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FDA approves Eisai-Biogen's lecanemab for Alzheimer's disease

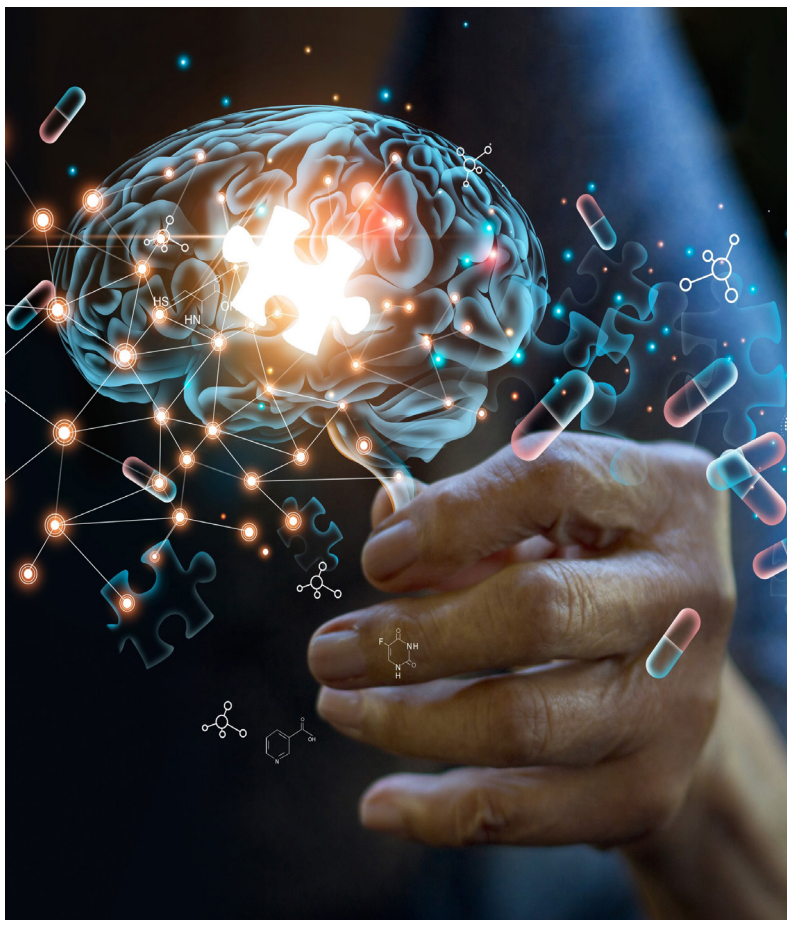
The FDA has approved new and contraversial Alzheimer's drug, lecanemab

The FDA has approved Eisai and Biogen's experimental antibody treatment lecanemab (also known as Leqembi) for the treatment of mild cognitive impairment or mild dementia in patients with Alzheimer's disease (AD).

The drug was approved under the FDA's Accelerated Approval Pathway and takes the form of a 100mg/mL intravenous injection. The approval follows positive data obtained in a phase 2 clinical trial during which lecanemab reduced plaque accumulation on the brain, which appears to be a defining feature of AD.

It is estimated that within three years, lecanemab could treat around 100,000 patients, with this figure increasing over the mid-to-long term. Eisai has already submitted a supplemental Biologics License Application (sBLA) to the FDA in order to obtain traditional approval from the FDA, as well as using data from the phase 3 confirmatory Clarity AD trial to support this application. Results from the Clarity AD trial showed lecanemab meeting the primary endpoint and all critical secondary endpoints.

Haruo Naito, Eisai's CEO, commented: "The FDA's approval of Leqembi under the Accelerated Approval pathway is an important milestone in Eisai's four decades of research in Alzheimer's disease and reflects our continued commitment to alleviating the burden of Alzheimer's disease for patients and their families. […] Eisai has made great efforts to understand the reality of the challenges and concerns facing patients and their families who are living in the various stages of Alzheimer's disease, and we are incredibly pleased to offer Leqembi as a new treatment option to help with the tremendous unmet needs of this community."



Future Focus

BioNTech and UK Government announce strategic partnership to provide mRNA cancer immunotherapies

German biotech company BioNTech and the UK Government have signed a Memorandum of Understanding (MoU), which will accelerate clinical trials of personalised mRNA immunotherapies. It is hoped this acceleration will lead to up to 10,000 patients receiving such therapies by the end of 2030.

As part of the MoU, trial site and patient recruitment for clinical candidates from BioNTech's pipeline will be accelerated, aided by the utilisation of the UK's clinical trial network, genomics and health data assets.

BioNTech also plans to invest in a UK R&D hub in Cambridge, UK, with an expected capacity of more than 70 highly skilled scientists.

The next steps in the plan include selection of candidates, trial sites and the set up of a development plan, with the aim to enrol the first cancer patient in the second half of 2023.

Ugur Sahin MD, Chief Executive Officer and Co-Founder of BioNTech stated: "The UK successfully delivered COVID-19 vaccines so quickly because the NHS, academia, the regulator and the private sector worked together in an exemplary way. This agreement is a result of the lessons learnt from the COVID-19 pandemic as we all experience that drug development can be accelerated without cutting corners if everyone works seamlessly together towards the same goal. Today's agreement shows that we are committed to do the same for cancer patients. Our goal is to accelerate the development of immunotherapies and vaccines using technologies we have been researching for over 20 years. The collaboration will cover various cancer types and infectious diseases affecting collectively hundreds of millions of people worldwide. If successful, this collaboration has the potential to improve outcomes for patients and provide early access to our suite of cancer immunotherapies as well as to innovative vaccines against infectious diseases – in the UK and worldwide."

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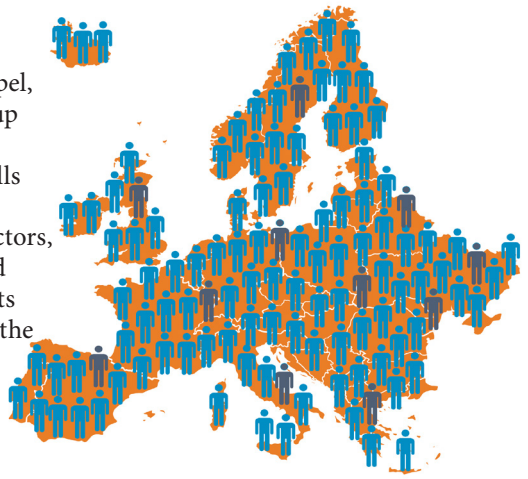
Page 13 - Prostate cancer in Europe: the time to act is now

Professor Hendrik Van Poppel, a member of the expert group for the Let's Talk Prostate Cancer (LTPC) initiative, tells Pharmafocus about its new campaign, exploring risk factors, new screening measures and what European Governments should be doing to improve the state of prostate cancer care



Top News

Comment

Welcome to the January/February issue of Pharmafocus!

As we welcome the new year, we look ahead at what 2023 will bring for the pharma industry.

Throughout the year, we will be keeping our eyes on the new drugs that are being reviewed by the FDA, EMA and other regulatory agencies, and will be reporting on the new treatments as they are approved and become available for patients.

This issue includes news stories on the pay disputes fuelling the nursing and ambulance strikes (page 5), expanded access to medication abortions (page 8), new blood tests to detect hidden cancers (page 9). It also includes news on Moderna's first acquisition (page 10), eco-friendly additions to Sanofi's manufacturing campus (page 11) and new AI devices to detect CVD (page 12).

Prostate cancer is often in the news, and in this issue we bring you an article that highlights the Let's Talk Prostate Cancer campaign. Read more on page 13 as Professor Hendrick Van Poppel talks about the new campaign and the new research grants that aim to reduce the impact of prostate cancer across Europe.

We hope you enjoy this issue.

Betsy Goodfellow

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COVID-19 antiviral treatment shown to speed up recovery in trial

Molnupiravir, made by Merck, Sharp and Dohme (MSD), has been found to reduce the recovery time of COVID-19 patients, however it did not decrease mortality rates or hospital admissions.

The trial was conducted to see whether it followed previous studies of molnupiravir, which had looked at its effectiveness at reducing hospital admissions among patients with mild-to-moderate COVID-19. However, the biggest difference was that these trials were performed on unvaccinated patients before the Omicron variant.

The drug was given to more than 25,000 high-risk patients – those at risk due to age or underlying health conditions – twice a day for five days while they had the Omicron variant. Their recovery time was measured against those who also had the infection but were just receiving standard care.

Results showed that the treatment reduced recovery time by around four days, while also reducing the viral load.

Chris Butler, who is a professor of primary care in the Nuffield Department of Primary Care Health Sciences, said, "Finding effective, safe and scalable early treatments for COVID-19 in the community is the next major frontier in our research response to the ongoing worldwide pandemic. It is in the community where treatments could have a massive reach and impact. But decisions about who to treat should always be based on evidence from rigorous clinical trials that involve people who would most likely be prescribed the drugs."

Former deputy chief medical officer for England, Prof Sir Jonathan Van-Tam, who is pro-vice-chancellor for the Faculty of Medicine and Health Sciences at the University of Nottingham and study co-author, furthered: "While molnupiravir was originally found to work well to reduce hospitalisation in patients with COVID-19, these were unvaccinated patients. This latest research has repeated the exercise in the highly vaccinated population, demonstrating that the vaccine protection is so strong that there is no obvious benefit from the drug in terms of further reducing hospitalisation and deaths. However, symptom duration and virus shedding are both markedly reduced, and we have to wait much longer to know if there will be any discernible effects on long COVID."

Eli Lilly and Sosei Heptares enter into multi-target collaboration and licence agreement for diabetes and metabolic diseases

Japan-based Sosei Heptares announced that it has joined forces with UK global biopharma company Eli Lilly to discover, develop and commercialise small molecules that modulate novel G protein-coupled receptor (GPCR) targets associated with diabetes and metabolic diseases.

Sosei Heptares will be eligible to receive $37m in upfront cash from Eli Lilly, with another $694m in further development and commercial milestone payments, plus tiered royalties.

The agreement will leverage Sosei Heptares' StaR® technology and structure-based drug design (SBDD) platform, and Eli Lilly's drug development and commercialisation and therapeutic area expertise. Sosei Heptares will focus its efforts on multiple GPCR targets nominated by Eli Lilly to deliver novel target-sensitive small molecule hit candidates.

Matt Barnes PhD Head of UK Research & Development, Sosei Heptares commented: "This new agreement with Lilly further reinforces our position as a global partner of choice for GPCR-focused drug discovery targeting major diseases where patients remain in need of new and effective therapies. We provide a highly attractive approach that is recognised by many of the world's leading biopharmaceutical companies and are delighted to add Lilly to that list. Lilly is a recognised world leader in diabetes and metabolic diseases, and we look forward to a collaboration that brings together our respective and complementary expertise with the goal of identifying and developing novel candidates to advance in these important areas of unmet need."

Ruth Gimeno PhD, Group Vice President, Diabetes and Metabolic Research, Lilly said, "Continued innovation across diabetes and metabolic diseases has been a key priority for Lilly for many years. This requires us to access cutting-edge expertise and technologies to successfully advance our mission in this area. We look forward to combining forces with Sosei Heptares and are confident that this new partnership will enable us to unlock new targets and generate novel treatments for these diseases and bring new treatments to patients."

GlaxoSmithKline enters into $3.3bn pact with Wave Life Sciences

UK-based GSK has announced a partnership with American company Wave Life Sciences, valued at up to $3.3bn. The partnership will allow GSK to use Wave's PRISM technology – an oligonucleotide platform that combines chemistry with multiple therapeutic modalities, including editing, splicing and silencing.

Oligonucleotides are short strands of DNA or RNA, which can disable disease-causing genes through different mechanisms. Notably, they can address a range of genomic targets in multiple therapeutic areas, including those diseases that are difficult to treat with small molecules or biologics.

Currently, GSK has two oligonucleotide programmes: bepirovirsen for chronic hepatitis B and GSK4532990 for non-alcoholic steatohepatitis (NASH).

Within the deal, GSK will also receive an exclusive global licence for Wave's preclinical asset WVE-006. This is an RNA editing programme that targets alpha-1 antitrypsin deficiency (AATD), a disease which impacts the lungs and liver.

GSK will pay Wave $170m upfront, of which $120m will be cash and $50m in an equity investment. Additional developmental, regulatory and commercial milestones may total up to $3.3bn.

Tony Wood, President and Chief Scientific Officer, GSK, said, "Oligonucleotide therapeutics are becoming a mainstream modality, and this collaboration will enable us to use our leading position in human genetics and genomics to advance novel oligonucleotide therapies. Pairing GSK's genetic expertise with the best-in-class PRISM platform enables us to accelerate drug discovery for newly identified targets, by matching target to modality. The addition of WVE-006 complements more advanced, clinical-phase oligonucleotides in our pipeline, including bepirovirsen for chronic hepatitis B and GSK4532990 for non-alcoholic steatohepatitis (NASH)."

"For the past decade, Wave has been building a unique oligonucleotide platform that combines novel chemistry with the means to optimally address disease biology through multiple therapeutic modalities. In 2022, we started to deliver on the promise of our platform with the first data showing translation in the clinic for our next-generation stereopure PN-chemistry containing candidates. Now with our GSK collaboration, we are excited to leverage their expertise in genetics to continue building a differentiated oligonucleotide pipeline, with a focus on our best-in-class RNA editing and upregulation capability. Additionally, GSK is the ideal partner for our WVE-006 programme, due to their long-standing history and global reach in respiratory diseases. The collaboration meaningfully extends our cash runway into 2025 and offers the potential for significant future milestones, providing new resources to deliver life-changing medicines to patients," stated Paul Bolno, MD, MBA, president and chief executive officer, Wave Life Sciences.

GSK chooses London's West End for new headquarters

GlaxoSmithKline has chosen to establish its new headquarters in London's West End, on the corner of New Oxford Street and Earnshaw Street in the Capital's centre. The new hub is expected to open in 2024.

The building is currently still under construction but it is scheduled to be completed next year. The new headquarters marks part of GSK's plans to locate itself within 'London's Knowledge Quarter', an area filled with universities, such as University College London, and other scientific and research organisations.

GSK's new HQ will have space for approximately 3,000 staff, and marks something of a homecoming for the company, which was established as Plough Court Pharmacy in the City of London in 1715. The company moves to its new West End home from its old offices in Brentford, West London. The company's plans to move its offices followed its split from consumer healthcare business Haleon, which took place in the summer.

Haleon, GSK's previous partner, is also constructing a new head office for £120m. Its office will be based in Weybridge. Following their split, Haleon's shares gained 1% while GSK's fell 0.9%.

Emma Walmsley, GSK's chief executive officer and board director, commented: "As a global biopharma company, we are proud to call London our home and look forward to the opportunities for even closer collaboration with the city's world-class science, academic and healthcare institutions."

LumiraDx receives $14m in funding for point-of-care TB test

UK-based point-of-care diagnostics company LumiraDx has been given $14m in grants from the Bill & Melinda Gates Foundation to support the ongoing development of its point-of-care molecular tuberculosis (TB) test system.

According to WHO's 2022 Global Tuberculosis Report, the gap between TB infection and its diagnosis widened in 2020 and 2021, compared to 2019. LumiraDx says that its test is designed to bridge this gap by fulfilling requirements in the TB testing market and increasing access to testing. It's developing the test to include a tongue swab sample, which makes the test inexpensive and easier to do.

LumiraDx is designing the molecular TB test for use with its LumiraDx multi-assay Platform, which will provide accurate results at a low price. The company states that its Platform is the only point-of-care instrument that supports both molecular and immunoassay technologies and runs various sample types.

As the LumiraDx Platform weighs only 1.1kg and has a rechargeable battery, it is portable and allows the TB test to be used in countries with limited access to laboratories. The company has already started preclinical studies of the TB molecular test in Africa.

LumiraDx CEO Ron Zwanziger said, "The advancement of our TB molecular test signifies an important step forward in LumiraDx's mission to increase access to accurate and affordable testing worldwide as well as an important step forward in our molecular testing technology.

The support from the Gates Foundation is critical in our development of the TB test and ensuring it reaches communities where access to testing is most challenged. The availability of these immediate results can be game-changing."

Unison boss states Government "adamantly refused" to engage in a "proper discussion" on pay ahead of December's ambulance strikes

Unison general secretary Christina McAnea said that the ongoing ambulance strikes will continue to go ahead without a "very firm commitment" on pay, as the Government has "adamantly refused" to engage in a "proper discussion" about pay rises.

Around 10,000 ambulance staff in England and Wales were on strike on several days throughout December. This follows multiple nurses' strikes, which led to thousands of rescheduled appointments and surgeries.

Health Secretary Steve Barclay has voiced his concerns about the strikes, stating that there was a lack of clarity when it came to what services were still being offered during the ambulance strike, and that the unions had to ensure they "met their obligations" for emergency cover.

Under trade union laws, life-preserving care must be provided during the strikes. To ensure this, unions have said that discussions are still taking place with ambulance Trusts to draw up detailed plans for cover. However, the Government called in the armed forces to help, with 750 military staff using civilian ambulances, 600 drivers and 150 support staff.

The nurses' strike saw around 10,000 staff absent while nearly 16,000 appointments, procedures and surgeries were rescheduled.

Both Unison and the Royal College of Nursing (RCN) union have threatened further strikes in 2023 if an agreement isn't reached.

AstraZeneca shares two new drug approvals in the EU

Recently, AstraZeneca announced two drug approvals in the European Union (EU), the first being Imfinzi's approval for the treatment of biliary tract cancer, and the latter being Lynparza for prostate cancer.

The European Commission (EC) approved Imfinzi, also known as durvalumab, for the first-line treatment of adult patients with unresectable or metastatic biliary tract cancer, in combination with chemotherapy.

This approval was based on results from the TOPAZ-1 phase 3 trial, as well as considering the updated results presented at the European Society for Medical Oncology Congress 2022. The drug was also recommended for approval by the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) in November.

Dave Fredrickson, executive vice-president of the oncology business unit, commented: "With this approval, Imfinzi plus chemotherapy becomes the only immunotherapy-based treatment option available to patients in the EU with advanced biliary tract cancer."

Similarly, Lynparza, also known as olaparib, in combination with abiraterone and prednisone or prednisolone, was approved for the treatment of metastatic castration-resistant prostate cancer (mCRPC) in adult men for whom chemotherapy was not recommended.

This approval was based on results from the PROpel phase 3 trial, and followed another positive recommendation from the CHMP in November.

Fredrickson commented: "Many patients with mCRPC are only able to receive one line of active therapy, as the disease can progress quickly. Lynparza in combination with Abiraterone has been shown to reduce the risk of disease progression by 34% versus the standard of care treatment in the PROpel trial."

European Commission approves Dupixent® as the first and only targeted medicine for prurigo nodularis

Regeneron Pharmaceuticals and Sanofi have announced that the European Commission (EC) has expanded the marketing authorisation for Dupixent® (dupilumab) in the European Union to treat adults with moderate-to-severe prurigo nodularis who are candidates for systemic therapy.

Prurigo nodularis is a chronic, debilitating skin disease with underlying type 2 inflammation. Its impact on quality of life is one of the highest among inflammatory skin diseases, due to the extreme itchiness it causes. Symptoms include an intense, persistent itch with thick skin lesions (otherwise known as nodules), which can cover most of the body. Although high-potency topical steroids are commonly prescribed, these come with long-term safety risks, and it is estimated that around 70,000 adults living with prurigo nodularis need new treatment options.

The EC's decision was based on data from two phase 3 trials, PRIME and PRIME2, which evaluated the efficacy and safety of Dupixent®. In these trials, 44% and 37% of patients taking Dupixent® experienced a clinically meaningful reduction in itchiness at 12 weeks, compared to 16% and 22% for the placebo.

The improvement increased at 24 weeks, with approximately three times as many Dupixent® patients experiencing a clinically meaningful reduction in itchiness.

George D Yancopoulos MD PhD, president and chief scientific officer at Regeneron, and a principal inventor of Dupixent, stated: "For the first time, patients with prurigo nodularis in Europe have a medicine that can help relieve the burden of itchy and painful nodules covering their skin, which can have a devastating impact on their day-to-day lives, both physically and mentally. Dupixent is now approved for its second dermatological disease and fourth disease overall. We remain committed to further investigating this innovative medicine for diseases – such as chronic urticarias and chronic obstructive pulmonary disease – in which type 2 inflammation may play a role."

ServBlock secures EU funding for pharma manufacturing data space

ServBlock, an Irish start-up, and Irish Manufacturing Research (IMR), have been given EU funding to build a data exchange system for outsourced pharmaceutical manufacturing.

ServBlock is a company that uses blockchain-based auditing and compliance to help pharma manufacturers guarantee quality across their supply chain. It aims to automate pharmaceutical compliance to make it more secure, timely and cost-efficient with the use of blockchain technology.

It is also leading an Irish consortium, which is being used as a test case for trusted data transfer in pharma supply chains, and has members such as Cork's Nexa Enterprise Asset Management, Dublin's Ingeniero Solutions, Limerick's Union Process Solutions and Waterford's Plant Quest.

A data space brings together multiple channels of data to make it more easily accessible for various reasons and this consortium data space will work to gain insight into the efficiency and competitiveness of the pharma manufacturing process. This EU funding will help bring in more experts to help further develop the data space, with experts coming from various fields including data science, manufacturing and engineering.

ServBlock was given the funding alongside IMR, a research and technology organisation, which researches emerging technologies for advanced manufacturing.

"IMR are excited to participate in this consortium and facilitate improvements in patient outcomes through improvements to pharmaceutical manufacturing and supply chain," commented Adrian Hovenden, IMR industrial solutions architect. He also stated that collaboration to create impactful results is key to "ensuring the continued growth and development" in the Irish manufacturing sector.

Gambian panel recommends Maiden Pharmaceuticals be held culpable for cough syrup

A parliamentary committee in the Gambia has recommended prosecution of the Indian pharma manufacturer Maiden Pharmaceuticals, as it has sold contaminated medicine that is believed to be linked to the deaths of at least 70 children in the Gambia.

In October 2022, WHO issued a global alert advising regulators to stop the sale of the cough syrups, after the deaths of children in the Gambia from acute kidney failure were linked to Promethazine Oral Solution, Kofexmalin Baby Cough Syrup, Makoff Baby Cough Syrup and Magrip N Cold Syrup, all manufactured by Maiden Pharmaceuticals.

After testing, the medicines were found to be contaminated with diethylene glycol and ethylene glycol, both of which are toxic to humans and can be fatal if consumed.

The committee has said it "is convinced that Maiden Pharmaceuticals [is] culpable and should be held accountable for exporting the contaminated medicines … The findings remain the same with the previous reports which indicates that Promethazine Oral Solution, Kofexmalin Baby Cough Syrup, Makoff Baby Cough Syrup and Magrip N Cold Syrup were contaminated with diethylene glycol and ethylene glycol."

It has recommended tough measures, such as the banning of all Maiden Pharmaceutical products in the country, and legal action against the company. It also wants the country's Medicine Control Agency to ensure all imported medicines are properly registered and manufacturers receive background checks, including visits to their facilities.

The panel's report also revealed inadequacies in the country's healthcare system, and has urged the government to strengthen it and provide better equipment and medicines in hospitals.

Maiden Pharmaceuticals continues to deny all allegations.

Tamiflu manufacturers report shortages during high point of flu season

The CDC has reported at least 23,000 hospitalisations due to influenza while this year's flu season is at a high point, which has led to multiple manufacturers reporting shortages of a flu drug, Tamiflu.

Shortages of Tamiflu, also known as oseltamivir, have been reported by the American Society of Health-System Pharmacists (ASHP), including several doses by five generic manufacturers: Amneal and Camber are short on the 30mg, 45mg and 75mg doses; Macleods is short on 30mg and 75mg doses; while Teva and Zydus are reporting shortages of oral power in the 60mL bottle amount.

There has been no official reason for the shortage, with the ASHP listing no explanation, although some manufacturers are still able to maintain their supply. There is also no confirmed date for when the drug will return to its normal supply.

Erin Fox, senior pharmacy director at the University of Utah Health, said that she "strongly suspects" that there has been a "mismatch in the amount ordered or contracted versus the amount produced," meaning manufacturers are having to catch up with demand for the drug.

Fox continued: "Most of the past shortages have been due to the company not being able to meet demand. Most of the shortages begin during flu season, in this case, we started getting reports in early May about a shortage of oseltamivir, so we entered this flu season already at a detriment."

Two biotech CEOs charged with defrauding investors over investigational HIV drug

Two US biotech CEOs have been highlighted for their roles in a conspiracy to defraud investors in CytoDyn, a company developing an investigational drug to treat human immunodeficiency virus (HIV).

Both Nader Pourhassen and Kazem Kazempour are alleged to have conspired to defraud investors through "false and misleading representations" relating to CytoDyn's development of HIV-fighting drug leronlimab. Pourhassen was CytoDyn's president and CEO at the time of the alleged fraud, and Kazempour is the co-founder, president and CEO of Amarex Clinical Research, who managed CytoDyn's clinical trials for leronlimab.

Evidence shows that the two CEOs allegedly deceived investors about the status of CytoDyn's submissions to the FDA to artificially inflate the price of CytoDyn's stock. Documents also show that, in April 2020, CytoDyn and Amarex repeatedly missed publicised timelines, and that Pourhassen allegedly directed Amarex to submit the company's incomplete biologics license application (BLA) so CytoDyn could announce to investors that it had been submitted. However, both CEOs knew that the FDA would refuse an incomplete BLA.

There are also allegations that Pourhassen made false and misleading claims about CytoDyn's investigation and development of leronlimab as a possible treatment for COVID-19, despite clinical studies failing to achieve necessary results for FDA approval.

"Financial crimes like securities fraud may not be violent, but they certainly are not victimless. The two individuals charged today capitalised on the hopes of investors and the public in supporting new treatments for ailments that affect people and their families. This indictment sends a message to all sophisticated white-collar criminals that no-one is beyond the reach of the FBI and our law enforcement partners and we do not tolerate the greedy intentions of those in such trusted positions," stated Special Agent in Charge Thomas Sobocinski of the FBI Baltimore Field Office.

BioNTech begins phase 1 trial for malaria vaccine

BioNTech has announced the start of its new first-in-human phase 1 trial for BNT165b1, a candidate from its programme that aims to develop a multi-antigen malaria vaccine.

The study will assess a set of mRNA-encoded antigens of the malaria-causing parasite, Plasmodium falciparum, in order to select the best candidate to progress to further stages of the trials. This initial trial aims to assess safety, tolerability and exploratory immunogenicity of BNT165b1.

WHO has estimated that there were over 247 million cases of malaria in 2021, leading to 619,000 deaths, with 95% of all cases taking place in the African region. Children under five appeared most vulnerable to the disease, with a high risk of severe disease progression and chronic complications. One vaccine is already approved in paediatric patients for the prevention of malaria, but there is still a great need for more efficient vaccines to eradicate malaria or at least reduce its impact in highly endemic areas.

Professor Özlem Türeci MD, chief medical officer and co-founder of BioNTech, commented: "The trial initiation is an important milestone in our efforts to help address diseases with high unmet medical need. Our objective is to develop a vaccine that can help to prevent malaria and reduce mortality. Over the next months we aim to evaluate different antigens with scientific rigor to identify the optimal candidate."

Türeci continued: "In parallel, we are working on establishing manufacturing facilities on the African continent and other regions. The containers for the first BioNTainer for the African network are ready for the transport to Rwanda. If successfully developed and approved, an mRNA-based malaria vaccine could be manufactured there."

FDA approves first gene therapy to treat patients with high-risk, non-muscle-invasive bladder cancer

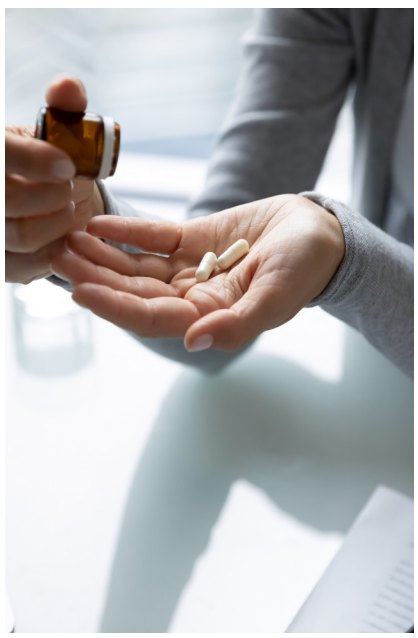
The FDA has approved Adstiladrin (scientific name nadofaragene firadenovec-vncg) for the treatment of adult patients with high-risk Bacillus Calmette-Guérin (BCG)-unresponsive non-muscle-invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) with or without papillary tumours.

Adstiladrin is an adenoviral vector-based gene therapy that is non-replicating, meaning it cannot multiply in human cells. Its safety and effectiveness were evaluated in a multicentre clinical study, which included 157 patients with high-risk BCG-unresponsive NMIBC, of which 98 had BCG-unresponsive CIS with or without papillary tumours and could be evaluated for response.

Patients received Adstiladrin once every three months for up to 12 months, or until there was unacceptable toxicity to therapy or recurrent high-grade NMIBC. The study found that, overall, 51% of enrolled patients achieved a complete response: the disappearance of all signs of cancer as seen on cystoscopy, biopsied tissue and urine. The median duration of response was 9.7 months, with 46% of the responding patients remaining in complete response for at least one year.

Peter Marks MD PhD, director of the FDA's Center for Biologics Evaluation and Research stated: "This approval provides healthcare professionals with an innovative treatment option for patients with high-risk non-muscle invasive bladder cancer that is unresponsive to BCG therapy. Today's action addresses an area of critical need. The FDA remains committed to facilitating the development and approval of safe and effective cancer treatments."

FDA expands access to abortion pills



Following new rules from the FDA under the Biden administration, patients can now obtain the abortion pill mifepristone from retail pharmacies, rather than having to collect the medication in person from their healthcare provider. A prescription for the drug is still required, however this can now be filled at an in-store pharmacy or by mail order.

This new ruling could help to expand access to medical abortions following the overturning of Roe V Wade: this removed the federal right to abortion, meaning various states have completely banned or harshly restricted access to abortions. However, according to the pro-choice Guttmacher Institute, more than half of abortions in the US are done with abortion pills rather than surgery, meaning expanding the availability of these medications can only help patients safely access the procedure.

The FDA's new requirements state that the drug 'can be dispensed by certified pharmacies or by or under the supervision of a certified prescriber.'

Mifepristone is one half of a drug combination commonly used to trigger medication abortions, used alongside misoprostol at around ten to 12 weeks of pregnancy. Misoprostol is not a restricted drug and is often used for miscarriages, so can be easily obtained at pharmacies with a prescription.

Pharmacies are now able to apply for certification to distribute mifepristone, allowing them to treat customers who have received a prescription from a certified prescriber. Chains such as CVS and Walgreens are already reviewing the FDA's new requirements.

The American College of Obstetricians and Gynaecologists has called this move "an important step" and has stated: "Although the FDA's announcement today will not solve access issues for every person seeking abortion care, it will allow more patients who need mifepristone for medication abortion additional options to secure this vital drug."

Belharra Therapeutics and Genentech join forces for small molecule medicine development

US-based biotech companies Belharra Therapeutics and Genentech have announced a multi year partnership to lead the discovery and development of small molecule medicines in multiple therapeutic areas, including oncology, immune-oncology, autoimmune and neurodegenerative diseases.

The partnership will utilise Belharra's novel photoaffinity-based, non-covalent chemoproteomics platform to identify "functional and actionable small molecule ligands for protein targets." These early preclinical activities will be led by Belharra using targets designed by Genentech.

Genentech will then take over the late preclinical and clinical activities, as well as the regulatory development and marketing.

Belharra will receive $80m as an upfront cash payment, will be eligible to receive development, commercial and net sales milestones that could

exceed $2bn, and tiered royalty earnings from products created from the partnership.

Jeff Jonker, CEO of Belharra said, "We are excited to work with Genentech and leverage its industry-leading biological acumen to develop novel drug candidates for key therapeutic targets across a range of severe diseases for which patients currently lack adequate treatments. Genentech is long recognised for its dedicated pursuit of groundbreaking science to illuminate the drivers of disease and enable the discovery and development of transformational medicines. This collaboration further underscores the promise of Belharra's novel platform to advance that cause."

James Sabry MD PhD, Global Head of Pharma Partnering at Roche commented: "Our collaboration with Belharra gives Genentech access to a drug invention platform that allows us to interrogate important therapeutic pathways and targets that we strongly believe drive disease pathogenesis, but have proven to be inaccessible to conventional approaches. Partnering with early-stage companies like Belharra provides Genentech with yet another way to advance groundbreaking science to discover and develop medicines for patients with serious and life-threatening diseases."

New blood test appears to detect hidden cancer

Biotech company Guardant Health has announced that its blood test-based cancer screening technique appears to be effective: the liquid biopsy detected cases of colorectal cancer in 83% of patients who had the disease. It also correctly detected people who did not have colorectal cancer 90% of the time. However, some investors are disappointed with the technology's ability to detect precancerous tumours.

Guardant Health has shared in a press release that it intends to use the findings of this study to submit the test to the FDA for approval in the first quarter of 2023.

One investor, SVB Securities, was slightly disappointed, noting that the 83% figure was significantly lower than the figure Guardant Health announced earlier this year.

It is also worth noting that the test was able to detect advanced adenomas or noncancerous tumours that indicate a risk for colorectal cancer only 13% of the time, arguably a disappointing figure.

Amir Ali Talasaz, Guardant Health's co-chief executive officer, commented: "We've been working steadily for many years to reach this milestone. […] As of today, blood-based colorectal cancer (CRC) screening is a reality."

There is still a long way to go before blood-based screening will replace colonoscopies entirely, however looking to the future, Talasaz stated that five years from now "we could have a blood-based screening test for colon cancer using blood for over 130 million people in the United States with no out-of-pocket cost."

New study shares effectiveness of asthma drug compared to standard of care

The University of Plymouth has co-authored a new study, published in *The Lancet*, which shows how an asthma drug, commercially known as Relvar Ellipta, was more effective than patients' usual care at improving their asthma control.

The study, developed by GlaxoSmithKline (GSK), demonstrated that the daily inhalation of a powder made up of fluticasone furoate and 25mg vilanterol was more effective for improving asthma control, assessed by the Asthma Control Test (ACT), compared to maintenance inhaler therapy alone.

The drug was given to 2,114 of the 4,233 patients enrolled in the study, and results were assessed at 12, 24, 40 and 52 weeks. At 24 weeks, a much higher percentage (71%) of patients with symptomatic asthma achieved better control of their asthma compared to patients continuing with their standard care strategies (56%). There were also statistically significant improvements at 12, 40 and 52 weeks.

Dr Rupert Jones, senior clinical research fellow in clinical trials and health research at Plymouth University Peninsula Schools of Medicine and Dentistry, explained: "As the study was carried out on people in the general public, rather than considering any strict exclusion criteria, we can be confident it is translatable to the general public too. […] Practices and pharmacists local to Salford were involved, and the study showed that people taking the medication have twice the odds of achieving asthma control as those on usual care. The Salford Lung Study was designed in collaboration with National Institute for Health and Care Excellence and not only the findings but the way the methodologies of the research could be really influential on future work."

AstraZeneca set to buy CinCor for $1.8bn

AstraZeneca has announced that it is set to acquire the clinical-stage biopharmaceutical company CinCor in a deal worth up to $1.8bn.

US-based CinCor focuses on the development of novel treatments for resistant and uncontrolled hypertension, as well as to treat chronic kidney disease.

The deal is intended to improve AstraZeneca's cardiorenal pipeline through the acquisition of CinCor's candidate drug, baxdrostat (CIN-107), an aldosterone synthase inhibitor (ASI) that lowers blood pressure in treatment-resistant hypertension.

The company hopes that baxdrostat will be its leading next-generation ASI due to the fact that it is highly selective for aldosterone synthase and tends to spare the cortisol pathway in human patients. It can also be used in combination with Farxiga, which "complements AstraZeneca's strategy to provide added benefit across cardiorenal diseases, where there is a high unmet medical need."

Mene Pangalos, executive vice president of biopharmaceutical research and development at AstraZeneca, commented: "Acquiring CinCor supports our commitment to cardiorenal disease and further strengthens our pipeline with baxdrostat."

He continued: "Excess levels of aldosterone are associated with hypertension and several cardiorenal diseases, including chronic kidney disease and coronary artery disease, and being able to effectively reduce this would offer a much-needed treatment option for these patients."

Cost of over 350 drugs expected to increase in 2023

With many pharma companies preparing for President Joe Biden's Inflation Reduction Act (IRA) to begin having an impact, and inflation continuing to soar, the cost of at least 350 drugs is expected to rise in the US throughout 2023.

Pfizer, AstraZeneca, GlaxoSmithKline (GSK), Bristol Myers Squibb and Sanofi, among others, are some of the drugmakers who are expected to raise the prices of their products from January this year.

As well as Biden's IRA, the upcoming price increases are also in response to the ongoing cost of living crisis and continuing supply chain issues, which have led to higher manufacturing costs for many medicines.

Following the IRA, the government's Medicare programme will be able to negotiate drug prices for drugs without competition from 2026. The drugs that have been selected for the 2026 price negotiations will be announced in September 2023.

Antonio Ciaccia, President of 3 Axis Advisors, told Reuters that "drugmakers have to take a harder look at calibrating those launch prices out of the gate… so they don't box themselves in into the point where in the future, they can't price increase their way back into profitability."

Moderna agrees first acquisition for $85m

After a pivotal few years, Moderna has agreed its first acquisition, worth $85m, which will allow the company access to cell-free DNA synthesis and amplification technologies. Moderna is set to acquire OriCiro Genomics K.K., gaining its expertise in DNA synthesis and amplification.

Now that the race to develop effective mRNA vaccines to combat the COVID-19 pandemic is all but over, many have wondered what is next for Moderna. The company seems to have turned to mergers and acquisitions, with Moderna set to purchase the Japanese DNA supplier as its first acquisition since its launch in 2010.

The purchase of OriCiro means that Moderna will no longer have to rely on the time-consuming process of E. coli cloning, which can take several days: OriCiro's amplification process only takes hours. Stéphane Bancel, Moderna's CEO, estimates that this could reduce large-scale manufacturing time by up to 30%.

It is expected that Moderna will continue to acquire further companies in the future, likely a therapeutics company, although it looks likely that its focus will remain on nucleic acid. This could include gene therapy or editing companies, however the acquisition of biotechs focused on small molecules is unlikely.

Bancel commented: "It's faster product to clinic, faster product to market. And then the research part is: We can iterate much faster."

He continued, explaining that acquisitions in other areas of research "might be helpful for the sales next year or stuff like that, but we're not solving for that. We're solving for [the] best RNA company because we believe that science is going to generate, for this platform, so many medicines."

$22m raised by PBS Biotech to expand single-use manufacturing products and services for cell therapy clients

PBS Biotech, an innovative, single-use bioreactor manufacturer and process development services provider, has worked together with Avego Management and BroadOak Capital Partners to raise $22m in financing. It will be used to improve the company's product portfolio, expand process development services and increase customer support for global cell therapy clients.

CEO of PBS Biotech Dr Brian Lee commented: "The investment from Avego Management and BroadOak ensures PBS Biotech will continue to provide the best manufacturing platform along with unsurpassed technical support to unlock clinical and commercial manufacturing of allogeneic cell-based therapies for decades to come."

PBS Biotech's Vertical-Wheel® bioreactors have unique and scalable fluid mixing conditions, which are ideal for a wide range of human cell-derived modalities. They are also well suited for induced pluripotent stem cell (iPSC), mesenchymal stem cell (MSC) and exosome-based therapeutics manufacturing.

These methods are helping to develop novel regenerative medicines as potential cures for life-threatening conditions, such as diabetes, cancer and heart disease.

Jerry Liao, Vice President at Avego, has joined the Board of Directors at PBS. He commented, "PBS has a remarkable and validated technology and product platform, as evidenced by projects with more than 200 customers. Avego is thrilled to partner with Dr Lee and the leadership team at PBS to support the continued growth of one of the leading technology and service providers in the cell therapy space."

"This financing positions PBS to expedite product development, enabling therapeutic developers from early-stage research through clinical development and commercial manufacturing in the coming years. We are excited to continue supporting PBS and to have Avego join as a new investor in the company," added Bryan Poltilove, Operating Partner at BroadOak and Director at PBS.

Sanofi plans eco-friendly additions to Brisbane manufacturing campus

Sanofi is aiming to expand its eco-friendly and renewable energy ecosystem with plans to install solar panels on the car park, add electric vehicle charging points to the staff car park and gradually convert the corporate cars to electric vehicles over a longer period of time.

In Australia, Sanofi has completed the installation of 1,500 solar panels at the North Brisbane manufacturing campus, as well as having announced its new commitment to doubling its green energy at the site.

Sanofi is one of the major medicines and vaccines companies in Australia, having over 50 medicines on the Pharmaceutical Benefits Scheme, six on the Life Saving Drugs Program, and 17 vaccines that are used in the country, seven of which being on the National Immunisation Program. It is estimated that up to 95% of young Australians will have a Sanofi vaccine by the time they reach five years old, and one in four Australians are thought to have had a Sanofi flu jab.

As well as being a leader in the Australian pharmaceutical market, Sanofi is leading the way with eco-friendly action. Its new solar panels in Brisbane mark just one step in the company's aim to become carbon neutral across its whole value chain by 2030.

Anika Wells, MP, Minister for Sport, and member of the House of Representatives for Lilley, commented: "As the Federal Member for Lilley, it's wonderful to see businesses in our local area acting on climate change and prioritising green energy to help future proof our community."

Karen Hood, Country Lead for Sanofi Australia and New Zealand, added: "As a global healthcare company, we recognise that climate change presents one of the greatest challenges of our age and that environmental action, taken by everyone, is key to protecting the health of people worldwide. […] Globally we are committed to achieving carbon neutrality by 2030 and net-zero by 2050 across all scopes. We have started a number of major programmes to deliver on these commitments including switching to renewable energy across all global operations. Locally, our solar panel programme in Brisbane is a proud part of this critical journey."

Sarepta Therapeutics and Catalent sign manufacturing deal for DMD gene therapy approval

Sarepta Therapeutics is a company focused on gene therapy, RNA and gene editing, engineering precision genetic medication for rare diseases. It has announced the signing of a commercial supply agreement with Catalent that will allow the company to manufacture delandistrogene moxeparvovec (SRP-9001), Sarepta's most advanced gene therapy candidate for the treatment of Duchenne muscular dystrophy (DMD).

The FDA granted Sarepta its biologics license application (BLA) seeking accelerated approval for delandistrogene moxeparvovec in November 2022.

Catalent has state-of-the-art facilities that currently house ten cGMP gene therapy manufacturing suites, each capable of accommodating multiple bioreactors of up to 2,000L scale. Its UpTempo Virtuoso adeno-associated virus (AAV) platform is a scalable, GMP-ready process for viral vector manufacturing that can reduce a typical 18-month development timeline for a drug product by half.

Doug Ingram, Sarepta's President and Chief Executive Officer said, "Sarepta is working as quickly as possible to advance new genetic medicines to treat progressive neuromuscular diseases like Duchenne and LGMD. We are excited to strengthen and expand our relationship with Catalent to meet anticipated demand for SRP-9001 and develop commercially scalable processes for additional gene therapy programmes in our pipeline. We appreciate the years of dedication and collaboration that Catalent has provided in supporting our clinical trials for SRP-9001, and we look forward to continuing our work together through this expanded partnership."

"Our partnership with the Sarepta team spans nearly a decade across multiple programmes and modalities, and we look forward to working together to manufacture these potentially life-changing and life-saving products for patients diagnosed with DMD and LGMD. We look forward to leveraging our deep expertise in gene therapy development, manufacturing and commercialisation to support these programmes as they advance toward potential regulatory approval," said Alessandro Maselli, Catalent's President and Chief Executive Officer.

AI model predicts CVD risk from single chest radiograph

A recently developed AI model has been shown to predict ten-year incidences with a similar level of success to the current standard of care.

The AI model uses data from a single chest X-ray to predict the ten-year risk of death from incidences such as heart attacks or strokes, following atherosclerotic cardiovascular disease (ASCVD). The results of this study were recently presented at the Radiological Society of North America (RSNA) conference 2022.

Risk assessment is a crucial part of the prevention of ASCVD, so a new method of detecting this risk ten years in advance appears to be a hugely positive step in identifying high-risk patients, giving them the possibility for various preventative and curative therapies. Currently, risk assessments rely on certain risk factors: age, sex, systolic blood pressure, antihypertensive treatment, total and HDL-cholesterol, diabetes and smoking.

The study developed the AI model using 147,497 chest radiographs from 40,643 participants from the PLCO cancer screening trial, the AI model was trained to predict CVD mortality from a single X-ray image.

Jakob Weiss, a radiologist associated with the Cardiovascular Imaging Research Center at Massachusetts General Hospital who was also involved in this study, commented that "variables necessary to calculate ASCVD risk are often not available, which makes approaches for population-based screening desirable." He continued that "as chest X-rays are commonly available, our approach may help identify individuals at high risk."

Anumana and Pfizer team up on AI-enabled ECG algorithm for detection of cardiovascular disease

Anumana, an AI-driven health technology firm, has signed a multi year deal with Pfizer in order to develop an AI electrocardiogram (AI-ECG) for the early detection of cardiac amyloidosis.

Anumana will conduct a clinical validation trial in order to pursue de novo classification for the algorithm as a Software-as-a-Medical-Device (SaMD), with the aim to gain regulatory approval in the US, Europe and Japan.

For patients with cardiac amyloidosis, their heart walls become stiff: the left ventricle finds it difficult to relax to take in blood, while at the same time struggles to pump out blood within the heart. It is a serious, progressive and underdiagnosed rare disease that leads to heart failure.

This research agreement will help Anumana with its AI-enabled early detection software that can reveal signals from ECGs that humans cannot interpret.

Anumana chief business officer David McMullin said: "The challenge in diagnosing cardiac amyloidosis can prevent patients from getting treatment while the disease continues to progress. We believe this collaboration will demonstrate the power of Anumana's AI-ECG algorithms to help clinicians intervene earlier, giving them greater ability to improve patient outcomes and prolong lives."

"AI-ECG solutions alert clinicians to humanly imperceptible patterns in ECG signals, providing an early warning for serious occult or impending disease. This stands to improve the lives of people with cardiac amyloidosis by improving the speed of triage and care of this group," stated Paul Friedman MD, chair of the Department of Cardiovascular Medicine at Mayo Clinic and chair of Anumana's Mayo Clinic Board of Advisors.

Withings announces hands-free connected

Connected health firm Withings has unveiled its new in-home biomarker analysis platform U-Scan. It is hoped the device will utilise the "wealth of health information in daily urine."

U-Scan is a urine health monitor that fits into the toilet bowl and is engineered to distinguish between extremal liquid and urine. A pump is activated when the thermal sensor detects urine, which "starts the sample's fluidic journey within a microfluidic circuit", according to Withings. The monitor then connects to the Withings Health Mate app: an in-home urine analysis platform that delivers information and insights based on daily readings.

The health monitor – a pebble-shaped reader – also involves changeable analysis cartridges to evaluate specific biomarkers. The platform will debut with two consumer cartridges and move into medical in the future. The cartridges are U-Scan Nutri Balance, a metabolic guide to hydration and nutrition, and U-Scan Cycle Sync, which tracks and synchronises women's monthly cycles.

Although the U-Scan is in development in the US, it will not be available until it is cleared by the FDA.

Withings CEO Mathieu Letombe said: "The ability of U-Scan to perform daily urine analysis from the home will allow Withings to take its mission to help consumers fully utilise urine data to an entirely new level. It's one of the most exciting and complex products we have ever announced. We begin this journey with U-Scan Cycle Sync and Nutri Balance, and look forward to announcing more cartridges on an ongoing basis as well as medical applications of the technology."

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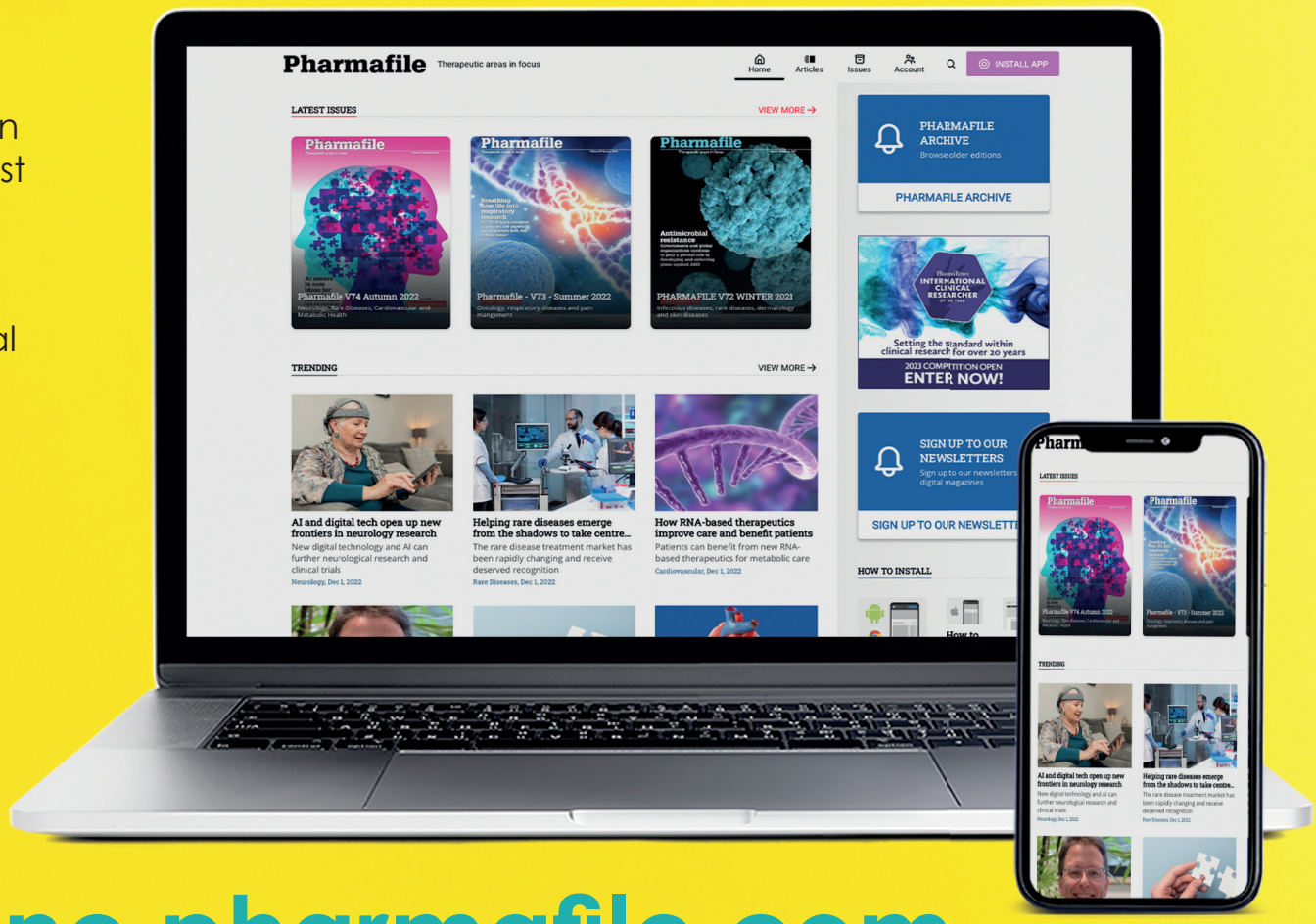

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Prostate cancer in Europe: the time to act is now

Professor Hendrik Van Poppel, former chief of the department of urology of KU Leuven Belgium, founder of the EAU Patient Office and chair of the Policy Office of the European Association of Urology, former chair of the European Cancer Organisation Inequalities Network and chair of its "Men and Cancer" Workstream and a member of the expert group for the Let's Talk Prostate Cancer (LTPC) initiative, tells Pharmafocus about its new campaign

***Pharmafocus*: Tell us about the new screening measures that the Let's Talk Prostate Cancer (LTPC) Expert Group is suggesting should be implemented across the EU.**

Professor Dr Hendrik Van Poppel: Prostate cancer is the most frequently diagnosed cancer among men in Europe[1] but, if it is caught in the early stages, patients are able to access effective treatment options and experience fewer and more manageable side effects. Organised, early detection is paramount in reducing the morbidity and mortality rate of prostate cancer.[2] So, publication of *Europe's Beating Cancer Plan*[3] and of the updated EU cancer screening guidelines,[4] along with the renewed focus on EU health policy, all mark important steps towards the eradication of inequalities in cancer diagnosis and treatment.

The new screening guidelines aim to support Member States in ensuring that 90% of the EU population who qualify for breast, cervical and colorectal cancer screenings are offered such screenings by 2025. For the first time, the new recommendation calls for population-based organised cancer screening to include lung, prostate and, under certain circumstances, gastric cancers.[4] This is why we are making an urgent call for EU Member States to implement risk-based prostate cancer screening recommendations in national cancer plans, because outcomes for future patients with prostate cancer would improve if this step is prioritised by national policymakers.

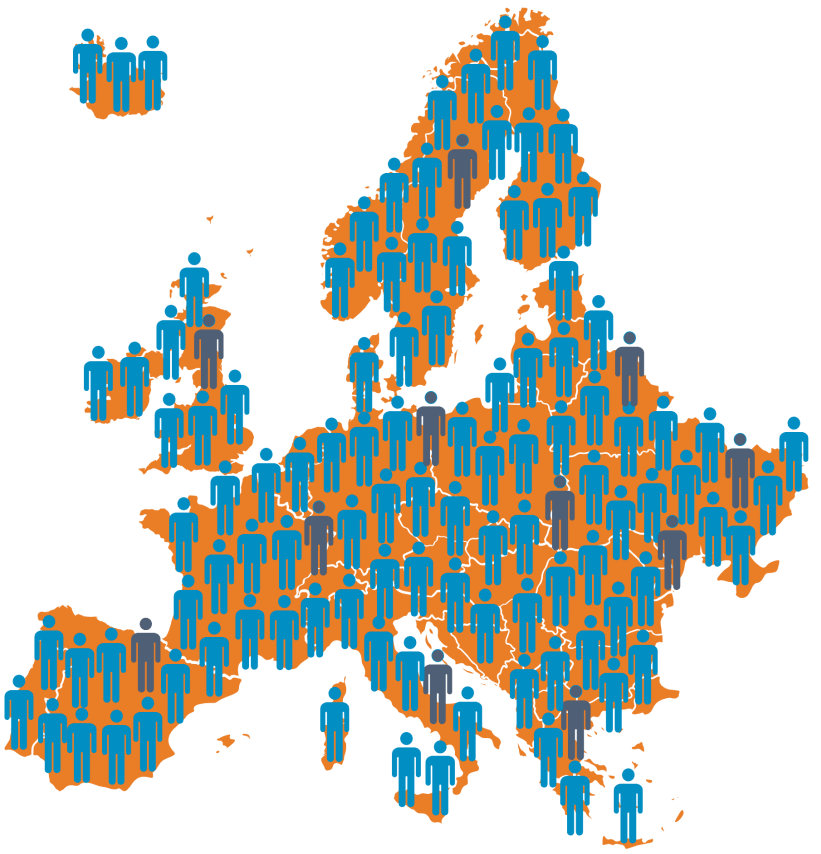
What are the reasons behind the poor uptake in prostate cancer screening?

There has been a relative decline in prostate specific antigen (PSA) testing in screening programmes for prostate cancer in Europe.[2,5] The most important issue was the overdiagnosis and overtreatment of a relevant number of men with non-aggressive prostate cancer, which in 2012 led the US Preventive Services Taskforce to recommend against prostate specific antigen (PSA) testing.

Sadly, this now means we are seeing higher rates of metastatic disease and advanced prostate cancer at time of diagnosis, which in turn is associated with an increase in mortality, a poorer quality of life and a higher cost for national health services.

The situation is compounded by men feeling uncomfortable to talk about their health or to take the initiative to go and see a healthcare professional. In many cases, men may not be aware of what their prostate is or the need to be aware of their health, particularly as they age, or if they are part of high-risk groups such as men of African American origin, and those with a family history of the disease.[1]

The new cancer screening recommendation is based on PSA testing to identify men with a PSA above 3ng/ml as having a high risk of significant disease. These men would not undergo biopsy immediately (as before) but would receive an MRI at follow-up and this, combined with active surveillance, is expected to significantly reduce overdiagnosis and overtreatment.[4,1]



Each year in Europe, approximately 1 in 10 male cancer deaths are as a result of prostate cancer.[8]

As the most frequently diagnosed cancer in men, what is leading to the increased mortality from prostate cancer? And what can be done to combat this?

The COVID-19 pandemic had a significant impact on prostate cancer as it delayed both screening and treatment for patients, resulting in a record number of advanced prostate cancer cases.[6] In fact, a recent report from *The Lancet Oncology* Commission states that the disastrous effects of the pandemic on early diagnosis and treatment could set back cancer outcomes in Europe by almost a decade, making urgent action a crucial priority.[7]

Coupled with this, prostate cancer has been relatively low on the health policy agenda of the EU, as compared with breast and cervical cancers, for example. Across Europe, prostate cancer kills more men than breast cancer does women.[1] Early detection is absolutely critical to improve patient outcomes and reduce mortality. It's important that we work with national and international policymakers to prioritise prostate cancer on political agendas and dismantle stigma around the disease – it's often viewed as an 'old man's disease', that you rather die with than from, or men just simply think it won't happen to them, but prostate cancer is a killer. It is the second most common male cancer killer in Germany and the number one in Sweden, before lung cancer.[8] To do this we need to ensure there are better resources so patients, partners and families can be fully informed about prevention, early detection, diagnosis, treatment and ongoing care. It is only by detecting cancer at earlier stages that it will be possible to not only reduce mortality but most importantly improve the quality of life of patients.[2]

> **Despite progress in recent years, there is still insufficient political pressure and policy action on early detection, diagnosis, treatment and post-diagnosis, to address the issues facing people with prostate cancer and this must change. The time to act is now.**

Which factors will be assessed by a risk-based screening system, how can this ensure that as many cases of aggressive prostate cancer as possible are efficiently detected, while not over-diagnosing inoffensive indolent cancers?

The new recommendations mean prostate cancer screening should be systematically implemented on invitation with ample information on the pros and cons, using PSA testing and risk calculators to recognise those at risk for having significant prostate cancer. If so, magnetic resonance imaging (MRI) scanning will be done before considering a biopsy in those males at greater risk of having significant prostate cancer.[4] The screening recommendation is paying particular attention to equal access to screening and targeting the needs of particular socioeconomic groups, people with disabilities and people living in rural or remote areas.[4] Helpfully, the use of new technologies such as AI can enable the rapid processing of health data, which supports better targeted screening and may ultimately lead to quicker diagnoses.[3]

What are the greatest risk factors of prostate cancer? And should there be more focus on spreading awareness of these factors to help with early detection?

The greatest risk factors for prostate cancer are age, being Black from African or Caribbean descent, or having a family history of the disease.[1] Unfortunately, studies show that an increasing proportion of these individuals are diagnosed with metastatic or late-stage prostate cancer,[9] so raising awareness is vital if we are to see the situation improve.

In addition, ensuring the new cancer screening recommendations are implemented in full by every country within the EU will be critical alongside supporting health systems to treat patients holistically, with multidisciplinary teams and complementary therapies needed to circumvent, prevent and help people cope with the secondary effects of the treatment, like counselling, physiotherapy and sex therapy.

What are the current standard of care treatment options for prostate cancer? Do you think there should be a greater focus on research into new treatments?

It is often argued that although lots of men get prostate cancer, it is fatal to few. This is not the case and prostate cancer is the first or second cause of male cancer death in most countries across Europe. Prostate cancer survival has improved in all EU countries in the last decade,[10] and innovations in treatment and care across the prostate cancer pathway have offered greater opportunities to enable those affected to live longer lives.

However, treatment of prostate cancer is multifaceted. The effects of hormonal treatment, for example, will include sexual dysfunction and loss of libido, and this has an impact on quality of life for not only the patients, but their partners too. Everybody should be enabled to enjoy their best possible quality of life.

How successful do you think new detection measures would be in reducing mortality rates?

If EU Member States implement the recommendations for risk-based screening for prostate cancer, the result on mortality rates will have a substantial impact, with the aim being that men die with the disease rather than from the disease. The opportunity for improving the outcomes for patients in terms of psychosexual health will be significant too. We shouldn't forget that treating depression as a result of side effects of treatment for late-stage cancer also costs money for health services. If we can avoid a patient reaching that stage in their treatment journey, then it's not just important for their well-being, but it also reduces pressure on already stretched health services and on their families and partners.

What are the most significant obstacles that need to be overcome to improve the timely detection and adequate treatment of prostate cancer?

There are three key Calls to Action from the Let's Talk Prostate Cancer Expert Group.[11] The first is to prioritise prostate cancer on political agendas, to increase the knowledge and understanding of the challenges facing patients, including breaking taboos associated with prostate cancer and the emotional and sexual health burden of the disease.

The second obstacle is healthcare inequalities. We're calling for policymakers in Europe to support research into the inequalities that affect men with prostate cancer to close this gap. Finally, we are urging European governments to ensure a timely implementation of the EU recommendation on cancer screening within national cancer plans. It's an extremely positive step to see prostate cancer be included in the screening recommendations, but we need the implementation to happen in the EU where health is still an issue of the Member States, if we are to see real change.

Why does the LTPC Group feel that EU governments should focus on prostate cancer as opposed to other cancers, or other diseases in general?

Compared with other tumours, such as breast cancer, prostate cancer has never recieved the attention it deserves and therefore has been relatively low on political agendas in the EU.[1] This might well be due to the incorrect perception that prostate cancer is a less serious form of cancer, when in fact it had the highest estimated incidence rate among all cancers in 2020, with 159 new prostate cancer cases per 100,000 detected in the EU27 (in comparison breast cancer counted 143, colorectal cancer 72 and lung 67 new cases per 100,000).[12] Despite progress in recent years, there is still insufficient political pressure and policy action on early detection, diagnosis, treatment and post-diagnosis, to address the issues facing people with prostate cancer and this must change. The time to act is now.

Prof. Dr. Hendrik Van Poppel is Chair of the Policy Office of the European Association of Urology, Former Chair of the European Cancer Organisation Inequalities Network and a member of the expert group for the Let's Talk Prostate Cancer (LTPC) initiative. *This article was initiated and developed in collaboration with Astellas Pharma Europe Ltd. Astellas Pharma Europe Ltd., Amgen Inc., and Pfizer Inc. support the goals and objectives of the Let's Talk Prostate Cancer Expert Group. The activities of the Expert Group are funded by Astellas Pharma Europe Ltd. and Amgen Inc.*

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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

Biogen appoints Priya Singhal as executive vice president and head of development

Biogen Inc has announced that Priya Singhal MD MPH and current head of global safety and regulatory sciences and interim head of research and development, has been promoted to the role of executive vice president and head of development. Singhal's promotion follows a decision to split R&D into two separate functions, both of which will report to the CEO directly.

Biogen is therefore also looking for a new executive vice president and head of research, although Singhal will also be covering this role until a new employee is appointed.

Singhal has previously worked as senior vice president and head of global safety and regulatory sciences and interim head of R&D at Biogen, as well as overseeing Japan and China R&D. Prior to this she worked as head of R&D and manufacturing at Zafgen Inc, vice president of clinical trials and benefit-risk management at Biogen, vice president of medical affairs at Vertex Pharmaceuticals, and led the benefit-risk for Velcade and two compounds in the development portfolio at Millennium Pharmaceuticals, where she began her drug-development career.

Christopher A. Viehbacher, president and chief executive officer at Biogen, commented: "Throughout her tenure at Biogen, Priya has demonstrated excellent leadership and judgement. In this new role, Priya will focus on delivering on our development programmes while working closely with a new dedicated head of research to strengthen Biogen's translational science capabilities. We believe having two dedicated leaders will enhance productivity in bringing to patients worldwide medicines to treat some of the most challenging diseases, while assuring better risk management and resource stewardship."

Dawn Sauro appointed to Chief Operating Officer at Elligo Health

Elligo Health Research has announced that Dawn Sauro has been named Chief Operating Officer (COO), with the aim of furthering the company's growth, efficiency and mission of optimising the intersection of healthcare and research through methods including new technology, custom research practice methods and direct access to patients.

Elligo Health is a healthcare-enabling research organisation that accelerates clinical trials and has access to over 150 million patients and their HIPAA-compliant healthcare data. Sauro has previously worked as executive vice president of Research Strategy at Elligo, and brings more than 30 years of drug and device development experience to her new role.

Before joining Elligo, Sauro worked as chief development officer at Clinpace Clinical Research (now known as Caidya), during this role she grew the organisation so it became a trusted partner for various sponsors across a range of therapy areas.

Commenting on Sauro's appointment, Elligo's CEO John Potthoff, said "Dawn is a drug development and clinical research business leader with deep subject matter expertise across a broad spectrum of therapeutic areas, but specifically brings vast knowledge in haematology and oncology. She is a valued member of company leadership with decades of industry insight, client relationships and an understanding of unique needs that help sponsors and clinical research sites drive results."

Sauro added: "I look forward to continuing in this new leadership role with Elligo, but also continuing to focus on delivering outcomes that move us all closer to our ultimate goal – providing everyone with easier access to participate in clinical research."

Elaine Sun appointed to the board of directors at Asher Bio

Asher Biotherapeutics has announced that Elaine Sun has been appointed to the Board of Directors. Asher Bio is a biotechnology company with a focus on developing therapies to engage specific immune cells to fight cancer.

Sun currently works as the chief operating officer and chief financial officer of Mammoth Biosciences, and brings more than 25 years of experience to her new role. She has also previously worked as senior vice president and chief financial officer at Halozyme Therapeutics, and chief financial officer and chief strategy officer at SutroVax (now known as Vaxcyte).

Craig Gibbs PhD, chief executive officer at Asher Bio, commented: "We are excited to welcome Elaine to our Board, as she brings exceptional strategic, operational and financial experience and leadership to our organisation. Elaine's impressive track record of creating value in the biopharmaceutical industry and fostering the growth of both early- and late-stage biotechnology companies will be a tremendous resource for Asher Bio as we advance our pipeline of precision immunotherapies into the clinic."

Sun added: "I am impressed with the potential of Asher Bio's cis-targeting platform to transform immunotherapy and the team's tremendous progress in advancing its pipeline candidates into the clinic. The company's ongoing development of potential therapies intended to precisely engage specific immune cells to address disease areas with high unmet need positions Asher Bio to stand out in the field and potentially deliver important new medicines that could lead to meaningfully improved treatment options for patients. I am honoured to join Asher Bio's board and look forward to working with the management team and other Board members at this pivotal stage for the company."

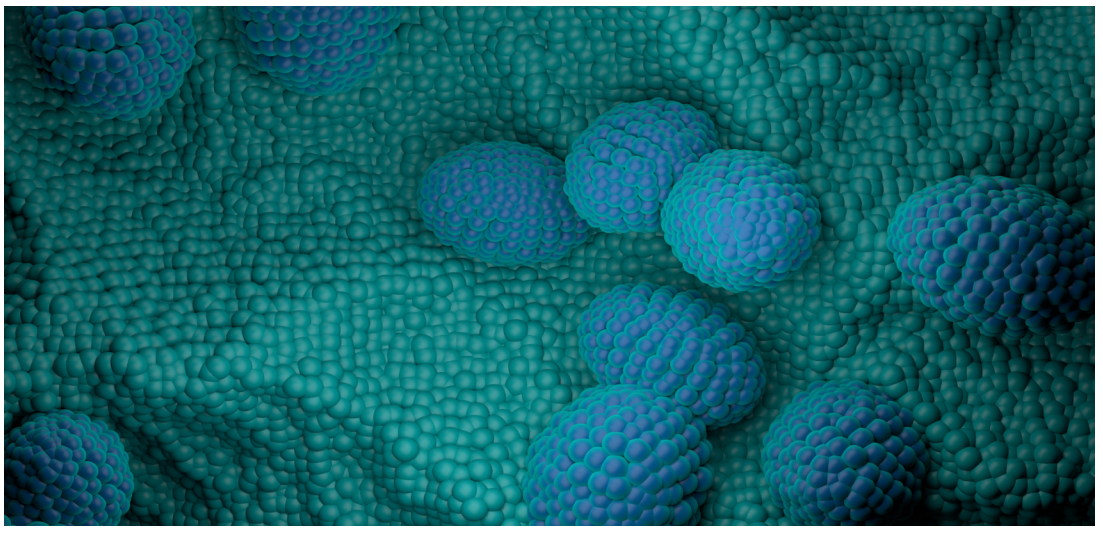
Maha Radhakrishnan appointed as Minovia Therapeutics' board member

Minovia Therapeutics has announced the appointment of a new board member: Maha Radhakrishnan MD, chief medical officer at Biogen.

The clinical-stage company, which focuses on developing novel Mitochondrial Augmentation Technology (MAT), has appointed Radhakrishnan as the company aims to advance its clinical programmes in primary mitochondrial diseases and haematological disorders associated with mitochondrial dysfunction. Radhakrishnan is currently the chief medical officer at Biogen, and has previously worked as senior vice president and global head of medical, primary business care unit at Sanofi; senior vice president and head of worldwide medical at Bioverativ Therapeutics; and head of Europe and Canada medical and US medical at Biogen. She has previously also worked at Bristol Myers Squibb, Cephalon and United Health Group.

Natalie Yivgi Ohana, co-founder and CEO of Minovia Therapeutics commented: "Mitochondrial diseases are often fatal and currently viewed as untreatable, something we are working relentlessly to change. So far twelve patients suffering Primary Mitochondrial Diseases were dosed with our Mitochondrial Augmentation Technology, both through a compassionate use programme and a phase 1/2 trial in Israel. Minovia invested greatly in research and development in the last two years, establishing strong scientific and GMP foundations, which will enable us to seek approval for Pearson Syndrome and expand to other disease areas. As a board member at Minovia, we will be able to draw on Maha's considerable medical, regulatory and drug development expertise and experience in bringing successful treatments to patients with primary and secondary mitochondrial diseases."

Five facts about prostate cancer



1. The direct cause of prostate cancer is unknown, however chances of developing the disease increase with age, and with predispositions from family history. Some other factors include race (prostate cancer is more common in Black men and less common in Asian men) and BMI (it is thought that obesity increases risk of the disease).

2. One in eight men will develop prostate cancer at some point in their lifetime. This equates to around 52,000 men across the UK each year, or 143 men every day.

3. The three main treatment options for prostate cancer are: surgery, external beam radiotherapy and brachytherapy. However, sometimes prostate cancer does not require treatment at all as it occasionally grows so slowly that it does not cause health issues or impact how long a patient lives.

4. The main symptoms of prostate cancer are: an increased need to urinate, straining during urination and a feeling that your bladder is not fully empty.

5. 12,000 men die from prostate cancer in the UK each year – this equates to one death every 45 minutes. However, around 475,000 men are currently living with or after prostate cancer.

References:
Visit: nhs.uk/conditions/prostate-cancer/
Visit: prostatecanceruk.org/

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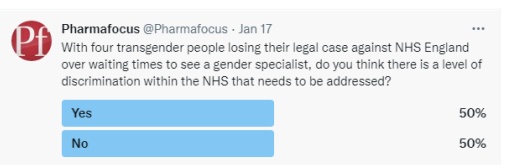

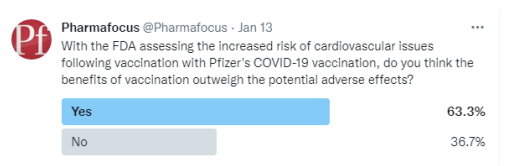

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