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Haemophilia drug costing $3.5m per dose has been approved

CSL Behring's Hemgenix has been approved by US regulators, however the drug costs $3.5m per dose

CSL Behring's haemophilia B gene therapy has recently been approved by US regulators, however the treatment has an enormous price tag. Costing $3.5m per dose, the one-off infusion therapy has become the world's most expensive medicine currently available.

CSL Behring's Hemgenix is a one-dose treatment that appeared to reduce the number of bleeding events by 54% over the course of a year. The treatment also seemed to free 94% of patients from expensive and time-consuming infusions of Factor IX, which is the current standard of care for the often fatal condition.

Pricing has long been a problem for novel medicines, with high prices for treatments such as Biogen Inc's Alzheimer's drug Aduhelm and Bluebird's Zynteglo.

Treatments for haemophilia have been developing, however therapies to prevent bleeding can often negatively impact a patient's quality of life, according to Peter Marks, at the FDA's Center for Biologics Evaluation and Research. Marks

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continues that Hemgenix signals some important progress in the development of treatments for patients with the disease. Current standard of care treatments involve infusing missing proteins, known as clotting factors, so the body can form clots and stop the bleeding. Hemgenix, however, provides a gene that can produce the missing proteins into the liver so it can make the proteins needed.

Brad Loncar, a biotechnology investor and CEO of Loncar Investments, commented: "While the price is a little higher than expected, I do think it has a chance of being successful because 1) existing drugs are also very expensive and 2) haemophilia patients constantly live in fear of bleeds. […] A gene therapy product will be appealing to some."

Future Focus

FDA grants approval to WISE for neuromonitoring cortical strip

WISE, a medical equipment manufacturer based in Italy, has obtained FDA approval for its single-use medical device WISE Cortical Strip (WCS), used for Intraoperative Neurophysiological Monitoring (IONM). WCS is designed for intraoperative use with other medical equipment for recording, monitoring and stimulating the brain's electrical signals.

Traditionally, cortical electrodes are made of stiff metal discs, with neuromonitoring and neuromodulation requiring surgical implantation of electrodes and leads into neural tissues to create stimuli or to measure electrical activity. However, WCS features stretchable platinum contacts embedded in a soft and thin film of silicone, allowing it to conform to the brain's surface. Also, its unique Supersonic Technology enables the production of electrodes using stretchable electronic circuits integrated into thin elastomeric foils.

WISE has stated that its electrodes are highly ergonomic with superior adhesion while being minimally invasive and adaptable.

The FDA validated the performance of WCS in a multicentre clinical study, which showed the product to have superior performance with electrical impedance in physiological conditions, compared to conventional electrodes. It also had better adhesion, conformability and stability on the brain surface.

WISE CEO Luca Ravagnan said: "The FDA clearance is a crucial milestone for our commercial development, allowing us to expand the distribution of the WISE Cortical Strip from Europe to the US, and fuelling the development of the WISEneuro Monitoring product family. European clinicians are already demonstrating strong appreciation for the benefits of our product, we are looking forward to starting commercialisation also in the US."

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Words from the Editor

Welcome to the December issue of Pharmafocus! As the year draws to a close, it's the perfect time to reflect on everything that has happened this year.

Since our last edition, the UK has seen the resignation of Prime Minister Liz Truss and the appointment of Rishi Sunak, and further strikes have taken place on the rail networks, postal service and by the Royal College of Nursing (RCN). In more light-hearted news, the Qatar World Cup has been in full swing, which has also brought its own controversies.

This month *Pharmafocus* brings you the latest news, including Lupin Limited's carbon-neutral inhaler (see page 11), positive results for the new Alzheimer's drug lecanemab, despite facing some criticism (see page 8) and the news that Merck has donated doses of its Ebola vaccine for testing to combat a resistant strain of the disease (see page 8).

This issue includes an article about Flanders in Belgium that highlights why so much of the vaccine industry is centred around the area, despite the challenges posed by COVID-19 and Brexit (page 13). We also have a Q&A from the Follicular Lymphoma Foundation about the future of treatments for rare blood cancer (page 16).

After the recent freezing cold weather, accompanied by some beautiful snow, we wish you a warm and happy festive season!

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Bayer and Orion Corporation-developed prostate cancer treatment approved by NHS England and MHRA

NHS England and the Medicines and Healthcare products Regulatory Agency have approved a prostate cancer treatment, developed jointly by Bayer and Orion Corporation – the first of its kind to have been made available following accelerated regulatory approval under Project Orbis.

The treatment is Nubeqa (Darolutamide) and androgen deprivation therapy (ADT) in combination with docetaxel, which will now be used to treat patients with metastatic hormone sensitive prostate cancer (mHSPC). It was originally licensed to treat patients with non-metastatic castration-resistant prostate cancer (nmCRPC) in 2020.

The approval came after data from the ARASENS phase 3 clinical trial was presented: 1,305 patients participated in the trial, and the combination treatment showed a statistically significant 32.5% reduced risk of death. The trial's secondary endpoints were time to pain progression and time to first symptomatic skeletal event.

Project Orbis is a programme to review and approve promising cancer drugs, helping patients to access treatments faster. It is coordinated by the FDA and involves, alongside the MHRA: the regulatory authorities of Australia (Therapeutic Goods Administration (TGA)); Canada (Health Canada); Singapore (Health Sciences Authority (HSA)); Switzerland (Swissmedic); and Brazil (Agência Nacional de Vigilância Sanitária (ANVISA)).

Dr Ursula McGovern, FRCP consultant medical oncologist, University College London Hospitals NHS Foundation Trust and UK chief investigator in the study, said, "Intensification of treatment was generally well tolerated, and this novel combination […] should be considered for appropriate patients with mHSPC."

CEO of Bayer UK & Ireland, Antonio Payano, said, "We are delighted that men with prostate cancer in England will have early access to another innovative treatment option. It's vital that NHS patients are able to benefit from the best standard of care and full range of emerging therapies today and in the future."

NHS nurses vote to strike on 15 and 20 December

The Royal College of Nursing (RCN) has agreed to strike on 15 and 20 December in a continuing pay dispute with the government. The RCN says it was given no choice after ministers blocked further talks about a pay rise. Emergency care will still be provided, however.

Under trade union laws, the RCN had to ensure life-saving care was provided during the strikes, meaning some urgent care services, urgent tests and scans and ongoing care for vulnerable patients were protected, alongside A&E and intensive care.

RCN general secretary Pat Cullen said, "Ministers have chosen strike action. Nursing staff have had enough of being taken for granted, enough of low pay and unsafe staffing levels, enough of not being able to give our patients the care they deserve."

The RCN asked for a 19% pay rise – 5% above the RPI inflation rate,

which currently stands at above 14%. Nurses at more that 40% of England's hospitals and mental health and community services were not entitled to strike due to a low turnout for voting. The NHS Trusts and boards that were eligible to strike, however, only found out when the official notices went out regarding whether they would see walkout on the two dates, or dates in the new year.

England's Health Secretary Steve Barclay has highlighted that the Government met the recommendations of the independent NHS Pay Review Board when they gave an estimated 4% pay award. This was followed by a 3% pay rise last year in recognition of the work done during the pandemic.

Other major health unions, including the Royal College of Midwives, GMB and Unite, have started balloting members.

Stem cell transplants could be offered to MS patients in new trial

In a world-first trial, the University of Sheffield and Sheffield Teaching Hospital NHS Foundation Trust will investigate the efficacy of stem cell transplantation compared to four drug treatments currently the standard of care for the treatment of multiple sclerosis (MS).

The trial will assess whether patients with aggressive or relapsing forms of MS could be treated with stem cell transplants as a first-line treatment, especially as patients with highly active MS often don't respond to drug treatments.

The £2.3m trial has already begun in Sheffield, and plans to eventually operate across 19 UK sites. The new treatment consists of autologous haematopoietic stem cell transplantation (AHSCT), which will be compared to four drugs: alemtuzumab, ocrelizumab, ofatumumab and cladribine. This research will build on the results of the MIST trial, which showed that stem cell transplants could reverse disability in MS patients, and that AHSCT was more effective than disease-modifying drugs, however there have been vast developments in the drugs available since the MIST trial concluded.

Basil Sharrack, lead trial neurologist, honorary professor of clinical neurology at the University of Sheffield and consultant neurologist at Sheffield Teaching Hospitals NHS Foundation Trust, commented: "Currently, there is no cure for multiple sclerosis, but huge advances have been made in recent years, with the MIST trial offering renewed hope for people living with this devastating condition. We now want to bring this research up to date, by taking into account all the latest advances in treatments."

Professor Sharrack continued: "This could also provide us with the solid evidence we need to demonstrate that AHSCT can be offered as a first-line treatment for those with the aggressive form of the condition. We are delighted to be using our internationally renowned expertise in stem cell transplantation to bring this latest research to the potential benefit of thousands of patients."

NICE recommends Cabometyx (cabozantinib) for hepatocellular carcinoma

Cabometyx (cabozantinib) has been recommended by NICE for previously treated hepatocellular carcinoma (HCC) in adult patients. The CELESTIAL phase 3 trial has shown significant improvements in progression-free survival as well as overall survival when compared with a placebo group.

Ipsen UK gratefully received this recommendation from NICE for the use of its drug to treat advanced HCC, a type of primary liver cancer, in patients who have already been treated with sorafenib, with a Child-Pugh grade A liver impairment and an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1.1. The phase 3 CELESTIAL trial had generally positive results which presumably influenced this recommendation, with the trial including a patient population who received cabozantinib in second- or third-line treatment with sorafenib.

The primary endpoint of this trial was overall survival, with the new drug providing a statistically significant improvement in this area, when compared to the placebo group. The median overall survival with cabozantinib was 10.2 months, while the placebo group only saw 8.0 months. Similarly, cabozantinib appeared to improve progression-free survival, with the median in this area being 5.2 months, while the placebo only had 1.9 months.

Vanessa Hebditch, director of communications and policy at the British Liver Trust, commented: "People living with the most common form of primary liver cancer, HCC, have a poor prognosis and there are very few treatments available. Often, the disease is diagnosed so late that palliative care is the only option. The nurses on the British Liver Trust's helpline hear every day from patients who are completely devastated. They live with uncertainty, hopelessness, and often stigma and isolation due to the image of liver cancer. Treatments that buy extra time can not only positively impact those individuals but can also have a huge positive impact on families and the wider community, so today's recommendation is an important step forward in the treatment of HCC."

Professor Tim Meyer, professor of experimental cancer medicine at UCL Cancer Institute and honorary consultant in medical oncology at the Royal Free Hospital, added: "HCC is the third leading cause of cancer death worldwide and has one of the lowest five-year survivals of all cancers. For patients with advanced disease, treatment options remain limited, and outcomes are poor. Today's recommendation by NICE will make cabozantinib available to such patients and provides an important addition to the therapeutic landscape for HCC. Cabozantinib has been proven to improve survival, slow disease progression and delay deterioration in symptoms when used as a second- or third-line treatment, and the decision to allow its use will be welcomed by doctors treating this challenging disease."

Oxford-AstraZeneca vaccine team turns to malaria

The team behind the Oxford-AstraZeneca COVID-19 vaccine has begun working on a new vaccine to combat malaria. The vaccine, R21, is being tested for its ability to trigger an antibody response. The team has said that its jab is the 'best yet' for preventing the disease.

The Oxford-AstraZeneca team is applying for pre-qualification status for the vaccine, meaning the jab could be used in malaria outbreaks globally. 20 million doses are already stored in a refrigerated warehouse in Pune, India, awaiting the approval from WHO. If approved, it would become the second vaccine to combat malaria, with GSK's RTS,S jab being the first malaria vaccine to gain this approval.

Vaccination against malaria has been especially difficult due to the parasite's complex life cycle and the way it is able to avoid detection by the immune system.

Professor Katie Ewer, professor of vaccine immunology at the Jenner Institute, commented: "The real trick… is to make the vaccine target the parasite [early in the] life cycle, to stop people getting sick in the first place. We're blocking the parasites before there are millions circulating in the blood, or an infection takes hold in your liver."

Data from the trial looks positive so far: 450 volunteers in Burkina Faso have been dosed, showing that R21 was 77% effective against the disease in areas where malaria is seasonal. It also appears that with a booster dose a year after the initial three jabs, efficacy remained at 80%. There were no safety concerns raised around the vaccine.

Upstaza given marketing authorisation for AADC deficiency by MHRA

Aromatic L-amino acid decarboxylase (AADC) deficiency is a rare genetic disorder that is often fatal. It can cause severe disabilities and suffering for the first few months of a patient's life, and impacts all aspects of life: physical, mental and behavioural. Children with the disorder also often experience seizures, frequent vomiting, behavioural problems and difficulty sleeping.

Upstaza (eladocagene exuparvovec) has been granted authorisation by the Medicines and Healthcare Products Regulatory Agency (MHRA). It is the first and only approved disease-modifying treatment for AADC deficiency, as well as the first marketed gene therapy to be infused directly into the brain.

PTC Therapeutics' Upstaza is a one-time gene replacement therapy to treat patients aged 18 months and older with a clinical, molecular and genetically confirmed case of AADC deficiency. The gene therapy intends to correct the underlying genetic defect, through the delivery of a functioning DDC gene directly into the brain, increasing the AADC enzyme, and restoring the production of dopamine.

Stuart W Peltz, PhD, CEO of PTC Therapeutics, commented: "We are thrilled with the MHRA's rapid authorisation of Upstaza. Patients in the UK with AADC deficiency are one step closer to having access to a much-needed disease modifying therapy. This is another milestone towards our commitment to advance innovative treatments and improve outcomes for people living with rare diseases."

Kirsty Hoyle, CEO of Metabolic Support UK, added: "The approval of an AADC deficiency gene therapy in the UK will provide the opportunity to transform the prognosis for those born and living with the disease, and we are hopeful for access in the coming months. Without treatment, most children with AADC deficiency will have difficulty with their development and many of the symptoms can be distressing and life-threatening. The impact on those living with AADC and their communities is significant, with children facing frequent hospitalisations, emergency visits and requiring a multidisciplinary team of highly trained specialists."

EU approval recommended for three drugs from AstraZeneca

AstraZeneca has announced that three of its drugs have been recommended for EU approval. The three drugs are: Imfinzi, Enhertu and Lynparza, all of which can be used to treat different cancers.

Imfinzi can be used in combination with chemotherapy as an immunotherapy treatment for advanced biliary tract cancer; Enhertu can be used for patients with previously treated HER2-positive advanced gastric cancer; and Lynparza can be used in combination with abiraterone to treat metastatic castration-resistant prostate cancer.

In the PROpel phase 3 trial, Lynparza, in combination with abiraterone and prednisone or prednisolone, reduced the risk of disease progression or death by 34% in comparison with abiraterone alone. Progression-free survival was 24.8 months for Lynparza with abiraterone, compared to 16.6 months for just abiraterone.

Susan Galbraith, AstraZeneca's executive vice president of oncology R&D, said, "If approved, Lynparza in combination with abiraterone and prednisone or prednisolone will represent the first combination of a PARP inhibitor and new hormonal agent available to patients in the EU."

Results from the TOPAZ-1 phase 3 trial showed that Imfinzi alongside chemotherapy reduced the risk of death by 20% compared to chemotherapy alone. The median overall survival is reported as 12.9 months with Imfinzi, compared to 11.3 with chemotherapy alone.

Susan Galbraith commented: "If approved, Imfinzi plus chemotherapy will provide patients with advanced biliary tract cancer the first opportunity for treatment with an immunotherapy-based combination."

Finally, results from the DESTINY-Gastric02 and DESTINY-Gastric01 phase 2 trials, showed Enhertu had a confirmed objective response rate of 41.8%. The average duration of response was 8.1 months, while average overall survival was 12.2 months. The drug saw a 40% reduction in the risk of death compared to patients treated with chemotherapy alone.

Susan Galbraith added: "Gastric cancer is usually diagnosed in the advanced stage in many European countries and patients face high mortality rates. If approved, Enhertu would be the first HER2-directed medicine for patients with advanced gastric cancer in the European Union in more than a decade."

European Commission gives orphan status to selinexor to treat myelofribrosis

Karyopharm Therapeutics and the Menarini Group's Nexpovio (selinexor) has been granted orphan medicinal product designation by the European Commission (EC). The drug is intended to treat myelofibrosis (MF), a rare kind of bone marrow cancer.

MF interrupts the body's normal production of blood cells, often leading to widespread bone marrow scarring, which consequently causes severe anaemia.

Nexpovio is currently being assessed for its treatment of MF patients, specifically those who have already been treated with existing therapies and have not reacted.

The drug was given orphan drug designation by the FDA in May 2022.

Karyopharm and the Menarini Group signed an exclusive licensing agreement in December 2021, meaning Menarini will oversee the commercialisation of Nexpovio across the UK, Switzerland, European Economic Area, CIS countries, Latin America and Turkey.

Reshma Rangwala, Karyopharm's chief medical officer, said, "We are very pleased to receive orphan medicinal product designation from the EC for selinexor for the treatment of myelofibrosis. […] Building on our recent orphan drug designation from the FDA, this recognition continues to reinforce the significant unmet need for a drug with a novel mechanism of action like selinexor for this devastating disease. […] Our clinical plans remain on track, and we look forward to the continued development of selinexor in MF."

Olivia del Puerto, MD LMS, head of medical affairs oncology at Menarini, added: "Myelofibrosis is a difficult-to-treat and complex disorder of the bone marrow with limited therapeutic options and we are committed to bringing novel treatments to patients through our collaboration with Karyopharm. We are excited about the potential to bring selinexor to myelofibrosis patients in Europe, pending positive study read-outs and regulatory approval."

Molecure sees positive outcomes in clinical trials and announces financial results

Polish clinical stage biotechnology company Molecure has announced its third quarter results for the period ending 30 September 2022. Its press release also mentions its plans for its R&D day in December, and its strategies and preparations for various phase 1 and 2 clinical trials.

The report on Molecure's financial results can be accessed via its website, however Marcin Szumowski, CEO and president of the management board of Molecure, said: "We are delighted with the progress we are making on our strategic objectives, accomplished year to date. Our confidence in OATD-01's potential to be a best and first-in-class disease modifying therapy for sarcoidosis has been enhanced over the period as a result of our discussions with a group of leading global experts and clinicians in sarcoidosis. Their input has also been important to ensure the successful planning and execution of this high priority clinical programme. We are equally excited about the opportunity for OATD-02 in cancer, given this novel molecule's clearly differentiated mode of action, and remain on track to start a phase 1 study in late 2022."

Its planned R&D day in December 2022 is intended to provide updates on the development of Molecure's projects, with a focus on OATD-01 for the treatment of sarcoidosis and OATD-02 to treat cancer.

Molecure is currently preparing for its multicentre phase 2 trial for OATD-01, and hope that it will soon be able to initiate a phase 1 clinical trial for OATD-02. It is also aiming to continue to develop its mRNA platform, including collaborations with leading RNA centres.

Amoxicillin shortages and 15-hour hospital waiting times for US patients

A few weeks ago, the FDA warned of an amoxicillin shortage that may affect paediatric patients in the US; that shortage has now come to a head amid emergency room waiting times of up to 15 hours in some US hospitals. Many pharmacies across the country are also reportedly struggling to keep up with demand for the drug.

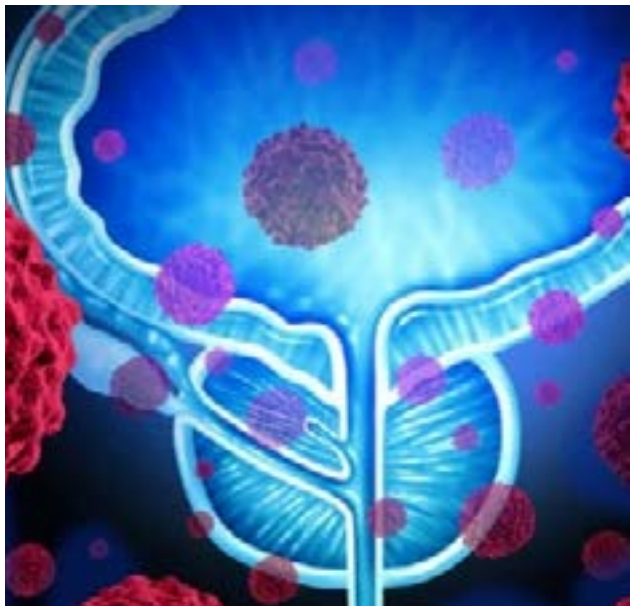
There has been a surge in demand for the common antibiotic amoxicillin, with unseasonably high figures of respiratory syncytial virus (RSV) as well as seasonal surges of strep throat, ear infections and various other respiratory illnesses. Many factors could be contributing to this higher rate of infections, though specialists suggest it may be partly down to weakened immune systems in children who have spent the majority of their lives in the COVID-19 pandemic.

These so-called 'pandemic babies' have been so protected against infection with measures such as lockdowns, social distancing and masks protecting them from COVID-19, however these measures may now have prevented their immune systems from developing as much as other children. The lifting of these measures has now led to increased rates of infections, subsequently causing the amoxicillin shortages and longer hospital waiting times.

Many large pharmacy chains, such as CVS and Walgreens, first assured customers that they would be able to keep up with the supply for amoxicillin, however many patients and their parents are now being informed that they are unable to supply the drug. It is generally the oral solution of the drug, which is usually reserved for treating paediatric patients, that is in short supply.

Sonika Patel, a pharmacist at Lo Cost Pharmacy in Savannah, Georgia has said that amoxicillin has "been on back order since October." She continued: "That's when we've been having a big uptick in bronchitis and RSV and everything. So the demand for it is so high that people aren't able to keep up with the supply." She was expecting supply to return at some point between late November and December.

AstraZeneca and MSD launch prostate cancer awareness campaign



AstraZeneca and MSD (known as Merck & Co. in the US and Canada) have announced their collaborative global prostate cancer awareness campaign. The campaign, called Never Miss, has the slogan: "Never miss a game. Never miss a goal. Never miss a chance at early diagnosis.", which aims to open up conversations about prostate cancer as well as helping men understand the risk of the disease.

With prostate cancer ranked as the second most common cancer in men globally, it is hugely significant to spread awareness. Often the disease shows no symptoms or symptoms that develop very slowly, so it is often not detected early. In 2020, there were 1.4 million new cases and 375,000 deaths globally.

The Never Miss campaign has been developed to tackle the prediction that prostate cancer mortality is likely to double in the next 20 years.

Sunil Verma, AstraZeneca's global head of oncology medical, commented: "Our top priority in breaking down barriers to prostate cancer awareness and detection is always to listen to the community affected by this disease, act on these insights and ensure the patient voice is heard."

Sophie Opdyke, Merck's senior vice president of global oncology marketing, added: "We know that when prostate cancer is detected early, the outcomes for patients may be greatly improved. Through the 'Never Miss' campaign, we hope to raise awareness of risk factors for prostate cancer, break down social barriers and empower men to take control of their health."

FDA hopes to make opioid overdose medication available without prescriptions

The FDA has announced that it is suggesting drugmakers apply for approval to make some opioid overdose medications available over the counter and without a prescription. It is currently focused on naloxone hydrochloride, which is currently a prescription-only drug, however it can be used to reverse the effects of an opioid overdose.

The opioid antagonist can reverse the impact of opioids such as fentanyl, heroin, oxycodone, codeine, morphine and hydrocodone according to the National Institute of Drugs Abuse (NIDA).
The drug attaches to opioid receptors, meaning it can block the potentially fatal symptoms of an opioid overdose, such as slowed or stopped breathing. The FDA has stated that the "prescription requirement for these naloxone products might not be necessary for the protection of the public health."

The drug is currently available in the form of an auto-injection and a nasal spray. The FDA is suggesting that a nasal spray containing up to 4mg or an auto injection containing up to 2mg could be approved for non-prescription use, however they would need more information before coming to a final decision.

Robert M Califf, FDA commissioner, said, "Today's action supports our efforts to combat the opioid overdose crisis by helping expand access to naloxone." He continued to explain that the FDA hopes to keep preventing and reducing substance abuse as a priority in the future. According to a report by the Department of Health and Human Services (HSS), upwards of 760,000 people have died from drug overdose since 1999, and two in every three overdose deaths in 2018 were due to opioids.

Merck donates Ebola vaccines for testing on resistant strain

Merck has donated its Ebola vaccine to an international immunisation group to be part of a trial, which will test three vaccines against a new and vaccine-resistant strain of the virus that is now spreading in Uganda.

The trial will test Merck's vaccine, now licensed to the International AIDS Vaccine Initiative (IAVI) in New York, as well as vaccines developed by the University of Oxford's Jenner Institute and the Washington-based Sabin Vaccine Institute. The trial runs in collaboration with Uganda's Ministry of Health.

Merck has donated enough vaccine ingredient for 100,000 doses, and it is expected that 75,000 doses will be made available to WHO, with the aim that the vaccine arrived in Uganda by the beginning of December.

Mark Feinberg, IAVI's CEO said that "the availability of the Merck doses has allowed us to significantly accelerate our programme."

The trial aims to begin controlling the outbreak in Uganda, or at least take a step towards achieving this goal. The current outbreak appears to be primarily comprised of the Sudan strain of the virus, which the current authorised vaccines do not protect against. The outbreak has so far led to at least 141 infections, 55 of which were fatal, so WHO and vaccine makers are eager to find an efficient vaccine to protect against the strain.

New Alzheimer's drug, lecanemab, slows disease but divides opinions

Japanese drugmaker Eisai and its US partner Biogen have announced that their new drug to treat Alzheimer's disease appeared to slow disease progression, however it has recently divided opinions. Lecanemab appeared to slow the disease's worsening, however following the deaths of two patients in clinical trials, some are more sceptical about the ongoing impact of the drug.

Throughout the clinical trials, patients were given an intravenous dose of lecanemab or a placebo infusion: those treated with lecanemab appeared to decline more slowly. The drug delayed patients' worsening by around five months, and the patients treated with the drug were 31% less likely to progress to the next stage of disease.

Dr Ron Petersen, Alzheimer's expert at the Mayo Clinic, thought that the drug's impact was "a modest one but I think it's clinically meaningful," as even a few months' delay in disease progression is a positive for individual patients.

However, Dr Madhav Thambisetty from the National Institute on Aging, said, "It is unlikely that the small difference reported in this trial will be noticeable by individual patients."

Side effects from the drug have included swelling and bleeding of the brain. Most cases were mild or asymptomatic, however two patients have died since joining the trial, due to brain haemorrhaging. Eisai has denied that the deaths are attributable to lecanemab.

Maria Carrillo, chief science officer for the Alzheimer's Association commented: "We all understand that this is not a cure and we're all trying to really grasp what it means to slow Alzheimer's because this is a first."

She continued, explaining that a delay in cognitive decline early on could be meaningful for "how much time we have with our loved ones in a stage of disease where we can still enjoy family and outings, vacations, bucket lists."

Pulmonx secures Japanese approval for Zephyr Valve for COPD/emphysema

Pulmonx, a US-based medical technology company, has secured approval from the Japanese Ministry of Health, Labour and Welfare (MHLW) for its Zephyr Endobronchial Valve, used to treat patients with severe chronic obstructive pulmonary disease (COPD) or emphysema.

The approval follows a positive recommendation from Japan's Pharmaceuticals and Medical Devices Agency (PMDA), which was given after the review of clinical results from the LIBERATE – patients with heterogenous emphysema distribution – and IMPACT-patients with homogenous emphysema distribution – studies. Both demonstrated that Zephyr Valves improved lung function, exercise capacity and the quality of life for patients.

Designed to be minimally invasive, the one-way Zephyr Valves are put into a lung lobe during a bronchoscopic surgery (without incision) to occlude the unhealthy lobe and lessen hyperinflation. This releases pressure on the diaphragm, which enables healthier sections on the lung to expand and work more efficiently.

Pulmonx president and CEO Glendon French said, "We are excited about this approval and the opportunity to enable the Japanese medical community to bring a much-needed treatment option to patients with severe COPD/emphysema. Japan is the second largest healthcare market in the world and represents a valuable opportunity to bring our innovative treatment to a large group of patients who have had few options once medical management alone fails to control their disease."

Amgen's obesity drug appears promising with few side effects

Amgen Inc's new obesity drug has appeared promising in its small phase 1 trial, meaning it will be able to go ahead with a larger mid-stage trial in 2023. The trial demonstrated that patients were able to maintain their weight loss for 70 days following the highest dose of the drug, known as AMG133.

Amgen has announced that the highest monthly dose of AMG133 resulted in a mean weight loss of 14.5% after 12 weeks, however the patients' average maintained weight loss fell to 11.2% after 150 days.

Side effects were generally mild and quickly resolved, however they included nausea and vomiting, according to Amgen.

The US CDC has estimated that 40% of the US population is obese, costing up to $173bn each year, so a new and promising obesity treatment is a hugely positive step. This is especially significant considering that obesity is a known cause of type 2 diabetes, as well as being linked to heart disease, some cancers and more severe COVID-19.

Like many previous obesity drugs, Amgen's AMG133 targets GLP-1, a hormone that causes the feeling of fullness following eating, however AMG133 also attempts to halt activity of the gene GIP, which reduces the rate at which stomach acid is secreted and slows the rate at which food travels from the stomach.

If the trials continue to go as planned, it is expected that a phase 3 trial could begin in 2024, with the drug potentially launching in 2026 or 2027, if it is ultimately approved.

Saptarsi Haldar, head of cardiovascular metabolic discovery at Amgen, explained that the drug's development identified genetic signals associated with lower levels of fat, lower body weight and healthy metabolic profiles, adding: "Genetics clearly showed in multiple large populations that decreased activity genetically of the GIP receptor gene was associated with lower body mass index (BMI)."

Collaboration between BioNTech and Ryvu Therapeutics to develop and commercialise immuno-modulatory small molecule candidates

Ryvu Therapeutics, a clinical-stage oncology therapeutics development company, has announced a collaboration with BioNTech, which will consist of two parts: multi-target research into several small molecule immunotherapy programmes and an exclusive licence agreement for Ryvu's STING agonist portfolio as stand-alone small molecules.

Ryvu Therapeutics and BioNTech will jointly begin drug discovery and research projects to develop multiple small molecule programmes directed at exclusive targets selected by BioNTech. The collaboration will primarily focus on immune modulation within oncology, with a scope for other applications in other disease areas.

BioNTech will have the option to license global development and commercialisation rights to the programmes at the development candidate stage, also giving BioNTech the exclusive global licence to develop and commercialise Ryvu's STING agonist portfolio as stand-alone small molecules, including as monotherapy and in therapeutic combinations.

Within the agreement, BioNTech will pay Ryvu Therapeutics an upfront fee of €20m in exchange for the rights listed above, and it has pledged an equity investment of a further €20m. Ryvu Therapeutics will be eligible to receive success-based development, regulatory and commercialisation milestone payments, and low, single-digit royalties on the annual net sales of any products successfully commercialised under the collaboration.

Prof Ugur Sahin, MD, chief executive officer and co-founder of BioNTech stated: "Small molecules targeting novel immune signalling pathways have a great potential to increase the efficacy of cancer immunotherapies. The collaboration with Ryvu provides us with the opportunity to complement our immunotherapy pipeline with a portfolio of potent immunomodulatory molecules."

"Ryvu is excited to bring its expertise in immuno-oncology to work with a global leader in the development of immunomodulatory targeted therapies. BioNTech's expertise in immunomodulatory mechanisms is a great match for Ryvu's platform and we fully expect to develop differentiated, therapeutically effective and safe molecules with our combined expertise," added Paweł Przewięźlikowski, chief executive officer, at Ryvu.

New insights into HIV vaccine revealed by researchers

Although researchers have previously always struggled to develop an efficient HIV vaccine, the results of a first-in-human clinical trial for a new vaccine appear promising. The new vaccine has been developed using a new design technique, which is being followed by researchers.

The research has been published in *Science*, after being undertaken by researchers at Scripps Research, IAVI, Fred Hutchinson Cancer Center (Fred Hutch), National Institutes of Health, National Institute of Allergy and Infectious Diseases (NIAID) and Vaccine Research Center (VCR). The research shows new insights into the novel vaccine strategy, including its approach to how it will produce antibodies to target various HIV variants.

The phase 1 trial, IAVI G001, assessed the safety and efficacy of the vaccine. This trial proved that the vaccine had a positive safety profile, as well as triggering the targeted response in 97% of vaccinated patients.

William Schief, PhD, co-senior author, professor and immunologist at Scripps Research and executive director of vaccine design at IAVI's Neutralizing Antibody Center, commented: "The data we are publishing in *Science* demonstrates for the first time that one can design a vaccine that elicits made-to-order antibodies in humans. We specified in advance certain molecular properties of the antibodies that we wanted to elicit, and the results of this trial show that our vaccine antigen consistently induced precisely those types of antibodies. […] We believe that this vaccine design strategy will be essential to make an HIV vaccine and may help the field create vaccines for other difficult pathogens."

Siemens Healthineers and Atrium Health team up in $140m deal

Atrium Health, a US-based non-profit health provider, has signed a partnership with Siemens Healthineers to buy $140m worth of healthcare equipment. The deal will help to improve Atrium Health's regional services, specifically in the south-eastern US.

The medical devices and equipment will include advanced imaging technology, radiation oncology and precision endovascular robotics.

The partnership is hoped to bolster Atrium Health's facilities in rural and underserved communities across North Carolina, South Carolina, Georgia and Alabama, all US, with a scope to expand if needed. Atrium Health will upgrade its healthcare infrastructure, use technologies to improve outcomes and quality, reduce healthcare costs and develop healthcare solutions.

Atrium Health president and CEO Eugene A Woods said: "This partnership between Atrium Health and Siemens Healthineers will create tremendous value for our communities and the healthcare field. Together, we will reshape the future of healthcare, invent new technologies, and grow the next generation of talented clinicians – all with a laser-like focus on equity and inclusive growth."

Siemens Healthineers recently unveiled a new mobile magnetic resonance machine, named Magnetom Viato.Mobile. Most notably, the new MRI scanner can be controlled remotely, meaning it can be used almost anywhere, with experts providing support from home.

Siemens Healthineers magnetic resonance imaging head Arthur Kaindl said: "With Magnetom Viato.Mobile, we plan to offer the most powerful innovations at 1.5 Tesla for mobile use. Installed in a trailer set up to provide greater flexibility in deploying MR imaging, the scanner can easily be taken from one place to the next or stay at the customer's site for longer use. For example, the solution can help with screening programmes in underserved regions – it's not the patient coming to the scanner, but the other way around."

AstraZeneca to acquire Neogene for up to $320m

AstraZeneca has announced that it is planning to buy Neogene for up to $320m. Biotechnology group Neogene has a focus in clinical-stage discovery and development of novel cancer therapies, and AstraZeneca plans to use this acquisition to advance its research in oncology cell therapies.

Currently, Neogene has a focus on discovering, developing and manufacturing new T cell-receptor therapies (TCR-Ts), providing novel cell therapy treatments for fighting cancer.

AstraZeneca will pay $200m immediately upon closing, with the opportunity for further payments up to $120m in both contingent milestones and non-contingent considerations. The acquisition is expected to be finalised during the first quarter of 2023, at which point Neogene will become a wholly-owned subsidiary of AstraZeneca, although it will be based in Amsterdam, the Netherlands and California, US.

Susan Galbraith, AstraZeneca's executive vice president of Oncology R&D, commented: "This acquisition represents a unique opportunity to bring innovative science and leading experts in T cell-receptor biology and cell therapy manufacturing together with our internal oncology cell therapy team, unlocking new ways to target cancer."

She continues: "Neogene's leading TCR discovery capabilities and extensive manufacturing experience complement the cell therapy capability we have built over the last three years, and allows us to accelerate the development of potentially curative cell therapies for the benefit of patients."

Full-Life Technologies to acquire Focus-X Therapeutics

Full-Life Technologies, a fully integrated global radiotherapeutics company, has announced that it has agreed to acquire US-based Focus-X Therapeutics.

Focus-X Therapeutics develops targeted radiopharmaceuticals to treat cancer, based on proprietary peptide engineering technology. This technology involves peptide radioliglands which precisely deliver alpha or beta emitters to break down cancer cell DNA. It allows for high-quality optimisation of peptide radioligland vectors for key pharmaceutical attributes such as biodistribution, binding affinity, and *in vivo* stability.

Such optimisation can present challenges to other ligand-targeting compounds such as antibodies, however the company has focused on both validated targets and new mechanisms.

Under the terms of the acquisition, Focus-X shareholders are eligible to receive an upfront payment from Full-Life, potential development, regulatory and sales-based milestones of up to $245m, and royalties on any commercial sales.

Lanny Sun, co-founder, chairman and CEO of Full-Life stated: "The Focus-X acquisition perfectly leverages Full-Life's radiotechnology and development platform by adding two development ready compounds, including a lead with initial human data, a robust pipeline and world class peptide discovery capabilities."

"Full-Life's integrated platforms will provide the manufacturing technology, logistics and clinical development expertise to accelerate development of our compounds as well as expand our discovery efforts. This world class radiopharmaceutical team has enormous potential to develop radiopharmaceutical therapeutics that impact patients worldwide," continued Fa Liu, PhD, Focus-X's co-founder and CEO.

Carbon-neutral inhaler launched for adult asthma patients in the UK

Lupin Healthcare, the UK-based subsidiary of Lupin Limited, has announced the launch of Luforbec 200/6 (beclomethasone 200mcg/ formoterol 6mcg) in the UK. The pressurised metered dose inhaler (pMDI) is approved for treating asthma in adult patients, and promises significant savings for the NHS, as well as being a carbon-neutral device.

The new inhaler is intended for the treatment of asthma in adults who have previously used an inhaled corticosteroid and long-acting beta2-agnonist (ICS/LABA). The inhaler has the same licensed indications as Fostair 200/6 pMDI and uses the same active ingredients, as well as having an extra fine formulation and similar device characteristics.

The NHS spent over £241m on Fostair 200/6 and 100/6 pMDIs in the year leading up to June 2022, and Luforbec appears to offer savings of up to 30% on this cost. This means that by prescribing Luforbec where appropriate, the NHS could save around £72m annually.

A Life Cycle Assessment (LCA) was undertaken in order to understand the carbon footprint of the new pMDI: Lupin is able to offset the carbon emissions linked to the inhaler, meaning it can be certified as carbon-neutral by Carbon Footprint Ltd.

Ben Ellis, General Manager of Lupin Healthcare UK, commented: "We are pleased to make Luforbec 200/6 pMDI available in the UK alongside the already available Luforbec 100/6 pMDI. This provides healthcare professionals with a choice of strengths to help optimally manage appropriate asthma patients, and offers the potential to deliver significant NHS savings. At Lupin we are proud that both inhalers are certified as carbon neutral; this is a positive step for Lupin on its sustainability journey."

Parthenon Therapeutics and ImaginAb announce licence and supply agreement

Parthenon Therapeutics, a precision oncology company that is focusing on inventing a novel class of anti-cancer therapies to reprogramme the tumour microenvironment (TME), is collaborating with ImaginAb Inc, a global biotechnology company developing imaging agents and radiopharmaceutical therapies (RPT) products.

The two companies have announced that they have entered into a multi-year, non-exclusive licence and supply agreement, meaning Parthenon will be able to use ImaginAb's CD8 ImmunoPET imaging technology in its phase 1 trial for its lead compound PRTH-101, which is due to start in 2023.

Laurent Audoly, CEO and co-founder of Parthenon Therapeutics, said, "Parthenon is developing an entirely new class of anti-cancer therapies that can modulate the TME in immune-excluded tumours through our proprietary approach that utilises biomarkers to match our therapeutic approaches to individual patients based on the specific characteristics of their cancer. ImaginAb's CD8 ImmunoPET technology will provide us with critical insight into the infiltration of CD8 T cells in the TME, not only for a small part of a single lesion but also for an entire tumour as well as all tumours throughout a patient's body. This approach is less invasive compared to the current biopsy-based standard of care and is consistent with the objective of generating a rich data set of biomarker endpoints leveraging orthogonal approaches in the earliest phases of our clinical trial.

"PRTH-101 targets discoidin domain receptor 1 (DDR1) to punch holes in the mechanical barrier that characterises immune-excluded tumours, thereby making them vulnerable to attack by the immune system. The CD8 ImmunoPET data will be used in our phase 1 trial to quantify the degree of immune infiltration into tumours before and after dosing, and be used to identify tumours that are 'hot', 'cold' or 'immune excluded'. This knowledge will help us design a clinical strategy to focus on those patients who will benefit the most from treatment with PRTH-101."

Eli Lilly's COVID-19 drug bebtelovimab loses FDA authorisation

The FDA has announced that Eli Lilly's COVID-19 drug bebtelovimab is not authorised for emergency use in the US, as it is not expected to neutralise the dominant Omicron BQ.1 and BQ.1.1 subvariants.

This announcement leaves Pfizer's Paxlovid, Merck's Lagevrio and Gilead Sciences' Veklury as the standard treatments for COVID-19.

Eli Lilly has halted its commercial distribution of the drug until further information is received from the FDA. The US government has also stopped the fulfilment of pending requests for the drug.

The initial authorisation for bebtelovimad was received in February 2022, after the drug had been discovered by Abcellera and commercialised by Eli Lilly.

The CDC has recently estimated that at least 57% of COVID-19 cases in the US are currently being caused by the Omicron BQ.1 and BQ.1.1 subvariants.

It is not all that unusual for COVID-19 treatments to lose their authorisation, with two monoclonal antibody combinations from Eli Lilly and Regeneron having had their authorisations halted last January, as they were 'highly unlikely' to work against Omicron.

Eli Lilly stated that both the company and the FDA "agree that it is not medically appropriate, at this time, to treat high-risk patients with mild-to-moderate COVID-19 with bebtelovimab in the US. Based on pseudovirus data, Lilly can confirm that bebtelovimab does not retain neutralisation activity against the BQ.1 and BQ.1.1 variants, most likely due to an aminoacid K444T substitution. Lilly will pause all distribution of bebtelovimab. Any unused bebtelovimab may be kept during the pause."

Eli Lilly loses billions on stock valuation after fake account verified by Twitter

Pharmaceutical giant Eli Lilly saw its stocks fall by 4.5% to 352.30 after a fake twitter account paid $8 to verify its account. The fake-but-verified account tweeted "we are excited to announce insulin is free now," leading many to question the cost of Eli Lilly's drugs and subsequently causing its valuation to fall.

Following the introduction of Elon Musk's Twitter Blue subscription option, where account owners are able to purchase a verification mark for only $8, many parody accounts have been causing chaos on the social media app. Twitter has long had a problem with sharing misinformation but this has only exacerbated the issue, with anyone able to make their tweets appear reputable at first glance.

Eli Lilly was forced to tweet a clarification from its real account, stating: "We apologize to those who have been served a misleading message from a fake Lilly account. Our official Twitter account is @LillyPad."

Various other accounts commented on the Eli Lilly situation. Bernie Sanders (@BernieSanders), stated: "Let's be clear. Eli Lilly should apologize for increasing the price of insulin by over 1,200% since 1996 to $275 while it costs less than $10 to manufacture. The inventors of insulin sold their patents in 1923 for $1 to save lives, not to make Eli Lilly's CEO obscenely rich."

Rafael Shimunov (@rafaelshimunov) then added: "We regret to inform you that we will not be giving away insulin, a publicly funded invention that was given away by its creator to be given away to people so they don't die." He followed this with a second tweet, reading: "Eli Lilly stock isn't just tanking because of a satirical Tweet on Musk's hellscape, it's tanking because millions of people are asking why we have to pay for insulin, when it was made to be free. That's why other insulin stocks are falling too. Happy Disability Awareness Month."

Elon Musk's Neuralink to conduct human trials in 2023

Neuralink owner Elon Musk announced that he has submitted paperwork to the FDA, which he hopes will allow Neuralink to undertake human trials in 2023. The company is developing brain-implant technology that aims to allow the brain to control devices through thought alone, in an attempt to treat patients with brain disorders or paralysis.

The technology has already been utilised in animal tests, with a monkey playing a game of *Pong* by just thinking about it in April 2021. More recently, though, a monkey has been shown using thought to move a cursor around a keyboard and create words: Musk has called this "telepathic typing." He continued, explaining the potential benefits of this technology so that "someone with no interface with the outside world [can] control their phone better than someone who has working hands."

There is a hope that as technology advances, there may be a version of Neuralink that will one day allow paraplegics to walk and blind patients to see, however it appears that this may be in the distant future at this stage of the device's development.

It is worth noting that other companies have also been working on similar technology, with some making significant progress.

"We want to be extremely careful and certain that it will work well before putting a device into a human, but we've submitted most of our paperwork

to the FDA and we think probably in about six months we should be able to have our first Neuralink in a human," Musk said. However, he has also stated that he would "feel comfortable" implanting the device into one of his own children if they needed, continuing: "At least in my opinion, it would not be dangerous."

Novo Nordisk's smart connected pens made compatible with Abbott's FreeStyle LibreLink app

Diabetes patients in the UK who already use Abbott's FreeStyle LibreLink app can now connect the FreeStyle Libre glucose sensing technology to Novo Nordisk's smart connected pens. This means patients can track information such as dose timings and amounts and compare the data to their individual glucose patterns.

Often diabetes patients are asked to track their insulin dose data, adding another level of context to their glucose readings for their healthcare professionals. This can be a time-consuming task when completed manually, and often leads to incomplete or inaccurate data. However, the new technology from Novo Nordisk and Abbott will allow the smart connected pens, NovoPen 6 or NovoPen Echo Plus, to link to a smartphone app, FreeStyle LibreLink, to automatically upload the data.

Su Down, nurse consultant in diabetes at Somerset Foundation Trust, said, "Individually, these two technologies provide valuable information for people managing their diabetes. Linked together however, they can provide an additional insight into the impact of both dosing and timing of injection on glucose levels. Providing people with diabetes and healthcare professionals with this insightful information offers an additional perspective, much like adding another piece to the puzzle – we see more of the overall picture, on which to base diabetes management decisions."

It is also hoped that this technology will help to tackle the NHS backlog as data suggests they may help diabetes patients to reduce their risk of hyper- or hypoglycaemic events.

Pinder Sahota, general manager at Novo Nordisk UK, commented: "People living with diabetes can make up to 180 additional health-related decisions a day compared to people without diabetes – the constant multitasking can be emotionally and physically draining. I hope that bringing glucose and insulin data together in one place will make some of these decisions a little easier, giving people living with diabetes in the UK more time and energy back for day-to-day life."

Over 90% of vaccines in UK imported from Flanders

Astrid Geeraerts, Head of Investment at Flanders Investment & Trade, explores why such a significant amount of the vaccines used in the UK comes from Flanders and what this means in the ongoing COVID-19 pandemic

As the COVID-19 pandemic slowly falls off our front pages and the industry has made the necessary changes to account for Brexit, there are some interesting lessons for everyone in the biopharmaceutical sector to learn from the vaccine, on the importance of continued collaboration and the critical role of logistics.

Between 1 April 2021 and 1 July 2022 official figures show that 151,248,820 COVID-19 vaccines were administered in the UK over three doses. In 2021, Flanders exported 115,825,505 COVID-19 vaccines to the UK, and during the first half of 2022 another 22,489,517, making a total of 138,315,022 coming from this region of Belgium or over 90% of all vaccines administered. This doesn't account for any vaccines wasted or that were then exported to other countries, but it does show the scale of the collaboration between the UK and Flanders in the pharmaceutical sector. It also shows that Brexit has not lessened the importance of that partnership.

The Belgian, and particularly Flanders, biopharma sector leads much of the EU (and the world). Per capita, Belgium invests more in R&D than any other country in the EU.

The infrastructure, logistics, specialist know-how and history of collaboration were therefore already in place pre-vaccine and the challenges of Brexit had already been managed

In 2021, Belgium:

- Invested around €14m per day in R&D
- Exported €230m in biopharmaceuticals every single day

The results are, in large part, driven by Flanders, which represents nearly 82% of all of Belgium's exports and where the export of pharma products alone reached over €58bn in 2021.

One of the challenges of Brexit was that, although the same rules apply in every EU country, there are significant differences in the way the new rules are interpreted. A single point of entry to the EU quickly became the sensible strategy to minimise bureaucracy, particularly in a sector that can be as complex as pharmaceuticals. This was just one of many reasons why Flanders became a hub for vaccines.

Brexit should have meant that the vaccines were no longer approved by the European Medicines Agency (EMA), but had to be signed off by the UK's MHRA. However, ahead of the agreement reached in December 2020, the MHRA asked for, and was granted, emergency powers to decide on vaccines without waiting for EMA. It was this that enabled the UK to approve the Pfizer vaccine ahead of the EU or other countries. The MHRA stated that it would keep adopting European authorisation decisions for another two years.

The practical impact of this decision was that EMA or MHRA approval was enough to legally supply the COVID-19 vaccine in the UK. In practice, this meant that either side of 'exit day', either EMA or MHRA approval would be enough to make it legal to supply a COVID-19 vaccine.

The next challenge for the vaccine was transportation, particularly with the vaccines that were temperature sensitive. In this, Flanders has geographical advantages and world-leading infrastructure.

The region is centrally placed in one of the world's highest concentrations of people, money and industries. Belgium is, of course, one of the closest of the EU countries to the UK, but Flanders can also boast that 60% of Europe's purchasing power is located within a 500km radius.

In terms of transport logistics, Flanders has three international seaports, three international airports, one of the world's densest road networks, and extremely well-connected railroad and inland waterway networks. The highways of Flanders link to those of France, Germany, the Netherlands and those of the UK via ferry links and the Channel Tunnel. As a result, logistics companies and distribution centres are able to transport goods from Flanders to most major European markets within 24 hours and, of course, time was of critical importance during the pandemic.

The dominance of Flanders' vaccine effort was given a significant boost by the national airport (air travel is usually the preferred option for vaccines). Besides being a hub that connects Flanders to the rest of the world (200 non-stop destinations), Brussels Airport also provides state-of-the-art infrastructure. The airport has a specialised hub for storing temperature sensitive pharma (and biotech) so they can be quickly exported globally. It was the first airport in the world to receive the CEIV (Centre of Excellence in Pharmaceutical Handling) Pharma certification.

The Airport developed the programme in collaboration with IATA (International Air Transport Association). It validated the CEIV checklist together with the pharmaceutical shippers in the BRU pharma shipper's forum. The majority of all pharmaceutical shipments handled at Brussels airport, are consequently going through a fully certified cool chain.

Flanders also has low supply chain costs, laws that encourage start-up businesses, similar corporation tax rates to the UK for SMEs and no business rates. As a result, even before the COVID-19 pandemic, global pharmaceutical companies, such as Pfizer, were already establishing bases in Flanders as the single-entry point to the EU. Over the past six years, Pfizer alone has invested over €500m into Flanders.

As a result, the infrastructure, logistics, specialist know-how and history of collaboration were therefore already in place pre-vaccine and the challenges of Brexit had already been managed. The pandemic simply provided an extreme and unexpected test.

Ken Chow, health tech counsel and science and technology officer at Flanders Investment & Trade, London, commented: "Flanders continues to place a very high value on our relationship with Britain; it remains one of the region's most important trading partners. At Flanders Investment & Trade (FIT), we have been helping numerous British pharmaceutical companies access the EU and Flanders, as well as innovative businesses in the HealthTech and MedTech space. Please do check with us before you engage expensive consultants. We may be able to give you the relevant advice at no charge, if not we can make sure that you're engaging someone reputable at a competitive price."

References:
1. *Visit: coronavirus.data.gov.uk/details/vaccinations*
2. *Visit: nbb.be/en*

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The future of follicular lymphoma treatment

Dr Mitchell Smith, Chief Medical Officer, and Dr Julie Dodds, Clinical Operations Lead, at the Follicular Lymphoma Foundation tell Pharmafocus about new research being conducted into rare blood cancer follicular lymphoma and their new research grant programme

***Pharmafocus*: Can you explain the main symptoms of follicular lymphoma (FL) and tell us about the current standard of care for patients with FL?**

Follicular Lymphoma Foundation: For most patients, FL is slow developing which means that it can take a long time for symptoms to appear. Typically, a person presents because of unexplained persistent swelling in the neck, armpit or groin; associated symptoms may be significant weight loss, fevers and drenching night sweats. The current standard of care can be observation without treatment if there are no symptoms, or, if treatment is indicated, a combination of a chemotherapy drug and a monoclonal antibody.

What is different about FL that makes it harder to treat than other blood cancers?

FL presents a paradox in that the treatment shrinks the disease in most patients but does not cure it. So, most FL patients have the disease go into remission but then have anxiety waiting for it to return. If the disease comes back within two years, then the outcome is worse.

What are the FLF's main goals for the next three years of research?

The aim of all our research programmes is to accelerate a transformative change in scientific research that will lead to better treatments and cures for FL patients. We are rolling out our first three programmes and are looking forward to reporting on rapid progress. This includes the CURE FL Awards grants programme described in detail below and the Centres of Excellence programme, which will focus on building strategic partnerships with expert academic institutions that will use innovative approaches to advance knowledge and treatments for FL, aligned with the FLF mission to find a cure – and fast. Finally, our Precision Medicine Programme, which has the goal of improving treatment strategies and speeding up the development of new treatments, and ultimately a cure for every patient.

What is the FLF hoping to achieve with the new funding grant?

For many people that suffer from FL, there are periods of remission into relapse and back again. Through the CURE FL Awards, we are funding investigation into areas we have identified, through a rigorous review process, as the most promising areas of research in order to understand the biology of FL and find a cure. Each of the new grants is designed to lead to a clinical trial within, or soon after, the two-year grant period. Advances in research give us hope that curative therapies can be developed in the near future. Our goal is to make this happen as soon as possible.

Which areas of FL research do you think are most promising at this stage?

An extensive review of the FL research landscape identified two areas as the most likely to lead to curative therapies and be available to FL patients as soon as possible:

- Cellular immunotherapy (CAR-T and others): Immunotherapy is believed to hold great promise for a curative effect. Immunotherapy treatments take advantage of the body's natural defences to fight cancer
- Targeted therapies (stand-alone or in combination with other treatments): Targeted therapies are cancer treatments that use drugs to target specific genes and proteins that are involved in the growth and survival of cancer cells.

These therapies have been the focus of the CURE FL Awards research grants programme.

What are the current unmet needs in FL treatment?

There are multiple unmet needs in FL: first, FL is a highly variable disease. It seems there are a series of genetic steps in the development of FL, and they may be different in different patients. So, we may need to tailor the treatment to the individual patient based on the steps that happened in their FL. To do this, we need to identify biomarkers specific to FL that could be targeted for treatment. Second, FL can change or transform to a fast-growing form, a serious problem that requires more intense treatment. We need a way to predict when this will happen, both so we can treat it earlier but also if we understood why transformation occurred, we could find better treatments. There are several effective, non-curative treatments for FL, but an unmet need is the ability to select the right treatment at the right time. Of course, new curative treatments are also needed.

How will this research help to improve the current standard of care and will it help to fulfil the unmet needs?

Many years of clinical trials of different chemotherapies failed to show much benefit. The addition of B cell-directed monoclonal antibodies, e.g., rituximab, were a major advance 25 years ago. Recent findings have generated excitement about immunotherapy, using the T cells of the immune system to attack lymphoma. The research being funded by CURE FL takes various approaches in search of ways to make immunotherapy

work better, perhaps even achieving cures. For patients who relapse early or transform and have worse outcomes despite more treatments, such therapy may be life-saving. For patients with more indolent FL, these treatments may allow them to avoid multiple courses of therapy and cumulative side effects.

What was it about these winners that made them stand out from the other entrants?

We were attracted by the fact that each project aims to develop a novel or combination therapy involving immunotherapy and targeted therapy, and will also have a clinical trial available or in late-stage planning by the end of the funding period. We hope our leading investigative teams will make strong progress and move quickly towards trials, enabling successful outcomes to be available to patients as soon as possible.

Can you explain the focus of the research that the four grant winners are planning to undertake?

The cellular immune therapy furthest along in the clinic is Chimeric antigen receptor modified T cells (CAR-T). CAR-T are a patient's own T cells engineered to attack a target, and currently available CAR-T attack a protein on all B cells, including FL. One CURE FL project will design and test CAR-T cells that attack an FL specific pathway they have identified as important for FL survival. Another will develop CAR-T that attacks not only B cells but also the surrounding microenvironment important for FL cell survival. The other two projects examine why some FL cells are not killed by CAR-T and look for ways then to make FL cells more sensitive to immune attack.

Are you hopeful that progress is being made in the search to find a cure for FL?

There is great excitement about new types of treatments approved since 2020: these include CAR-T cells, antibodies that activate the immune system and molecularly targeted drugs. We need to keep up the momentum, and it takes time, effort and funding to accelerate the pace of discovery and to focus these advances on FL.

With the right resources and the right people in our corner, plus the best and most advanced research programmes, we believe we will find a cure – and fast. Our aim is that by the 100th anniversary of the first diagnosis of FL (back in 1925) we will be on the path to a cure – better and less toxic and debilitating treatments, as well as improving the personal journey of every patient.

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Thank you so much again for organizing this great event with wonderful presentations and controversial discussions. It was a very good mix of participants and knowledge, each and every one an expert in their industry. Very well done, love to join again!

Miriam Götz, Product Manager Life Sciences & Healthcare Compliance, DHL Global Forwarding

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Move of the month

Amarin appoints Scott Curley as General Manager to UK and Ireland team

Following a positive NICE recommendation for VAZKEPA® (icosapent ethyl), which has allowed Amarin to continue with its commercial expansion, Amarin has appointed **Scott Curley** as general manager of its UK and Ireland team.

Curley previously worked at AstraZeneca, where he held many roles including some in leadership positions such as general manager of Hong Kong and Macau, member of the board of directors for the Hong Kong Association of the Pharmaceutical Industry, head of global and US commercial excellence, global head of commercial operations for the respiratory franchise and global medicines lead for integrated patient solution. He also previously worked at GlaxoSmithKline and SmithKlineBeecham, and brings with him a vast sum of knowledge and experience.

In his new role, Curley plans to focus on developing and growing Amarin's organisational infrastructure, ensuring the successful launch of new products, including VASKEPA.

Commenting on his new role, Curley said, "I'm really excited to join Amarin, it's a company that immediately feels different to traditional Big Pharma. My new role offers a unique opportunity to build a new UK and Ireland affiliate from the ground up. It's also rare to come to market in the CVD space immediately backed by a landmark study with NICE approval. With this, we have the potential to have a positive and lasting impact on thousands of UK and Irish patients."

He continued: "Doing all we can for patients with CVD will be our moral compass and the driving force behind our future success. For me, Amarin's CVD mission is personal as well as professional. Having lost three of my grandparents to CVD and having experienced first-hand the devastating impact it had on them and my family, I am determined to improve the lives of as many CVD patients across the UK and Ireland as we can."

Oxford Biomedica appoints Dr Frank Mathias as CEO

Dr Frank Mathias has been appointed as life sciences firm Oxford Biomedica's new CEO. Dr Mathias will take on his new role in March 2023, when he will replace Dr Roch Doliveux. The firm focuses on cell and gene therapies.

Prior to his role at Oxford Biomedica, Dr Mathias worked as CEO of Rentschler Biopharma SE from 2016. In 2019, Dr Mathias was awarded the title of 'EY Enterpreneur of the Year' in Germany. Before working at Rentschler, he was CEO of immuno-oncology company, Medigene AG, where his work focused on developing T cell-based cancer treatments.

In March 2023, Dr Roch Doliveux will step down as Interim CEO, at which point Dr Mathias will take his role, while Dr Doliveux will take the role of non-executive chair.

Dr Roch Doliveux commented on the appointment, stating: "Frank is an outstanding patient-centric leader with impressive experience from a top-end CDMO as well as from innovative biopharma companies. He has a strong track record of delivering growth and driving performance and innovation, which are core strengths required to implement our strategy of becoming an innovative global viral vector leader."

Dr Frank Mathias added: "Oxford Biomedica is a world-leader in the innovative development and manufacture of viral vectors for life-saving cell and gene therapies, demonstrated by the ever-expanding customer base of now more than 20 programmes across all vector types."

Peter Williams appointed General Manager, Incyte Biosciences UK and Ireland

Incyte has announced its appointment of **Peter Williams** as General Manager for the UK and Ireland division. His new role includes taking charge of the development of medical, regulatory and commercial strategy for the company's products in the UK and Ireland.

Williams brings 20 years of pharmaceutical experience with him, including having worked as a senior sales and marketing leader, and having held various commercial and senior management roles. He previously worked as senior director for sales and marketing at Gilead Sciences and a business unit director at AbbVie UK. He has demonstrated his industry experience through the creation and development of various business units, along with the launch of some significant medicines in immunology, oncology and haemato-oncology.

Jonathan Dickinson, executive vice president and general manager for Incyte Europe, stated: "On behalf of our leadership team, I would like to welcome Peter to Incyte. His extensive commercial experience will greatly enhance the teams in the UK and Ireland and support our continued growth."

Commenting on his appointment, Williams said, "Incyte is truly a dynamic company, founded on the premise that following the science and world-class R&D can lead to new solutions poised to positively affect patients' lives. I am very excited for the opportunity to lead the talented Incyte team here in the UK and Ireland. We have exciting new therapies in our portfolio, and an experienced, growing team, dedicated to the shared goal of ensuring patients have access to important treatments to meet serious unmet medical needs in Oncology and Dermatology."

Five facts about vaccines

1. The first vaccine was developed in 1796 by Edward Jenner and it protected against smallpox. Jenner had observed that those who had been infected with cowpox were immune to smallpox, so in May 1796 he used matter from a milkmaid's cowpox sore to inoculate an eight-year-old boy named James Phillips. Phillips reportedly felt ill for a few days but then made a complete recovery. In July, Jenner inoculated Phillips with matter from a smallpox sore and Phillips did not become ill. The term 'vaccine' therefore comes from the Latin for cow, *vacca*.


Edward Jenner

2. The first effective polio vaccine was developed between 1952 and 1955 by Jonas Salk. In 1953, Salk tested the vaccine on himself and his family and then the following year, in 1954, mass trials involving over 1.3 million children took place. In 1960, a second polio vaccine was developed by Albert Sabin – this was a live-attenuated vaccine and could be given orally, either on a sugar cube or as drops. It was first tested and produced in the Soviet Union and Eastern Europe, with Czechoslovakia becoming the first country to eradicate polio.

3. In 1998, Andrew Wakefield and a group of colleagues published a report in *The Lancet*, claiming that the measles, mumps and rubella (MMR) vaccine given to young children caused autism, despite the fact that there was, and still is, no scientific or medical evidence of this. *The Lancet* has since revoked Wakefield's paper, however many believe that his theories have added fuel to the fire of the anti-vaccination movement.

4. During the COVID-19 pandemic, vaccines were researched and developed at speeds that far exceeded recognised time frames. The first cases of COVID-19 were reported at the end of 2019, and the first doses of the first vaccine were administered only a year later in December 2020. Some of the COVID-19 vaccines utilised new mRNA technology. However, WHO has recorded that as, of July 2021, almost 85% of COVID-19 vaccines had been given in high- and upper-middle-income countries.

5. As of 2019, WHO estimated that immunisation has prevented 4-5 million deaths per year. This covers all age groups that have been protected from diseases including diphtheria, tetanus, pertussis (whooping cough), influenza and measles. However, it is also estimated that a further 1.5 million deaths could be avoided if global vaccination coverage were improved.

References
1. visit: who.int/news-room/spotlight/history-of-vaccination/a-brief-history-of-vaccination
2. visit: verywellhealth.com/who-is-andrew-wakefield-260623
3. visit: who.int/news-room/facts-in-pictures/detail/immunization

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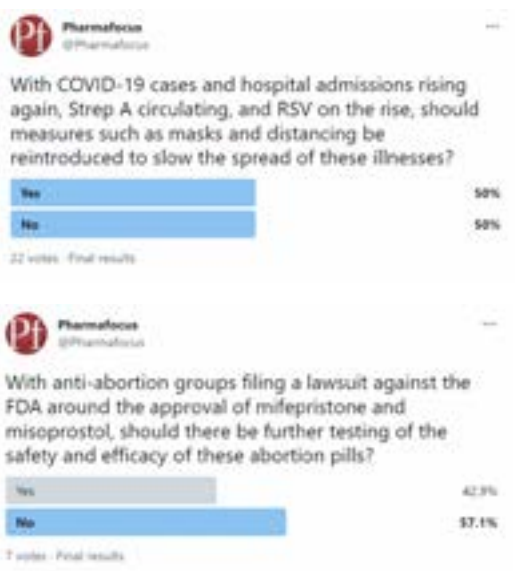

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