of treatments in uUTIs. Gepotidacin has the potential to offer healthcare professionals another oral option to treat this common community infection."

Merck's relapsing multiple sclerosis trial put on FDA partial clinical hold over liver injuries

Merck has announced that its clinical phase 3 study EVOLUTION has been put on partial clinical hold by the US Food and Drug Administration (FDA) over liver injuries found in enrolled patients.

EVOLUTION is a phase 3 clinical trial studying its investigational BTK inhibitor evobrutinib in relapsing multiple sclerosis (RMS). BTK's target and deactivate the Bruton's tyrosine kinase protein, which can help in RMS to lower levels of the autoantibodies that attack the protective lining around nerves, aiding in better disease outcomes.

The partial clinical hold disallows the initiation of new patients and patients with less than 70 days exposure to study medication in the US. The FDA decision was based on two cases where a patient's laboratory values indicated drug-induced liver injury. However, it was reported that both patients were asymptomatic, did not require medical intervention and that their liver enzymes normalised after discontinuation of study medication.

Danny Bar-Zohar, global head of R&D and CMO at Merck, told BioSpace: "The partial hold is a challenge, but we believe that with a good dialogue with experts as well as with [the] FDA we will be able to address it. As always, efficacy is key. The phase 2 data, as well as extension and biomarkers, make us confident in the benefit risk ratio for evobrutinib, and we await our phase 3 data readout to make a compelling case for its therapeutic benefit for patients with RMS."

Vicore announces initiation of proof-of-concept study for endothelial dysfunction treatments

Vicore Pharma Holding AB has announced that it has dosed the first patient with C21 in its randomised, double-blind, placebo-controlled, cross-over clinical study of endothelial dysfunction. The trial includes patients with type 2 diabetes mellitus (T2DM), a condition in which endothelial dysfunction is significant in the development of organ damage.

This trial will use Vicore's first ATRAG C21 and EndoPAT, a US Food and Drug Administration (FDA) approved, non-invasive, simple and robust technology in order to detect endothelial dysfunction. Results from the trial are expected in the fourth quarter of 2023. It is hoped that if the proof-of-principal is achieved, the results may strengthen the idea that ATRAGs can be useful in the treatment of multiple major common diseases, as well as demonstrate that the EndoPAT technique can be used in exploring therapeutic efficacy in diseases impacted by endothelial dysfunction.

Elin Rosendahl, vice president of Clinical Operations at Vicore Pharma, commented: "Measuring endothelial dysfunction with the EndoPAT technology in drug trials is a cost-effective and robust method for early documentation of proof-of-concept in pulmonary, renal and vascular diseases. This has the potential to substantially shorten the timelines and decrease the risk in clinical development programmes."

Jan Nilsson, professor in Experimental Cardiology at Lund University, Sweden and principal investigator in the trial, added: "Patients with diabetes mellitus have an increased risk of cardiovascular events and endothelial dysfunction is an important factor for this development. Treating endothelial dysfunction could be a major breakthrough in cardiovascular disease."

AstraZeneca's Farxiga approved to reduce risk of cardiovascular death

AstraZeneca has announced that the US Food and Drug Administration (FDA) has approved Farxiga to reduce the risk of cardiovascular (CV) death, hospitalisation for heart failure (hHF) and urgent heart failure (HF) hospital visits for adults with HF.

This additional approval is based on positive data from the DELIVER phase 3 trial. The drug was previously approved in the US for adults with HF with reduced ejection fraction (HFrEF).

The data from the DELIVER phase 3 trial showed Farxiga reaching a statistically significant and clinically meaningful early reduction in the primary composite endpoint of CV death or worsening HF in patients with HF with HFmrEF or HFpE.F.

Full results of the trial were published in *The New England Journal of Medicine* while an analysis of the trial was published in *Nature Medicine*; these demonstrated that treatment with Farxiga on the composite endpoint of CV death, hHF or urgent HF was consistent across the left ventricular ejection fraction (LVEF) range and established Farxiga as 'the first sodium glucose cotransporter 2 (SGLT2) inhibitor to demonstrate a mortality benefit,' according to the company's press release.

Ruud Dobber, executive vice president of the BioPharmaceuticals Business Unit at AstraZeneca, commented: "Approximately half of HF patients die within five years of diagnosis, highlight[ing] an urgent unmet need for well-tolerated treatment options that can bring life-saving benefits and reduce the risk of cardiovascular death. The approval of Farxiga in the US not only reinforces AstraZeneca's commitment to reducing the burden of this complex and life-threatening disease, but will help patients across the full spectrum of HF lead healthier lives."

FDA approves first orally administered faecal microbiota product for preventing serious gut infection

The US Food and Drug Administration (FDA) has announced that it has approved the first orally ingested faecal microbiota product for the prevention of the reoccurrence of Clostridioides difficile (C. difficile) infection (CDI) following antibacterial treatment for recurrent CDI in patients aged 18 and over.

CDI is caused by C. difficile, a bacterium that flourishes in the human intestinal tract when the balance of natural microorganisms is affected, commonly by antibiotics. C. difficile releases toxins, which cause diarrhoea, abdominal pain, fever and, in serious cases, organ failure and death. After recovering from CDI, individuals may get the infection again multiple times, known as recurrent CDI.

Vowst is a faecal microbiota regimen containing live bacteria manufactured from donated faecal matter from healthy individuals. The treatment includes four capsules taken once daily for three consecutive days.

Vowst's efficacy was evaluated in a randomised, double-blind, placebo-controlled, clinical study conducted in the US and Canada, which included 89 Vowst recipients and 93 placebo recipients 18 years of age and older with recurrent CDI. Through eight weeks of treatment, CDI recurrence in Vowst-treated participants was 12.4% compared to 39.8% in placebo-treated patients.

Peter Marks MD PhD, director of the FDA's Center for Biologics Evaluation and Research, stated: "Today's approval provides patients and healthcare providers a new way to help prevent recurrent C. difficile infection. The availability of a faecal microbiota product that can be taken orally is a significant step forward in advancing patient care and accessibility for individuals who have experienced this disease that can be potentially life-threatening."

FDA approves Pfizer's pneumococcal conjugate vaccine for infants and children

Pfizer has announced that the US Food and Drug Administration (FDA) has approved its PREVNAR 20 (20-valent pneumococcal conjugate vaccine) for the prevention of invasive pneumococcal disease (IPD) in infants and children from six weeks to 17 years of age.

The vaccine protects against IPD caused by 20 Streptococcus pneumoniae (pneumococcal) serotypes and builds on Pfizer's previous PREVNAR 13 vaccine, but includes an additional seven serotypes that have been shown to be linked to antibiotic resistance, heightened disease severity, invasive potential and prevalence in paediatric pneumococcal cases.

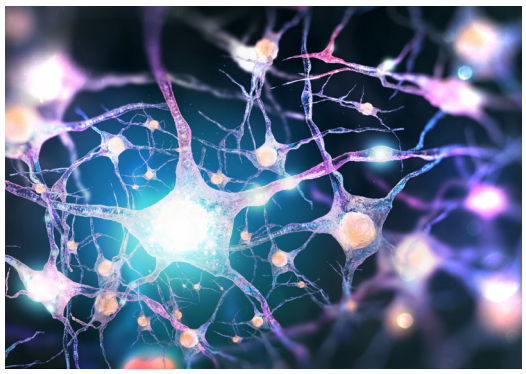
Annaliesa Anderson PhD, senior vice president and chief scientific officer, Vaccine Research and Development at Pfizer, commented: "Today's FDA approval of our vaccine, PREVNAR 20, now offers parents the ability to help protect their children against 20 pneumococcal serotypes in circulation, which represent the majority of pneumococcal disease in US infants and children. This important PREVNAR 20 approval builds on more than 20 years of real-world impact with PREVNAR and PREVNAR 13, safety data and effectiveness; highlighting Pfizer's leadership in developing groundbreaking pneumococcal conjugate vaccines to help protect infants and their families from life-threatening infections. We are grateful to the families and clinical investigators who participated in this research and our colleagues who have worked tirelessly to develop this breakthrough vaccine."

Dr Sheldon Kaplan, chief of the Division of Infectious Diseases, Department of Pediatrics at Baylor College of Medicine and chief of Infectious Disease Service at Texas Children's Hospital, both US, added: "With the approval of PREVNAR 20 for the paediatric indication, we now have an expanded vaccine to help provide infants and children with the broadest serotype protection in a PCV, helping to protect against the 20 serotypes in the vaccine, which includes the specific serotypes responsible for significant burden of disease in children under five. We are thrilled with this approval as it signifies a new chapter in paediatric pneumococcal conjugate vaccination. Based on the real-world results we've observed with PREVNAR 13, PREVNAR 20 has the potential to greatly reduce the substantial remaining burden of pneumococcal disease among US infants and children and help protect them against this potentially serious disease."

Neuspera Medical receives FDA approval for peripheral nerve pain system

Medical device company Neuspera Medical has announced that it has received US Food and Drug Administration (FDA) approval for its implantable system, used to treat peripheral nerve pain.

The Neuspera system comprises of a first-of-its-kind, leadless micro-implant, wearable transmitter and digital information trackers – including an app for smartphones and an iPad-based clinician programmer. The ultra-miniaturised implant uses peripheral nerve stimulation (PNS), a growing treatment option for managing chronic pain conditions.



Being 75 times smaller than the smallest commercial implantable pulse generator, it is hoped the Neuspera system will allow for better procedural flexibility through its ability to gain access to deeper anatomical targets.

Neuspera's pipeline also includes the Nuvella system, a potential treatment for overactive bladder. In June 2022, phase 2 of the SANS-UUI clinical trial – looking to evaluate the system's safety and efficacy – was announced.

Steffen Hovard, CEO of Neuspera Medical stated, "We look forward to bringing this innovative technology to physicians and patients in the US. The Neuspera ultra-miniaturised system has the potential to revolutionise the way physicians treat patients battling chronic pain while restoring patients' health and quality of life."

NICE recommends Otsuka's Lupkynis (voclosporin) in combination treatment for active lupus nephritis

Otsuka Pharmaceuticals has announced that the National Institute for Health and Care Excellence (NICE) has recommended Lupkynis (voclosporin) in combination with mycophenolate mofetil (MMF) as a treatment option for adult patients with active lupus nephritis (LN).

NICE's recommendation applies to England and Wales with stock already available in both of these countries. The recommendation follows the Medicines and Healthcare Products Regulatory Agency's (MHRA) recent authorisation of voclosporin as the first and only oral calcineurin inhibitor (CNI) to be licensed in Great Britain specifically to treat active LN in adult patients.

The recommendation also follows positive results from the pivotal phase 3 AURORA 1 study and the AURORA 2 continuation study, which assessed the combination of voclosporin with MMF and corticosteroids compared to MMF and corticosteroids alone.

Paul Howard, chief executive of LUPUS UK, commented: "We are delighted that NICE has recommended voclosporin for use in the NHS. The combination of symptoms such as joint pain, swelling and fatigue caused by lupus nephritis can be very detrimental to mental well-being and quality of life. From conversations with people living with lupus nephritis, we know that every day can be a challenge living with this disease. We hope that the introduction of voclosporin as a new combination treatment option could help to improve the lives of those living with lupus nephritis."

Ryan Gynne, managing director of Otsuka Pharmaceuticals, added: "The NICE recommendation of Lupkynis is an important milestone for those living with this serious condition, reinforcing the commitment of Otsuka to bringing innovative solutions to patients for better health worldwide."

NICE recommends two CAR T treatments for blood cancers to the Cancer Drugs Fund

The National Institute for Health and Care Excellence (NICE) has announced that it is recommending two personalised immunotherapy treatments to the Cancer Drugs Fund (CDF) for the treatment of aggressive forms of blood cancers.

Chimeric antigen receptor (CAR T) therapy takes the patient's own immune system cells – T-cells – and alters them in the lab to attach to and kill cancer cells. Both recommended CAR T therapies are one-off treatments introduced to the patient's bloodstream.

Axicabtagene ciloleucel (Yescarta, Kite) is recommended for adult patients with diffuse large B-cell lymphoma (DLBCL) that returns within a year of treatment, or is resistant to first-line chemoimmunotherapy. At the moment, the treatment is only available as standard care after two or more systemic therapies – this new recommendation will make it available after one therapy.

Brexucabtagene autoleucel (Tecartus, Kite) is recommended to treat relapsed or refractory B-cell acute lymphoblastic leukaemia in people aged 26 and over. Standard-of-care treatment at the moment includes chemotherapy and immunotherapies, however after the new recommendation Brexucabtagene autoleucel will be offered as an additional treatment.

Offering these treatments through the CDF allows data to be collected, so hesitations around the treatments' long-term efficacy and wider NHS applications can be addressed. Since 2016, NICE has made 55 CDF recommendations and more than 55,000 patients have benefited.

Helen Knight, director of medicines evaluation at NICE, said: "We know the devastating impact lymphoma and leukaemia have on people. These innovative new treatment options will help people live longer and improve their quality of life. Around 1,000 people in total could benefit from a range of different CAR T therapies, including these latest treatments, which have all been recommended by NICE in recent months. We are committed to constantly learning from data and implementation, so patients can benefit from groundbreaking treatments while more information is gathered, which will hopefully lead to them being offered routinely on the NHS in the future."

3B Pharmaceuticals and Novartis enter into licensing agreement for FAP-targeting technology

German biotechnology company 3B Pharmaceuticals (3BP) and Switzerland-based Novartis have announced that they have entered into a Global Exclusive Licensing Agreement regarding fibroblast activation protein (FAP)-targeting peptide technology.

FAP is a promising theranostic target that expresses across the majority of cancers. 3BP has created FAP-2286, the first peptide-targeted radioligand therapy (PT-RLT) targeting FAP to enter clinical development with its respective imaging agent. FAP-2286 is made up of two elements: a targeting peptide that binds to FAP, and a site that can be used to attach radioactive isotopes for imaging and therapeutic use. It is currently being tested in the phase 1 LuMIERE trial.

Novartis will have exclusive worldwide rights to develop and commercialise therapeutic and imaging applications for 3BP's FAP-targeting technology, including FAP-2286. 3BP will receive an initial payment of $40m, as well as up to $425m in development, regulatory and commercial milestone payments and tiered royalties on net sales.

Dr Ulrich Reineke MD of 3BP, stated: "We have focused for many years on developing a peptide technology platform to create innovative radiopharmaceuticals and this agreement validates the value of 3BP's platform. This partnership will allow us to continue to expand our core competencies and dedicate resources to the further development of our pipeline."

Boehringer Ingelheim and Ginkgo Bioworks collaborate over $406m undruggable targets deal

German pharmaceutical company Boehringer Ingelheim (BI) and cell programming and biosecurity platform builder Ginkgo Bioworks have announced a partnership to discover and develop novel therapeutic molecules. The companies are focusing on treatments for diseases considered 'undruggable' with high unmet patient needs.

BI will mine Ginkgo's metagenomic sequence database for structurally novel bioactive molecules that could potentially enable rapid identification of lead molecules as starting points for drugs. The database is comprised of over three terabytes of sequence data and over two billion proprietary protein sequences from a variety of molecules.

Ginkgo's database, one of the broadest and deepest in the world, is supported by Zymergen's core automation and software technologies. Ginkgo acquired Zymergen for $300m in July 2022.

Under the agreement, Ginkgo will receive up to $406m in upfront research fees, success-based research and development, regulatory and commercial milestone payments. It is also entitled to potential royalties from any products derived from the collaboration.

Jason Kelly, CEO and co-founder at Ginkgo Bioworks stated: "Ginkgo is well-positioned to help partners like BI complement their drug discovery efforts particularly when it comes to natural product discovery. We are thrilled to work with BI leveraging our Foundry and Codebase to unlock new possibilities in biopharma innovation."

Diabeloop announces collaboration with Novo Nordisk for connected diabetes treatment

Automated insulin delivery company Diabeloop has announced its collaboration with global healthcare company Novo Nordisk. This includes an agreement that covers integrating Diabeloop's DBL-4pen self-learning algorithm app for multiple daily insulin (MDI) therapy, with Novo Nordisk's connected and reusable insulin pens, NovoPen 6 and NovoPen Echo Plus.

Diabeloop's app can be used by patients with type 1 or type 2 diabetes who take MDI injections, while Novo Nordisk's insulin pens are connected devices with dose memory functions, meaning they can keep a history of the patient's last 800 insulin injections.

Cécile Ferracci, CCO of Diabeloop, commented: "We are proud to be able to further expand our DBL-4pen interoperability strategy with this collaboration with Novo Nordisk. Our collaboration aims to bring more automated solutions to people with diabetes, optimising their outcomes and improving their quality of life. With DBL-4pen, we have developed an efficient self-learning algorithm for insulin dose recommendation, a significant step forward for MDI therapy, and we are excited to explore this with the innovative generation of NovoPen6 and NovoPen Echo Plus connected insulin pens."

The companies also plan to launch a clinical programme with type 2 diabetes patients, to assess the efficacy of DBL-4pen, later including Novo Nordisk's devices to assess the efficacy and clinical benefits of the combined solution.

Pierre-Yves Benhamou, chief medical officer of Diabeloop, stated: "With this interventional, open, single-arm clinical trial involving adults with type 2 diabetes, we aim to evaluate efficacy, safety and also treatment compliance. In addition, we will measure the improvement in quality of life and satisfaction of the enrolled patients and also evaluate the effect of DBL-4pen on the development of HbA1c in the extension phase."

Thomas Thestrup-Terp, corporate vice president of Digital Strategy and Solutions at Novo Nordisk, added: "We are delighted about this collaboration with Diabeloop – a company that has a shared ambition of bringing innovative digital health solutions to help people manage their diabetes. Smart insulin pens offer digital connectivity for people living with diabetes and the potential to automatically recommend the ideal insulin dose in real time. This could significantly improve the way diabetes medicines are used. We look forward to the data from the upcoming clinical study, to look at the potential benefits of NovoPen6 and NovoPen Echo Plus alongside DBL-4pen."

National Institutes of Health awards grant for gammaCore clinical

Bioelectronic medicine and wellness company electroCore has announced that the National Institute on Drug Abuse (NIDA), part of the National Institutes of Health (NIH), has awarded Emory University and the Georgia Institute of Technology, both US, a three-year, $6m grant as part of the NIH Helping to End Addiction Long Term (HEAL) Initiative.

This grant is intended to be used to conduct a clinical trial of gammaCore, a non-invasive vagus nerve stimulator (nVNS) treatment for patients with opioid use disorder (OUD).

Between 1999 and 2020, deaths from opioid overdoses increased 8.5-fold in the US, making this the leading cause of accidental death in the US.

The double-blind, randomised, sham-controlled study is based on the completion of a pilot study, which showed that gammaCore nVNS reduced both the psychological and physiological symptoms

of acute opioid withdrawal. The trial is expected to include around 100 patients with OUD, with its primary endpoint being the peak difference in Subjective Opioid Withdrawal Score (SOWS) between nVNS and sham treatment on day two and three of the initial withdrawal period.

Dr Douglas Bremner, professor of Psychiatry and Radiology at Emery University School of Medicine and a principal investigator for the study, commented: "We are pleased to be able to proceed with a pivotal trial to define the role of nVNS as a potential treatment for opioid use disorder. While treatments exist to help patients initiate and maintain opioid withdrawal programmes, more effective options are needed."

Peter Staats MD, chief medical officer at electroCore, added: "We applaud the effort and leadership of Dr Bremner, Dr Inan and their clinical research teams at Emery University and the Georgia Institute of Technology, as well as Dr Volkow and her team at NIDA for their support of this grant. The personal, family and financial costs of opioid addiction represent an ongoing crisis in America and nVNS could offer a safe, effective and novel way to help patients through the critical initial phase of withdrawal thereby saving them pain and distress while also saving the healthcare system significant expense."

RetinAI and Boehringer Ingelheim partner over AI treatments for geographic atrophy

Swiss data management software company RetinAI and US-based Boehringer Ingelheim (BI) have announced a partnership to improve patient outcomes in geographic atrophy (GA) with AI. GA is a progressive form of age-related macular degeneration and a leading cause of sight loss.

RetinAI will combine its novel biomarkers analysis Discovery platform and AI tools, with BI's imaging data sets from clinical studies and real-world evidence in retinal diseases. The companies hope to identify additional, novel biomarkers and predictors of disease progression.

AI can aid in accelerating the development of much-needed novel treatments, and enable earlier and more precise diagnosis of GA.

Dr Carlos Ciller, CEO of RetinAI, commented: "RetinAI is excited to embark on this very important collaboration with BI, a leader in the development of innovative, more precise treatments and application of digital technologies in retinal diseases. Our Discovery platform and novel AI tools in GA accelerate research and provide robust disease insights. We are confident that this collaboration with BI can pave the way to novel treatments that are better tailored to a patient's disease to transform the lives of people living with retinal diseases."

Thermo Fisher and Pfizer collaborate on NGS-based cancer tests

Scientific equipment provider Thermo Fisher and US pharmaceutical firm Pfizer have announced a collaboration to advance next-generation sequencing (NGS)-based cancer testing.

Historically, single gene testing has been used to match patients with appropriate targeted therapies, however this can be time-intensive due to the possible need for sequential tests and lack of tissue available, which may mean extra biopsies. NGS screens a single tumour tissue or blood sample for multiple biomarkers simultaneously, meaning clinical teams can access genomic insights quickly and effectively and therefore prescribe the right treatment faster.

The joint effort will aim to bring NGS testing to more than 30 countries in Latin America, Africa, the Middle East and Asia where advanced genomic testing is lacking or not available.

As part of this, Thermo Fisher will highlight suitable local labs and implement NGS technology for breast and lung cancer testing, offering training, infrastructure and quality control measures. Pfizer will explore affordable patient access for these types of cancer and raise advanced testing awareness.

Gianluca Pettiti, executive vice president at Thermo Fisher Scientific, commented: "Anyone facing a cancer diagnosis should have access to cutting-edge testing that can match them with an appropriate, optimised treatment plan and better inform their care. Today, we aim to bring rapid NGS testing to an increased number of decentralised labs, closer to where patients are treated. We are moving one step closer to delivering precision insights to underserved patients so they can receive a more tailored path for their care no matter where they are in the world."

Nick Lagunowich, Pfizer's global president of Emerging Markets, said, "The more we understand the complex science behind cancer, the better we can treat it. Our experience has taught us that cancer cannot always be treated with a broad brush and often requires an individualised approach based on precise disease characteristics. In many parts of the world, access to NGS may be limited or unaffordable for cancer patients. This programme aims to improve their treatment journey and help increase their chances for improved outcomes."

Gilead acquires XinThera to strengthen pipeline in oncology and inflammation

Gilead Sciences has announced the acquisition of all outstanding shares of XinThera, a privately owned biotech company based in San Diego, US. This acquisition aims to strengthen Gilead's clinical development pipeline through the addition of XinThera's oncology and inflammation assets.

Gilead will gain the rights to a portfolio of small molecule inhibitors that target PARP1 for oncology and MK2 for inflammatory diseases; these could enter clinical trials by the end of 2023. Both the oncology and inflammation programmes have the potential to address various indications, with a wide range of development opportunities both alone and in combination with Gilead's portfolio.

Financial terms of the agreement have not been disclosed.

Flavius Martin MD, executive vice president of research at Gilead Sciences, commented: "The team at XinThera has developed research assets with the potential to target the DNA damage repair pathway in treating cancer and direct the body's immune response in inflammatory diseases, both of which may improve outcomes for people living with these diseases. Guided by our scientific framework, this acquisition will allow us to further expand our early pipeline of diverse assets that will continue to fuel our durable late-phase portfolio."

Chris LeMasters, who worked as XinThera's chief executive officer, added: "Gilead and XinThera share similar missions to discover new therapies to treat cancer and inflammatory diseases, which drive our determination to unlock the body's ability to better respond to these diseases. We are eager to join Gilead and together explore the potential of our precision medicines as critical components of the next generation of therapies targeting diseases with high unmet need."

GSK enters into £1.6bn deal to acquire Bellus Health

UK-based GSK has announced its plans to acquire Bellus Health, a Canadian late-stage biopharmaceutical company that focuses on treatments for refractory chronic cough (RCC). The acquisition will give GSK access to camlipixant, Bellus' first-in-class treatment for RCC.

Camlipixant is a highly selective P2X3 antagonist currently in phase 3 development, where P2X3 is a validated biological target implicated in cough reflex hypersensitisation. By selectively inhibiting P2X3 receptors, camlipixant may reduce cough frequency for RCC patients.

GSK's acquisition of Bellus Health will complement its expertise in respiratory medicines, and will make the most of GSK's leading R&D, manufacturing and commercialisation capabilities. It is hoped that camlipixant will achieve regulatory approval and be launched in 2026, with profits expected from 2031.

Luke Miels, chief commercial officer at GSK, said: "Patients suffering from severe forms of RCC can experience over 900 coughs daily, resulting in quality-of-life issues. Camlipixant, a novel, highly selective P2X3 antagonist, has the potential to be a best-in-class treatment with significant sales potential. This proposed acquisition complements our portfolio of specialty medicines and builds on our expertise in respiratory therapies."

Roberto Bellini, CEO of Bellus Health, commented: "This acquisition recognises the value of our highly selective P2X3 antagonist camlipixant and validates the hard work and dedication of all the Bellus employees in advancing camlipixant to date. As a leader in respiratory research for over five decades, GSK shares our commitment to bettering the lives of individuals suffering from a persistent cough and is the ideal company to rapidly bring camlipixant to the millions suffering from RCC around the world."

Sobi acquires CTI BioPharma Corporation for $1.7bn

Swedish Orphan Biovitrum (Sobi) has announced that it had entered into a 'plan of merger' with CTI BioPharma Corp (CTI), a biopharmaceutical company focused on blood-related cancers and rare diseases, by means of a tender offer valued at $1.7bn.

As part of the acquisition, Sobi will strengthen its haematology portfolio by adding Vonjo (pacritinib), a novel oral kinase inhibitor that inhibits JAK2, IRAK1 and ACRV1, while sparing JAK1. In February 2022, Vonjo was awarded accelerated approval by the US Food and Drug Administration (FDA) as a treatment for adults with intermediate or high-risk primary or secondary (post-polycythaemia vera or post-essential thrombocythaemia) myelofibrosis with a platelet count below 50×10^9/L.

Vonjo's continued approval is based on the confirmatory phase 3 PACIFICA trial, with results due mid-2025.

Guido Oelkers, president and CEO of Sobi, stated: "CTI represents a perfect fit for Sobi's haematology franchise today, adding a powerful and highly differentiated new product that will make a significant difference for patients. There is a large unmet medical need within myelofibrosis, in particular for patients suffering from thrombocytopenia who are inadequately treated by existing medicines. The combination of the talented team at CTI, together with Sobi's broad US and global haematology capabilities, will help get this much-needed new therapy to patients faster and more effectively. The acquisition of CTI is the latest in a series of transformative transactions Sobi has conducted to build its leading rare haematology franchise."

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Industry Insight

The climate crisis: what is it and is pharma to blame?

Stefan Woxström at AstraZeneca Europe and Canada tells *Pharmafocus* about the link between climate change and human health, as well as considering how the pharma industry has contributed to the climate crisis

Pharmafocus: **Can you tell us about the link between climate change and human health, and how the connection is becoming increasingly evident?**

Stefan Woxström (SW): The health of the planet and people are intrinsically linked, with climate change negatively impacting population health and increasing the burden of non-communicable diseases (NCDs).

Climate change is causing a growing physical, mental and economic burden on society, as a result of extreme temperatures, weather-related events, air pollution and the growing spread of food, water and vector-borne illnesses, all of which contribute to growing rates of disease.

In turn, the care required to treat increasing disease prevalence significantly adds to greenhouse gas (GHG) emissions from the healthcare sector, with many conditions often requiring extended, costly and resource-intensive therapy.

From an economic perspective, the climate crisis is predicted to result in direct health costs exceeding $2bn annually by 2030, putting additional pressure on already stretched medical services and threatening the resilience of healthcare systems for future generations.[1]

Ultimately, the best thing we can do for the health of the planet is to keep people healthy.

Pharmafocus: **The climate crisis is now the greatest risk to health of the 21st century – how is this specifically impacting global population health?**

SW: Over 14 million people die from environmental health risks each year, including seven million as a result of air pollution.[2,3,4] It is estimated that 23% of global deaths could be prevented through healthier environments and, according to the World Health Organization (WHO), the climate crisis will cause an additional 250,000 deaths every year between 2030-2050.[1,5] Nearly two-thirds of these environmental-related deaths are from potentially preventable chronic cardiovascular and respiratory diseases, leading to significant rises in hospital admissions and devastating consequences for population health.[5]

The climate crisis is also a health equity crisis, widening existing inequalities within and among countries. The detrimental impact of climate change is disproportionately felt by the most vulnerable – older populations, displaced persons, those with existing medical conditions or in marginalised communities.[1]

Pharmafocus: **How has the pharma industry contributed to the climate crisis?**

SW: The pharmaceutical industry, which exists to improve health, is unfortunately also contributing to the climate crisis. The research, development, manufacturing and delivery of healthcare is energy intensive – the healthcare sector as a whole accounts for approximately 5% of global GHG emissions.[6] 71% of these GHG emissions come from the healthcare supply chain, and hospitals have the highest energy use of all publicly funded buildings, emitting two and a half times more GHGs than commercial buildings.[4,7]

With ageing populations and growing rates of disease, it is predicted that the GHG footprint from the healthcare sector could as much as triple by 2050.[8] To realise long-term change, the industry must come together and commit to being part of the global climate solution. More sustainable choices must be made across every aspect of research and development (R&D) and the full value chain, reducing GHG emissions and finding patient care interventions that have a lower environmental impact.[9]

Pharmafocus: **What can the pharma industry – as a whole and as individual companies – do to reduce its negative impact on the climate?**

SW: Organisations have a responsibility to take action at scale to decarbonise their own operations and partner with others beyond their immediate business to accelerate the delivery of net-zero healthcare. The sector has recognised the urgent need for change and nearly half of pharma and biotech organisations have made broad commitments to reduce resource utilisation and GHG emissions through the United Nations' (UN) Race to Zero initiative.[10]

Some companies are already embracing 'green chemistry' to make drug design and discovery more sustainable, without sacrificing drug safety or effectiveness.[11] With labs on average consuming up to ten times the energy and four times the water of a typical office space, it is important to find greener chemicals, processes or products to maximise the efficiency of experiments, and reduce waste, conserve energy and eliminate the use of hazardous substances.[11]

The industry is also reviewing how best to run sites and operations to reduce GHG emissions, promoting efficient, circular use of water and natural resources. Renewable energy is being embraced, with many organisations shifting to more sustainable facilities.

To achieve real change, suppliers, distributors and manufacturers will similarly need to commit to high sustainability standards. That is why we are cascading our climate ambition and target setting down the value chain. By the end of 2025, many companies are aiming for 95% of their key suppliers and partners to have science-based targets, this involves supporting suppliers on the journey to net zero, with many also supporting Energize, a first-of-its-kind industry programme that provides resources and expertise to accelerate adoption of renewable energy throughout the value chain.[12]

Furthermore, the Sustainable Markets Initiative (SMI) Health Systems Task Force is another example of an initiative taking scalable action to collectively address emissions across supply chains, patient care pathways, and clinical trials. The Task Force recently announced a set of common supplier standards to incentivise and simplify decarbonisation efforts across the supply chain.[13] The industry must also consider how to reduce the environmental impact of patient care, helping to stop people from getting sick and requiring high-cost hospital care. Investing in preventative strategies and harnessing earlier and more effective interventions can reduce GHG emissions, improve patient outcomes and lower pressures on our healthcare systems.[14] For example, chronic kidney disease is frequently diagnosed at an advanced stage when it may be too late to alter the course of the disease. In Europe, half a million patients rely on dialysis for survival, which is expensive, invasive and a major contributor to climate change: dialysis requires 160 billion litres of water per year and generates over 900,000 tonnes of mainly plastic waste.[15]

Preventative strategies will provide benefit to both patients and the environment, as well as improvements to health systems, economies and society as a whole.

Pharmafocus: **What are the Sustainable Development Goals and what steps does the pharma industry need to take to adopt them?**

SW: As part of the UN 2030 Agenda for Sustainable Development, 17 Sustainable Development Goals (SDGs) were announced to address the most pressing issues we face as a global community — inequality, injustice, poverty and climate change.[16]

The 17 SDGs should not be viewed in silos; contribution to one SDG will affect outcomes in others. Recognising the synergies between improving economic prosperity, health, education and the environment will help set society on a transformative path towards a more resilient and sustainable future.

Across the sector, organisations have pledged their support to the SDGs, incorporating new initiatives into company practices as well as into those of suppliers and partners. This spirit of collaboration and learning is the guiding principle behind the Partnership for Health System Sustainability and Resilience (PHSSR), which is now active in more than 30 countries, bringing together academic, public and private sectors to strengthen health systems through evidence-based policy change.

The industry has a critical road ahead and all those involved in the provision of care have a role to play in accelerating the delivery of net-zero, patient-centric health systems for the benefit of patients, society and our planet.

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Author bio:

Stefan Woxström *is senior vice president, Europe & Canada (EUCAN) at* ***AstraZeneca,*** *responsible for leading the company's sales, marketing and commercial operations in 30 European countries and Canada. Woxström has been with AstraZeneca since 1996, when he began his professional career as a sales representative for AstraZeneca Sweden, before holding various roles including national sales manager, national sales director, marketing director cardiovascular, regional business director, Specialty Care of AstraZeneca's former 'Central Eastern Europe Middle East and Africa' (CEEMEA) Office in Belgium, country president of Ukraine & the Commonwealth of Independent States (CIS), and three further leadership roles within the company. He holds a BSc and an MSc in Business Administration & Economics from Stockholm University, Sweden.*

Why modelling patient heterogeneity is crucial in drug development

Prof Shai Shen-Orr at CytoReason explores the need for patient heterogeneity in drug development, and suggests why this is so central to successful drug development

Drug development is heavily dependent on our understanding of disease mechanisms, and patient heterogeneity is crucial for achieving improved modelling of the complex disease landscape – often reflected in diverse disease clinical phenotypes and severity levels. Prevalent approaches such as the use of cell lines, organoids and animal models, have limitations in accurately representing the complexity of human diseases and the diversity among patients. However, advancements in artificial intelligence (AI) have provided new opportunities to overcome some of these challenges. By accounting for patient-specific characteristics, computational disease models can provide a tailored and precise description of disease mechanisms, drug responses, adverse effects and potential therapeutic targets, enhancing personalised medicine and effective drug discovery strategies.

Patient heterogeneity modelling supports targeted drug development by patient stratification and identification of patients' sub-populations that are most likely to respond to a particular drug. This enables drug development efforts to focus on those patients and to enhance clinical trial design, leading to a more efficient development process and an increased likelihood of success. Ultimately, this approach promotes better patient outcomes and reduced costs related to trial and error procedures, which are highly time-consuming and expensive. Through stratifying patients based on their disease landscape and focusing on more homogenous cohorts, a greater number of genes associated with the mechanism of action (MOA) emerge. This also holds significant relevance in identifying drug resistance mechanisms.

Drug repurposing is an additional factor enhanced by identifying existing drugs that are effective in treating patient subgroups, originally not targeted by those drugs. The variation among patients can affect drug pharmacodynamics that is related to drug activity, and pharmacokinetics that includes aspects of drug absorption, metabolism, distribution and excretion. All of these can contribute to different outcomes in drug therapy. A broad understanding and precise mapping of drug MOAs, and specific characteristics across indications of patient sub-populations, may enable better matching of existing drugs for new indications, and thereby accelerate drug development and reduce costs. Beyond this, patient heterogeneity is also important for drug toxicity assessment, through the identification of sub-populations expressing distinct features causing high predisposition to increased risk of drug toxicity.

While patient heterogeneity aims to identify variations observed among real patients, another complementary approach uses virtual patients and digital twins to focus on simulating a dynamic virtual representation of an individual to better understand and predict health outcomes at the patient level. This is particularly useful in making informed treatment decisions, monitoring and optimising interventions for a specific patient. While both approaches are valuable, the former prioritises disease-oriented research, whereas the latter emphasises patient insights.

There are multiple approaches to model patient heterogeneity, which places molecular omics data, together with machine learning (ML) tools including supervised, unsupervised and reinforcement learning, at the forefront of pharma research. Expanding the ability to generate patient-specific data advances the use in ML approaches for drug development and treatment decision-making. Extensive and high-resolution types of patient data are measured for these purposes including genomics, transcriptomics, metabolomics, epigenetics, microbiome, spatial and temporal data and electronic health records (EHR).

While genetic heterogeneity is widely recognised, patient heterogeneity extends beyond genetics

The computational modelling of patient heterogeneity in drug development offers a powerful approach to enhance our understanding of disease complexity, optimise treatment strategies and accelerate the discovery of effective therapies

and is influenced by various additional factors, including environmental exposures, lifestyle choices, comorbidities and demographic factors. Disease development and progression encompass a continuum of changes occurring in numerous parameters, covering both intra- and inter-individual variations in cellular composition and regulatory programmes over time and space. To capture and represent this multifaceted diversity, trajectory inference methods have been used, which enable the pinpointing of factors that drive state transitions and putative causal drivers of the onset and progression of the disease. Dissection of these system-wide effects substantially helps designing new drug targets and treatment manipulations to modulate the identified disease drivers.

Systems biology and network-based approaches are powerful tools in the study of disease biology. While many network analyses rely on population-level averages, recent advancements have enabled the creation of sample-specific networks that can capture the complex molecular interactions present at the individual level. These networks allow identifying key signaling pathways that are dysregulated in a particular patient, leading to the discovery of potential therapeutic targets that are specific to a patient sub-population. Drug-response networks can be constructed using patient-specific data on drug treatments. These networks can help identify drug responses, biomarkers and drug resistance mechanisms, empowering optimisation of treatment strategies accordingly.

Bayesian modelling, which involves developing probabilistic models to predict disease and drug responses, is used to model patient heterogeneity by incorporating prior knowledge and uncertainty into the analysis. Bayesian modelling can help identify patient subgroups and their associated properties, and support decision-making related to treatment selection. For large sized data sets, as well as complex unstructured data such as documents, images and text, including medical imaging and electronic health records, recently deep learning algorithms have been used to model disease heterogeneity, in order to predict the risk of disease development or patient-specific disease outcomes.

Taken together, the computational modelling of patient heterogeneity in drug development offers a powerful approach to enhance our understanding of disease complexity, optimise treatment strategies and accelerate the discovery of effective therapies. This comprehensive approach holds great promise for advancing personalised medicine and transforming the field of drug development.

Author Bio

*Systems biologist and data scientist **Shai Shen-Orr** is the co-founder and chief scientist of **CytoReason** and a professor in the faculty of medicine at the Technion, where he directs the laboratory of systems immunology and precision medicine. In his research, he develops new analytical methodologies for grappling with the intricate complexities of the immune system; his research has been cited numerous times and has been featured in systems biology textbooks for students. Shen-Orr received a BSc from the Technion in Information Systems, an MSc in Bioinformatics at the Weizmann Institute of Science and a PhD in Biochemistry from Harvard University. He performed his postdoctoral studies at Stanford University.*

How regulators are keeping pace with technology

Fiona Maini from Medidata Solutions, speaks about pharmaceutical regulation and the opportunities and policy challenges posed by digitalisation and a rapidly evolving industry

The past few decades have seen science and technology accelerate at a rapid pace, bringing greater efficiency and quality across all aspects of our lives. The pharmaceutical industry is no different, benefiting massively from innovative approaches. But one area in which this rapid digitalisation has posed a problem is regulation, with policymakers struggling to keep up. Regulators are right to carefully consider and evaluate policy, but this has historically made it impossible to keep pace with such rapid change in the industry.

To put things into context, the pharmaceutical industry is still working to International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) Good Clinical Practice (GCP) guidelines, which, while updated in 2016, were first introduced in 1996. Technological capabilities have taken off exponentially since then, but some of the benefits have been constrained – and some of the dangers have been exposed – by outdated regulation. This pacing problem is not unique to the life sciences industry, but recent moves by global regulators to address some of these discrepancies are most welcome; in terms of innovation, we are only as good as our regulatory framework. The US and EU, for instance, are bringing in cyber laws requiring companies to highlight IT vulnerabilities in medical devices before they go to market. To the policymakers of the 1990s, the idea that a medical device could be hacked would have sounded crazy, but this is now a potential problem in devices such as pacemakers. This is the technological labyrinth in which regulators are operating and having to react to.

In recent years there has been a flurry of regulatory updates in the US, EU and UK, in a bid to better reflect the realities and considerations of the modern pharmaceutical industry – and clinical trials in particular. Cyber-security, the use of artificial intelligence (AI) in the field and the importance of championing diversity and inclusion in medical development are all points absent from the regulation of the 1990s and which global regulators are now addressing.

Decentralised Clinical Trials and Regulation

Remote technology solutions for clinical trials, such as electronic patient diaries, wearables and sensors have existed for some time, but COVID-19 accelerated the move towards the wider adoption of decentralised clinical trials (DCTs). This is a positive development that supports the democratisation of trial access, enriching data sets and ultimately facilitating scientific discovery. DCTs are, however, an area with a particular need for regulatory revamp as the ICH was created when this technology didn't even exist.

As a consequence, while COVID-19 helped to drive adoption of decentralisation, many pharmaceutical companies and CROs in the industry have found that the lack of guidance from regulators has prevented them from fully embracing the benefits of DCTs. Thankfully, regulation is modernising. While the details are yet to be confirmed, the EU's GCP revision 3 will hopefully bring a more adaptive regulatory approach to DCTs later in the year. Similarly, the US Food and Drug Administration (FDA) has recently released guidance for 'Decentralized Clinical Trials for Drugs, Biological Products, and Devices'. While there are some limitations, the supportive attitude from the agency to facilitate a more flexible approach to clinical trials can hopefully unlock the benefits for trial sites and patients alike.

Regulation of AI

The promise that AI offers the life sciences sector is colossal, the benefits of which are already being seen in clinical trials. For example, vast amounts of data are generated from clinical trials and AI can be used to forecast potential issues, optimise trial design or even create a synthetic control arm. While the industry is harnessing the power of AI, there are still some concerns around safety, ethics and privacy, which could be assuaged with robust regulatory frameworks.

The AI Act Europe will be the first global regulation of AI, heavily influenced by GDPR and covering all industries. The regulation takes a risk-based approach, with ethical considerations at the forefront of the industry. The life sciences industry is deemed to be high risk given the potential impact on people's lives. This may be restrictive in some cases, however it is likely to provide some much-needed guidance and reassurance. Many companies will need to look at the act and consider what activities they conduct using AI before seeking certification that they are appropriately compliant.

Although the regulation should lay a good foundation from which to operate, there are some

elements that will need modifying. For example, there are potential duplications between the EU Medical Device Regulation and the AI Act, both of which require companies to perform a conformity assessment. Life sciences companies using AI might need to undertake two conformity assessments illustrating the same thing, expending unnecessary time – although this is currently under discussion. Regulation will also add costs to life sciences businesses using AI, which could arguably deter investment in the technology. For the sake of quality control and ensuring companies know where they stand, the regulation is a big step in the right direction – but we must hope that it does not stifle innovation. Trying to regulate such a rapidly evolving technology is always going to be difficult – which is why policymakers must collaborate with industry to resolve these teething issues and ensure the regulatory frameworks encourage the use of AI. This technology has the capability to vastly change the life sciences industry as we know it and provide solutions to society's toughest medical problems.

Real-World Data

There is also massive potential to leverage the power of real-world data (RWD) in clinical trials, however this is not an easy task. Using RWD alongside clinical data requires a strong technology platform that can process the data and deliver it in a way that can have a meaningful impact. But in principle, global regulators seem to be supportive of this approach and are implementing frameworks to support the use of RWD in clinical trials, unlocking the potential of this groundbreaking technology.

Currently, the industry is seeing significant guidance emerge. For example, in October 2022 the FDA launched the Advancing Real-World Evidence Program, facilitating agency advice before protocol development and study initiation. Similarly, the European Medicines Agency (EMA) and the European Medicines Network are in the process of establishing a Data Analysis and Real World Interrogation Network, known as Darwin EU. The project supports regulation by looking to deliver real-world evidence from across Europe on diseases, populations and medicines. It is again through support from regulatory authorities that the industry can properly harness this technology; regulation and policy within the EU and US appear to be catching up with developments in the field.

Patient Engagement and Diversity and Inclusion

Diversity and Inclusion (D&I) are at last being meaningfully considered in pharmaceutical regulation in the US and EU, with the FDA Reauthorization Act of 2017 requiring companies to have D&I plans for the development of their drugs and medical devices. The EMA is also placing increased emphasis on diversity. D&I is a cornerstone of patient engagement that will enrich the quality of data and research available. Looking forward, it is a matter that is likely to be further prioritised.

The revamped ICH guidance also points to patient engagement more widely and the importance of ensuring participants have positive views of their clinical trial experiences. The UK's Medicines and Healthcare Products Regulatory Authority (MHRA) Patient Engagement Programme also underscores it. An important part of this is making sure that patients are engaged throughout the life cycle of a trial, from the planning phase until beyond the readout, meaning they feel involved and as though their participation made a real difference. Patient engagement can also be enhanced with the power of DCTs, which is especially helpful when attempting to access patients in traditionally hard-to-get geographies or in rare diseases where patients are disparate. While some of these aspects are not covered by regulation, we are seeing increased guidance from regulatory authorities as they appear to be increasingly recognising the need to engage with patients during clinical trials.

Looking Forward, What Needs to Change?

The continued digitisation of clinical trials is inevitable and regulation and policy must continue to evolve and keep pace to reflect this. Looking forward, training the next generation and upskilling the population is a must. As we become increasingly reliant on this technology we must ensure we have skilled data scientists who understand the algorithms and regulators who are willing to embrace change and evolve regulatory frameworks.

The speed at which technology advances will always outpace regulatory change, but while there will always be an element of playing catch up, the key is ensuring that this gap is not too wide. If regulators can continue to modernise and become more nimble, they will play a crucial role in guiding the pharmaceutical industry towards fully harnessing digitalisation.

Author bio

For the past 20 years, ***Fiona Maini*** *has been providing advisory services consulting within the pharmaceutical arena and mobile health technologies for clinical trials. Currently principal for Global Compliance and Strategy at* ***Medidata,*** *she is active in the EU Artificial Intelligence Alliance and ACRO Working Party on Virtual Trials.*

Could climate change along with pandemics equal a recipe for disaster?

Betsy Goodfellow from *Pharmafocus* considers the effects of climate change and how this could impact future pandemics

With the World Health Organization (WHO) officially declaring that COVID-19 is no longer a public health emergency on 5 May 2023, many would consider this a time of relief and celebration – however, some experts believe that the world is not in as strong a position as we may like to believe.[1] Although it is positive news that the COVID-19 pandemic is no longer considered an emergency, a threat remains from both COVID-19 and other pandemics and viruses that may emerge.

The WHO's emergencies director, Michael Ryan, commented: "The battle is not over. We still have weaknesses... [that] ...will be exposed by this virus or another virus."[2]

Even more concerning is the fact that the Earth's changing climate may make new pandemics a bigger and more immediate threat. Since the 1800s the Earth has warmed by 1.1°C, meaning it is unlikely that we will meet the Paris Agreement target to keep global temperature from exceeding 1.5°C above pre-industrial levels.[3] This target was set as an upper limit to avoid the worst impacts of climate change.[3]

One of these impacts would be a negative effect on health, especially regarding infectious diseases. Climate change has already had an impact in this area, making it easier for some infectious diseases to spread, including Lyme disease, waterborne diseases such as typhoid fever or cholera and mosquito-borne diseases like malaria and dengue fever.[4]

There is also a connection between rising levels of infectious diseases and climate change through habitat loss. The agriculture industry requires vast amounts of land to grow crops and raise livestock, which decreases the available areas for animal habitats and also means fewer food sources, causing animals to migrate to areas already occupied by humans.[4]

Many diseases are transferred zoonotically (from animals to humans) through both wild and domesticated animals that can host harmful pathogens.[4] Living in such close proximity to each other and other species provides an easy breeding ground for countless infectious diseases.[4]

This becomes especially problematic due to the frequency and accessibility of long-distance travel, allowing what may have once been a localised outbreak to become a major health emergency like the COVID-19 pandemic.

Air pollution is another major contributor to climate change that has a detrimental impact on health. According to the WHO, there is significant evidence that indicates a strong link between breathing polluted air and poor respiratory and cardiovascular health. There is also some evidence that breathing poor quality air can lead to a myriad of health conditions including cognitive development, mental health issues, adverse pregnancy outcomes, pneumonia and COVID-19.[5] It is well known that people with respiratory and cardiovascular health conditions, among others, are more vulnerable to COVID-19, including those with long-term lung or heart conditions.[6]

Climate change not only raises the risk of another – potentially worse – pandemic, but also increasing the number of people who would be at a heightened risk from another respiratory virus if the next pandemic were to take a similar form to COVID-19.

What can be done to prevent the impact of climate change from triggering or worsening future pandemics?

and improving air quality, which in turn improves health, among other goals.[8] This report acknowledges that the impacts of climate change have become 'increasingly dangerous [for] nature and people in every region of the world'.[8]

Climate change is recognised as having a significant impact on human health and, if left unmanaged, will trigger further pandemics that potentially could have a more devastating impact than the COVID-19 pandemic. However, there are some simple steps individuals can take to reduce their impact while also campaigning for wider change from government.

The UN recommends ten steps individuals can take to limit their impact on climate change:[7]

1. Saving energy at home by lowering heating and cooling systems, switching to LED light bulbs and energy efficient devices, washing laundry in cold water and hanging it up to dry instead of using a tumble dryer. It also suggests investing in your home's energy efficiency[7]
2. Walking, cycling or taking public transport instead of driving to reduce your greenhouse gas (GHG) emissions[7]
3. Eating more vegetables and plant-based foods, and less meat and dairy – this can significantly lower GHG emissions and requires less energy, land and water[7]
4. Considering travel choices carefully, by taking fewer flights, meeting virtually or avoiding long-distance trips[7]
5. Being conscious of food waste, as this also wastes the resources and energy used to produce it. Reducing food waste also reduces the impacts of methane emissions from rotting food[7]
6. Reducing, reusing, repairing and recycling wherever you can, from electronics to clothes[7]
7. Changing energy sources to renewable where possible[7]
8. Switching to electric when to buying a car[7]
9. Choosing to support companies that are eco-conscious and spending money responsibly with these companies[7]
10. Speaking up and encourage others to take action.[7]

No one individual can stop climate change and its subsequent health risks, but following this advice will make a difference. Major change is needed on an international level to combat this, and the Intergovernmental Panel on Climate Change (IPCC) has recently released a report outlining the steps it plans to take.[8] These steps include prioritising 'climate resilient development', which includes ensuring access to clean energy and technology

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Move of the month

Alex C Sapir appointed as Fulcrum Therapeutics' CEO

Clinical stage biopharmaceutical company, Fulcrum Therapeutics, has announced the appointment of Alex C Sapir as chief executive officer and president effective, 1 July 2023. Sapir will also join the company's board of directors, alongside Robert Gould PhD, Fulcrum's interim CEO who will continue to serve on the board following the transition.

Previously Sapir worked as a part-time special advisor to the interim president and CEO at Fulcrum. He has over two decades of industry experience and has recently served as CEO of ReViral Ltd, which was acquired by Pfizer in 2022.

Dr Gould commented: "We are delighted to welcome Alex as our new CEO. Alex brings a wealth of experience leading innovative companies through periods of strategic change, and a strong track record of delivering growth and enhanced value to patients, employees and stockholders. We have great confidence in his ability to shepherd our company through the next phase of our journey."

Speaking on his new role, Sapir added: "I am both honoured and excited to lead Fulcrum at this pivotal stage. Fulcrum's progress to date is a testament to what can be achieved when a commitment to patients and visionary science come together. I look forward to building on this strong foundation as we work to advance and expand our pipeline to deliver on its unique promise for patients."

Ishwaria Subbiah appointed as SCRI's executive director for Cancer Care Equity and Professional Wellness

Oncology research organisation, Sarah Cannon Research Institute (SCRI) has announced that Ishwaria Subbiah MD MS, has been appointed to the role of executive director of Cancer Care Equity and Professional Wellness.

In her new role, Subbiah will focus on the reduction of cancer outcomes disparities and the diversification of clinical trial participation within SCRI's combined research network, which comprises over 1,300 physicians in more than 250 locations across the US.

Howard A Burris III MD, president of SCRI, commented: "Participating in a clinical trial is the first step in fighting cancer, and we must ensure that more patients – especially underserved populations – can access these treatment options. With Ishwaria's leadership, we can implement strategies to reduce barriers while accelerating drug development and improving patient outcomes."

Commenting on her new role, Dr Subbiah said: "Broadening access to high-quality cancer care and cutting-edge cancer therapies on clinical trials is possible by bringing all stakeholders to the same table and enacting changes together. With SCRI's national reach, we have the ability to develop transformational approaches to diversify clinical trial recruitment and reduce care disparities at an unprecedented scale. At the same time, we have an opportunity to also focus on workplace experiences for thousands of clinicians engaged in research across SCRI's network. By strengthening our workforce, we can strengthen the fight against cancer for every individual we treat."

LEON appoints Dr Setu Kasera as CSO

Leon-nanodrugs GmbH (LEON) has announced the appointment of Dr Setu Kasera as its new chief scientific officer (CSO) effective 15 June 2023.

Previously, Kasera has acted as LEON's head of Science and Engineering; having held this role since October 2022 she has worked to increase the development of the company's devices and put its proprietary technology to practice. Kasera has vast expertise in nanotechnology from her R&D work at the University of Cambridge where she received her MPhil and PhD, as well as independent research projects, alongside experience within the pharma industry and chemistry, manufacturing and controls (CMC).

Kasera succeeds Dr Frank Stieneker, who will continue to support LEON as an exclusive advisor.

Dr Robert Becker, chairman of the LEON Supervisory Board, commented: "Setu has hands-on experience in nanotechnology, and has already taken a leading role in bringing our technology to application. As CSO, Setu will continue the development of LEON's devices to completion and tailor the product offering to LEON's target groups. I also express my sincere gratitude to Frank Stieneker, who has been a vital driver in the development of LEON's ingenious reactor technology and who has significantly contributed to LEON's strategic outline. We are very pleased that we will continue to work with him and can count on his expertise and support in his new advisory role."

Stieneker added: "Conceiving LEON's technology and, together with the team, putting theory to practice by realizing the FR-JET reactor, which now serves as a core piece of LEON's manufacturing devices, was a truly rewarding experience. As I will continue to advise and support LEON in the future, I look forward to seeing the potential of LEON's devices unfold and revolutionise the manufacturing of nanomedicines and ultimately, enhance access for patients."

Commenting on her new role, Kasera said: "Managing the implementation of the FR-JET technology and seeing its performance first-hand, I can only underline that LEON's encapsulation devices are certain to cause a disruptive impact in the R&D and GMP-manufacturing of nanomedicines. I take great pleasure in continuing to direct the development of LEON's devices and in facilitating the adaptation of this advanced technology to the processes of our business partners and clients, finally accelerating the timeline from drug development to patient."

Patrick Johnson appointed to Aviceda Therapeutics' board of directors

Private clinical-stage biotech, Aviceda Therapeutics has announced that it has appointed Patrick Johnson to its board of directors.

Johnson has vast experience of business leadership with entrepreneurial expertise, and has seen various pharmaceutical and biotechnology companies maximise the value of their brands and realise the potential of their innovations. His experience spans various areas of corporate operations, including global M&A, business development, strategic transactions, fundraising, clinical operations, scientific research and corporate finance.

Mohamed A Genead MD CEO and president of Aviceda Therapeutics, commented: "We are thrilled to welcome Patrick to Aviceda's board of directors as we advance our pipeline through key milestones in 2023 and beyond. Patrick will bring significant industry expertise, and his strategic counsel will be invaluable to Aviceda as we continue to advance our technology platform in late-stage clinical development for patients with geographic atrophy (GA) due to age-related macular degeneration and broader therapeutic applications."

Johnson added: "It is a privilege to join Aviceda's board as the organisation advances towards delivering new treatment options for people living with retinal diseases, many of whom have been significantly underserved for decades. I look forward to working alongside this dynamic team and advancing a diverse pipeline through development and into commercialisation."

Five facts about climate change and health

1. There are three main ways in which global warming affects human health:
   a) Extreme weather, such as heatwaves, flooding, wildfires, storms and drought, can impact physical and mental health – for example through physical injuries and trauma. Events such as these are expected to increase in number and severity in the future.
   b) The Earth's life support systems will be impacted, including rising sea levels and safe water availability, which can lead to alterations in the patterns of zoonotic and vector-borne disease (including malaria and dengue fever, among others), reduced pollination and crop failure, both of which can lead to food shortages.
   c) Some social systems can be impacted, leading to problems such as livelihood loss, rising food and fuel prices, supply chain disruption, pressure on health and care services and conflict.[1]
2. Each year environmental factors lead to 13 million deaths. This makes climate change the largest health threat facing humanity currently.[2]
3. At least 90% of people breathe air contaminated with unhealthy levels of pollution, with much of this coming from burning fossil fuels, which are a driving factor of climate change.[2]
4. The death rate from climate change is expected to increase by 250,000 additional deaths between 2030 and 2050 from malnutrition, malaria, diarrhoea and heat stress.[3]
5. The direct damage costs to health, which excludes costs in health-determining sectors including agriculture, water and sanitation, is estimated to reach $2-4bn per year by 2030.[3]

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