Friday, 4 October 2024

INSIGHTS

CONTENT

A-601, Marathon Innova, Opp. Peninsula
Corporate Park, Off Ganpatrao Kadam Marg,
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DEALS/ FUNDING

Gilead signs deal with 6 generic drugmakers to sell HIV drug in low-income countries

Reuters, 3 October 2024

Gilead Sciences said on Wednesday it has granted royalty-free licenses to six generic drug manufacturers to make and sell cheaper copycat versions of its HIV prevention medicine in 120 low and lower-middle income countries.

The U.S.-based drugmaker also plans to provide the companies branded version of the drug, lenacapavir, in 18 countries, such as Botswana, Ethiopia and Kenya, until they set up manufacturing capacity and can fully support demand, Gilead said. These countries represent about 70% of HIV cases.

https://www.reuters.com/business/healthcare-pharmaceuticals/gilead-signs-deals-with-6-generic-drugmakers-sell-hiv-drug-low-income-countries-2024-10-02/

★★★★★★

Drug giant Pfizer sells $3.3 bln stake in Sensodyne-maker Haleon

Reuters, 1 October 2024

Pfizer sold a stake in British consumer healthcare group Haleon worth about $3.26 billion on Monday, cutting its shareholding in the maker of Sensodyne toothpaste and Panadol and Advil painkillers to 15% from 22.6%. Shares in Haleon, which was created by the merger of GSK and Pfizer's consumer healthcare businesses in 2019 and spun off from the British drugmaker in 2022, fell 1.2% to 388 pence in morning trade on Tuesday.

https://www.reuters.com/business/healthcare-pharmaceuticals/pfizer-offload-about-59-stake-uks-haleon-says-bookrunner-2024-09-30/

★★★★★★

Lilly to invest $4.5 bln on new facility to scale-up pipeline drug production

Reuters, 3 October 2024

U.S. drugmaker Eli Lilly said on Wednesday it will invest $4.5 billion to create a new center in Indiana that will focus on developing new ways to manufacture its drugs and increasing production of experimental medicines used in clinical studies. Lilly and Danish rival Novo Nordisk are market leaders for a class of weight-loss treatments known as GLP-1 agonists, which work by suppressing appetite. Some analysts expect this market will reach $150 billion by the early 2030s.

https://www.reuters.com/business/healthcare-pharmaceuticals/lilly-announces-new-45-bln-manufacturing-site-indiana-2024-10-02/

★★★★★★

Mankind Pharma to Raise Rs 5,000 Cr Through Private Placements

Businessworld, 30 September 2024

Mankind Pharma fund raising committee finalised a comprehensive plan to issue non-convertible debentures (NCDs) and commercial papers (CP) to raise a total of Rs 5,000 crore on Monday.

In a stock exchange filing, the company said it will issue up to 500,000 secured, rated, and listed non-convertible debentures, with a nominal value of Rs 100,000 each, aggregating to a total of Rs 5,000 crore. These debentures will be issued in three to four distinct series with maturities of up to 48 months. The debentures are set to be listed on the Bombay Stock Exchange (BSE), providing investors with a secure and reliable investment option.

https://businessworld.in/article/mankind-pharma-to-raise-rs-5000-cr-through-private-placements-534807

★★★★★★

Triveni scores $115m to expand immunology pipeline

Pharmaceutical technology, 2 October 2024

The Series B funds will expedite pipeline expansion and cover a clinical proof-of-concept study for TRIV-573. Triveni Bio has secured $115m in a Series B funding round to advance its preclinical antibody candidates for immunological and inflammatory diseases. The round was led by Goldman Sachs Alternatives and included support from both returning and new investors such as Fidelity Management & Research Company and Deep Track Capital. Triveni Bio raised $92m in its Series A financing round in October 2023. CEO Vishal Patel said the funding will accelerate the company's candidate TRIV-573 to a proof-of-concept study. TRIV-573 is a bispecific antibody designed to target kallikrein 5/7 (KLK5/7) and interleukin 13 (IL-13). KLK5/7, a serine protease, affects processes such as skin desquamation, inflammation, and immune response while IL-13 plays integral roles in allergic inflammation and fibrosis.

https://www.pharmaceutical-technology.com/news/triveni-scores-115m-to-expand-immunology-pipeline/

Genentech buys Regor's CDK inhibitors in $850m deal

Pharmaceutical technology, 1 October 2024

Genentech's parent company Roche said the $850m deal lines up with its plan to focus on three therapeutic areas including oncology. Genentech is strengthening its oncology pipeline by acquiring Regor Pharmaceuticals' portfolio of breast cancer cyclin-dependent kinase (CDK) inhibitors in an $850m deal. The deal, anticipated to close in Q4 2024, was unveiled by Genentech's parent company Roche at its pharma day in London. The pharmaceutical giant also shared that it is focusing on three major therapeutic areas – one being oncology.

Regor will continue to oversee its two ongoing Phase I trials of the CDK4/2 inhibitor RGT-419B until their completion. At that point, Genentech will take over the global clinical development, manufacturing, and commercialisation of the candidate. The deal also includes preclinical candidate RGT-587, which is a "Phase I ready" CDK4 inhibitor, intended to treat brain metastases.

https://www.pharmaceutical-technology.com/news/genentech-buys-regors-cdk-inhibitors-in-850m-deal/

★★★★★★

CCI approves Mankind Pharma's purchase of Bharat Serums for $1.6 bn

Business standard, 2 October 2024

Mankind Pharma, which has brands including Manforce condoms and Prega News pregnancy tests, signed an agreement to acquire Bharat Serums.

India's anti-trust regulator approved Mankind Pharma Ltd.'s Rs 13,630 crore ($1.6 billion) acquisition of vaccine-maker Bharat Serums and Vaccines Ltd., according to a release by the Competition Commission of India. Mankind Pharma, which has brands including Manforce condoms and Prega News pregnancy tests, signed an agreement to acquire Bharat Serums from a number of funds owned by private equity giant Advent International back in July. The proposed acquisition also requires approvals from the Turkish Competition Authority and Federal Ministry of Economic Affairs and Climate Action.

https://www.business-standard.com/companies/news/cci-approves-mankind-pharma-s-purchase-of-bharat-serums-for-1-6-bn-124100200927_1.html

★★★★★★

AI healthcare firm Qure.ai completes $65 mn Series D funding round

Business standard, 3 October 2024

The investment will expedite expansion into the US market and other geographies, increase investment into foundational AI models and enable complementary med-tech company acquisitions.

Qure.ai, an AI-led healthtech company, said that it has completed a $65 million Series D funding round. The Series D round saw the participation of new strategic and financial investors led by Lightspeed and 360 ONE Asset, joined by Merck Global Health Innovation Fund and Kae Capital. Existing investors also participated in the round, including Novo Holdings, Health Quad, and TeamFund.

https://www.business-standard.com/companies/start-ups/ai-healthcare-firm-qure-ai-completes-65-mn-series-d-funding-round-124092501368_1.html

★★★★★★

858 Therapeutics secures $50 million in series B funding

Pharmaletter, 27 September 2024

San Diego-based start-up 858 Therapeutics has raised $50 million in a series B financing round, led by Avidity Partners.

The funding round included participation from new investors Insight Partners, Mirae Asset Capital, and Alexandria Venture Investments, along with existing backers Versant Ventures, NEA, and Logos Capital. As part of the financing, Monal Mehta, managing director at Avidity Partners, has joined 858's board of directors.

https://www.thepharmaletter.com/pharmaceutical/858-therapeutics-secures-50-million-in-series-b-funding

★★★★★★

LoQus23 Therapeutics secures £35 million in series A funding

Pharmaletter, 2 October 2024

UK-based biotech LoQus23 Therapeutics has closed a £35 million ($43 million) series A financing round, led by Forbion, with support from SV Health Investors' Dementia Discovery Fund and Novartis Venture Fund.

The company, founded in 2019, is focused on developing small molecule drugs to address DNA instability in Huntington's disease and similar disorders.

The financing will drive the preclinical development of LoQus23's lead candidate, an allosteric MutSβ inhibitor, aimed at halting the progression of Huntington's disease.

https://www.thepharmaletter.com/pharmaceutical/loqus23-therapeutics-secures-35-million-in-series-a-funding

★★★★★★

Aktis raises $175M to fuel radiopharma drug development

BioPharma Dive, 30 September 2024

The company now has more than $300 million in cash at its disposal, which it plans to use to test alpha radiopharmaceuticals against solid tumors.

Boston-based Aktis Oncology has raised $175 million in fresh funding to advance its pipeline of radiopharmaceutical medicines for cancer.

The Series B round, announced by Aktis Monday, was led by RA Capital Management and co-led by RTW Investments and Janus Henderson Investors. It also drew in pharmas that had previously backed Aktis, namely Bristol Myers Squibb, Eli Lilly and Merck & Co., the latter of which invested via its MRL Ventures Fund.

https://www.biopharmadive.com/news/aktis-series-b-radiopharmaceutical-cancer-ra-capital-funding/728419/

★★★★★★

Arch raises another $3B biotech fund in pursuit of 'coolest' new science

BioPharma Dive, 27 September 2024

Even in a selective investment climate, the firm is "in the 'taking lots of risk' mode," according to co-founder Robert Nelsen. Arch Venture Partners, a prominent creator of biotechnology startups, has raised more than $3 billion for its 13th fund, the firm announced Thursday. The fundraise comes only two years after Arch secured a similar-sized haul that, at the time, was its largest to date. As it has in the past, the 38-year-old firm intends to use that cash to bet on cutting-edge science it believes can change healthcare. Arch has been a big proponent of the use of high-powered computing tools in drug discovery, for instance, and in a statement, co-founder and managing director Robert Nelsen noted how its team believes artificial intelligence can help enable "a more preventive, curative and equitable healthcare system."

https://www.biopharmadive.com/news/arch-venture-biotech-startup-fund-artificial-intelligence/728100/

Mithradote Bio Closes $1M Seed Funding

Finsmes, 2 October 2024

Mithradote Bio, a San Diego, CA-based biotechnology company developing the first self-administered antidote against drink spiking, closed a $1m seed funding round.

The round was co-led by Taho Pharma and Vickers Venture Partners and supported by development agreements with Haorui Pharmatech for API manufacturing and Taho Pharma for an oral delivery formulation.

The company intends to use the funds to advance development of M-101, a novel sublingual self-administered antidote against a spectrum of "date-rape" drugs, and initiate another pipeline program.

https://www.finsmes.com/2024/10/mithradote-bio-closes-1m-seed-funding.html

★★★★★★

Lonza completes US$ 1.2 billion acquisition of Roche's biologics site in US

Indian chemical news, 2 October 2024

The Vacaville site is one of the largest biologics manufacturing facilities in the world. Lonza, one of the world's largest healthcare development and manufacturing organizations, announced it has completed its acquisition of the Genentech large-scale biologics manufacturing site in Vacaville, California (US) from Roche for US$ 1.2 billion.

The Vacaville facility significantly extends Lonza's capacity for mammalian manufacturing in the US, the world's largest pharmaceutical market. It complements Lonza's existing East Coast manufacturing site in Portsmouth, New Hampshire, as well as its international network across Europe and Asia Pacific.

https://www.indianchemicalnews.com/general/lonza-completes-us-12-billion-acquisition-of-roches-biologics-site-in-us-23546

Evotec and Novo Nordisk in technology development partnership

Expresspharma, 26 September 2024

Evotec to receive funding and potential milestone payments as Novo Nordisk explores stem cell-based therapies in diabetes and cardiovascular diseases.

German drug and development company Evotec, has entered into a technology development partnership with Novo Nordisk to support clinical and commercial manufacturing of stem cell-based therapies, Evotec said on Thursday.

Evotec will receive funding for technology development activities in Germany and Italy, research and development funding, an undisclosed upfront payment and possible milestone and royalty payments, it added.

https://www.expresspharma.in/evotec-and-novo-nordisk-in-technology-development-partnership/

★★★★★★

PHARMA AND BIOLOGICS

SMALL MOLECULE

Boehringer Ingelheim opens $66.8m new cancer research facility

Pharmaceutical technology, 26 September 2024

The Angelika Amon research building will house 150 employees across 11 floors researching cancer therapies.

Boehringer Ingelheim has opened a €60m ($66.8m) research building in Vienna, Austria, as the company looks to double down in the oncology therapeutics space.The building is named after Angelika Amon, a Viennese pioneer in cell biology who died in 2020 following a battle with ovarian cancer. Boehringer Ingelheim said the scientist "was closely connected" to the company.

The Angelika Amon research building will house 150 employees across 11 floors, according to a 25 September press release.

https://www.pharmaceutical-technology.com/news/boehringer-ingelheim-opens-66-8m-new-cancer-research-facility/

★★★★★★

Recipharm and Exela announce exclusive strategic alliance for sterile manufacturing

Pharmaceutical manufacturer, 1 October 2024

Recipharm and Exela Pharma Sciences announced an exclusive strategic alliance aimed at enhancing sterile manufacturing capabilities in the United States.

This collaboration will provide Recipharm with access to Exela's manufacturing facility located in Lenoir, North Carolina. Recipharm will add to Exela's capabilities by offering its robust analytical capabilities, commercial expertise and Manufacturing Science and Technology (MSAT) support.

https://pharmaceuticalmanufacturer.media/pharma-manufacturing-news/latest-pharmaceutical-manufacturing-news/recipharm-and-exela-exclusive-strategic-alliance/

LARGE MOLECULE

Rwanda to start vaccine trials for Marburg disease in a few weeks

Reuters, 3 October 2024

Rwanda is poised to start vaccine and therapeutic clinical trials in the next few weeks to treat Marburg disease, its health minister said on Thursday, as the African nation battles its first outbreak of the viral fever that has killed 11.

The disease was detected in late September, with 36 cases reported so far, health ministry data shows.

https://www.reuters.com/business/healthcare-pharmaceuticals/rwanda-start-marburg-vaccine-trials-health-official-says-2024-10-03/

★★★★★★

AbbVie (ABBV) Submits Biologics License Application to the FDA for Telisotuzumab Vedotin

Streetinsider, 27 September 2024

AbbVie (NYSE: ABBV) today announced submission of a Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) for accelerated approval of telisotuzumab vedotin (Teliso-V) in adult patients with previously treated, locally advanced or metastatic epidermal growth factor receptor (EGFR) wild type, nonsquamous non-small cell lung cancer (NSCLC) with c-Met protein overexpression.

Approximately 85% of lung cancers are classified as NSCLC[1] and despite advances in treatment, lung cancer remains the leading cause of cancer-related deaths throughout the world.[2] The c-Met protein is a receptor tyrosine kinase found to be overexpressed in approximately 25% of advanced EGFR wild type, nonsquamous NSCLC patients[3] and is associated with a poor prognosis.[4,5,6] Teliso-V is being evaluated within this patient population who currently have very limited treatment options.

https://www.streetinsider.com/Corporate+News/AbbVie+%28ABBV%29+Submits+Biologics+License+Application+to+the+FDA+for+Telisotuzumab+Vedotin/23772423.html

★★★★★★

Improving the Downstream Processing of Biological Products

Genengnews, 2 October 2024

Despite the importance of downstream bioprocessing, there are many opportunities for improvement, according to a report by Alois Jungbauer, PhD, a retired professor of biotechnology at the University of Natural Resources and Life Sciences (BOKU) in Vienna, Austria, and his colleagues.

As these scientists noted: "Downstream processing plays an important role in the supply of pharmaceuticals and, in particular, biopharmaceuticals, where a large proportion of the production costs are attributable to the recovery and purification processes."

https://www.genengnews.com/topics/bioprocessing/improving-the-downstream-processing-of-biological-products/

★★★★★★

Roche plans to launch drugs and slash development costs

Financial times, 30 September 2024

Swiss pharma group is a high spender on R&D but has had misses in Alzheimer's and cancer. Please use the sharing tools found via the share button at the top or side of articles. Copying articles to share with others is a breach of FT.com T&Cs and Copyright Policy. Email licensing@ft.com to buy additional rights. Subscribers may share up to 10 or 20 articles per month using the gift article service.

Roche is planning to launch 20 medicines by the end of the decade and cut research costs for new drugs by a fifth, according to a strategy update on Monday. Thomas Schinecker, chief executive of the Swiss pharmaceutical company, outlined a focus on five areas: oncology and haematology, neurology, cardiovascular and metabolic diseases, eye diseases and immune diseases, as part of a shake-up of the company's research and development. The company later clarified that nine of the 20 drugs had already been launched. Medicines would have to combine significant therapeutic benefits with commercial opportunities or their research programmes could be axed, he said. The company will also aim to increase the success rate of late-stage phase 3 trials by more than 20 per cent, and cut research costs for each new drug launched by 20 per cent.

https://www.ft.com/content/a6bf0e1b-278d-42c0-8888-06a3d9da8933

★★★★★★

Sanofi's dupixent approved in the US as the first-ever biologic medicine for patients with COPD

Indian pharma post, 27 September 2024

Dupixent is indicated for the approximately 300,000 adults in the US with inadequately controlled COPD and an eosinophilic phenotype.

The US Food and Drug Administration (FDA) has approved Dupixent (dupilumab) as an add-on maintenance treatment of adults with inadequately controlled chronic obstructive pulmonary disease (COPD) and an eosinophilic phenotype. Dupixent is the first biologic medicine approved in the US to treat these patients.

https://www.indianpharmapost.com/drug-approval/sanofis-dupixent-approved-in-the-us-as-the-first-ever-biologic-medicine-for-patients-with-copd-16246

★★★★★★

REGULATORS AND REGULATORY ACTIONS

Glenmark Pharma Aurangabad unit clears FDA test

CNBC TV 18, 23 September 2024

The United States FDA inspection, conducted between September 9-20, concluded with with zero observations. Shares of Glenmark Pharmaceuticals Ltd ended at ₹1,635, down by ₹16.15, or 0.98%, on the BSE. "This is to inform you that the U.S. FDA has issued Form 483 with zero observations after an inspection at the company's formulation manufacturing facility based out of Chhatrapati Sambhaji Nagar (Aurangabad), India between September 09 and September 20, 2024," the company said in a stock exchange filing. The inspection, conducted between September 9-20, 2024, concluded with zero observations.

https://www.cnbctv18.com/market/stocks/glenmark-pharmaceuticals-share-price-aurangabad-facility-us-fda-inspection-zero-observations-19480075.htm

★★★★★★

Fresenius Kabi wins FDA approval for Stelara biosimilar Otulfi

Pharmaceutical technology, 1 October 2024

Otulfi is the fourth Stelara biosimilar approved in the US but will not launch until early 2025. Fresenius Kabi and Formycon have won US Food and Drug Administration (FDA) approval for Otulfi (ustekinumab-aauz), a biosimilar that references Johnson & Johnson's (J&J) blockbuster inflammatory drug Stelara (ustekinumab). As with Stelara, Otulfi is

approved for the treatment of Crohn's disease, ulcerative colitis, moderate to severe plaque psoriasis and active psoriatic arthritis, as per a 30 September press release. The FDA based its decision on data that showed comparable efficacy, safety, pharmacokinetics and immunogenicity to J&J's drug in patients with moderate to severe psoriasis vulgaris, according to Fresenius Kabi and its commercial partner Formycon.

https://www.pharmaceutical-technology.com/news/fresenius-kabi-wins-fda-approval-for-stelara-biosimilar-otulfi/

★★★★★★

Alembic Pharma gets USFDA nod for generic medication

ETHealthworld, 3 October 2024

The approved ANDA is therapeutically equivalent to GlaxoSmithKline LLC's Lamictal XR extended-release tablets in strength of 200 mg, 250 mg, and 300 mg, it added

New Delhi: Alembic Pharmaceuticals on Monday said it has received approval from the US health regulator to market a generic medication used to treat moderate-to-severe psoriasis of the scalp. The company has received final approval from the US Food & Drug Administration (USFDA) for its abbreviated new drug application (ANDA) for Betamethasone Valerate Foam, the drug firm said in a statement.

https://health.economictimes.indiatimes.com/news/pharma/drug-approvals-launches/alembic-pharma-gets-usfda-nod-for-generic-medication/113901931?utm_source=latest_news&utm_medium=homepage

★★★★★★

Lupin says USFDA issues three observations for its Pithampur facility

CNBC TV 18, 28 September 2024

Lupin Share Price | The USFDA inspected the facility from September 16 to September 27. The pharma company said it is addressing the observations comprehensively and will respond to the US drug regulator within the stipulated timeframe.

https://www.cnbctv18.com/market/lupin-share-price-usfda-three-observations-pithampur-facility-stock-reaction-19484085.htm

★★★★★★

India's Alkem Labs denies its products failed quality test

Reuters, 27 September 2024

BENGALURU- India's Alkem Laboratories on Friday denied claims that batches of its products, Pan-D and Clavam 625, are not of standard quality as the country's drug regulator flagged, adding that those samples were fake.

https://www.reuters.com/business/healthcare-pharmaceuticals/indias-alkem-labs-denies-its-products-failed-quality-test-2024-09-27/#:~:text=BENGALURU%2C%20Sept%2027%20(Reuters),that%20those%20samples%20were%20fake.

★★★★★★

UBS picks 2 pharma stocks that are likely to give 23-26% returns

Economics times, 28 September 2024

Ascribing sell ratings to Lupin, Dr Reddy's Laboratories, Zydus Lifesciences and Aurobindo Pharma, the brokerage said the US generic market has been declining and the pace could worsen.
Brokerage UBS prefers Sun Pharma and Cipla among Indian drugmakers and expects the stocks to return 26% and 23%, respectively, over Friday's closing.

https://economictimes.indiatimes.com/markets/stocks/news/ubs-picks-2-pharma-stocks-that-are-likely-to-give-23-26-return/articleshow/113754061.cms?UTM_Source=Google_Newsstand&UTM_Campaign=RSS_Feed&UTM_Medium=Referral&from=mdr

★★★★★★

Biocon gets 4 observations from USFDA for Bengaluru API facility

Money control, 28 September 2024

The US Food and Drug Administration (USFDA) conducted a surveillance inspection of the API facility (Site 2), located at Bengaluru from September 23- 27, 2024, the company said in a regulatory filing.

Biocon on Saturday said the US health regulator has issued four observations after inspecting its Bengaluru-based API (active pharmaceutical ingredient) facility.

https://www.moneycontrol.com/news/business/biocon-gets-4-observations-from-usfda-for-bengaluru-api-facility-12831531.html

Zydus gets USFDA approval to produce its generic prostate cancer drug

Business Standard, 1 October 2024

Enzalutamide capsules are androgen receptor inhibitors indicated for the treatment of patients with metastatic castration-resistant prostate cancer. Zydus Lifesciences on Saturday said it has received approval from the US health regulator to produce generic prostate cancer treatment drug.

The company has received approval from the US Food and Drug Administration (USFDA) to manufacture Enzalutamide capsules (40 mg), it said in a regulatory filing.

https://www.business-standard.com/companies/news/zydus-gets-usfda-approval-to-produce-its-generic-prostate-cancer-drug-124092800576_1.html

★★★★★★

Aurobindo Pharma stock drops 4.5% after USFDA flags 10 observations for arm Apitoria's API unit

Money control, 30 September 2024

Last week, brokerage firm UBS Securities also initiated a 'sell' call on Aurobindo Pharma, assigning it a price target of Rs 1,333, predicting a 12 percent downside.

The US drug regulator conducted its inspection of the Telangana API (Active Pharmaceutical Ingredient) manufacturing unit on September 23-27. The company further stated that these observations are procedural in nature and will be responded to within the stipulated time.

https://www.moneycontrol.com/news/business/markets/aurobindo-pharma-stock-drops-4-5-after-usfda-flags-10-observation-for-arm-apitorias-api-unit-12832305.html

★★★★★★

Zydus Life shares gain 1% today after US FDA approves cancer drug worth $870 million

Money control, 30 September 2024

Zydus Lifesciences has received a significant approval from the US FDA for Enzalutamide capsules, which are used in treatment of metastatic castration-resistant prostate cancer.

Zydus Life share price has jumped 76 percent over the past year, taking the company's market capitalisation to over Rs 1.1 lakh crore.

Zydus Lifesciences Ltd's shares gained as much as 1 percent in the opening trade amid a muted market on September 30, after the company received final approval from the United States Food and Drug Administration (USFDA) for its prostate cancer medicine -- Enzalutamide Capsules, 40 mg.

https://www.moneycontrol.com/news/business/stocks/zydus-life-shares-gain-1-today-after-us-fda-approves-cancer-drug-worth-870-million-12832055.html

★★★★★★

EU withdraws marketing authorisation for Abbvie's hepatitis C drug

Reuters, 1 October 2024

The European Medicines Agency said on Tuesday that it has withdrawn the marketing authorisation for Abbvie's hepatitis C drug Exviera at the request of the company.

The regulator said it withdrew the authorisation on Sept. 25. It added that the authorisation holder, AbbVie Deutschland GmbH & Co. KG, had informed the European Commission of its decision to "permanently discontinue the marketing of the product for commercial reasons."

EU withdraws marketing authorisation for Abbvie's hepatitis C drug | Reuters

★★★★★★

Moderna fends off Alnylam US patent lawsuit over COVID shots, for now

Reuters, 3 October 2024

Alnylam Pharmaceuticals admitted defeat, for now, in a lawsuit in Delaware federal court that accused Moderna's blockbuster COVID-19 vaccines of infringing one of its patents.

Alnylam and Moderna told U.S. District Judge Colm Connolly in a joint filing, on Wednesday that Alnylam could not win its case after the judge interpreted part of the patent in a way that favored Moderna.

The companies asked the court to dismiss the case without prejudice and allow Alnylam to refile the lawsuit if an appeals court disagrees with Connolly's interpretation.

https://www.reuters.com/legal/litigation/moderna-fends-off-alnylam-us-patent-lawsuit-over-covid-shots-now-2024-10-02/

★★★★★★

Synchron's brain-computer interface clears year-long safety study

Fierce Biotech, 2 October 2024

Synchron has reported that its miniature brain-computer interface implant, threaded up through the blood vessels to help read the activity of the motor cortex, showed no major side effects in a year-long human safety study.

The company's COMMAND trial enrolled six participants who had lost the use of their arms to paralysis, with support from the NIH's BRAIN Initiative. All six met the study's primary endpoint, showing no device-linked serious adverse events related to the brain or vasculature.

https://www.fiercebiotech.com/medtech/synchrons-brain-computer-interface-clears-year-long-safety-study

★★★★★★

UNICEF secures one million mpox vaccines for Africa

Pharmaceutical technology, 27 September 2024

Bavarian Nordic has already said it would prioritise mpox vaccine production to fulfil orders this year. UNICEF has reached an agreement with mpox vaccine manufacturer Bavarian Nordic to supply one million doses of the shot for the hardest-hit countries in Africa. The supply, which includes a 500,000-dose commitment by the Global Alliance for Vaccines and Immunization (GAVI) announced last week, means 2.5 million doses of the MVA-BN vaccine have been outlaid to Africa, according to Bavarian Nordic's CEO Paul Chaplin.

The company said it would work with UNICEF to "swiftly deliver the vaccines upon request", in a 26 September statement.

https://www.pharmaceutical-technology.com/news/unicef-secures-one-million-mpox-vaccines-for-africa/

★★★★★★

Aspen Neuroscience, underway with Parkinson's cell therapy trial, bolsters manufacturing with new San Diego facility

Fierce Pharma, 2 October 2024

After a relatively quiet stretch, Aspen Neuroscience is rolling out a major upgrade to its in-house manufacturing. The project will support production for Aspen's autologous cell therapy studies and future capacity needs for the company's personalized medicines.

The new 22,000-square-foot facility near Aspen's headquarters in the Torrey Pines neighborhood of San Diego will specialize in the production of induced pluripotent stem cell (iPSC)-derived cell therapies. Specifically, the plant will be designed for production and testing of Aspen's iPSC cell therapy candidate ANPD001, which the company is trialing in Parkinson's disease, Aspen said in a release.

https://www.fiercepharma.com/pharma/parkinsons-cell-therapy-trial-advances-aspen-neuroscience-unveils-22000-sq-ft-expanded-house

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MEDTECH

FDA clears Pi-Cardia's leaflet-splitting device for valve-in-valve TAVR procedures

FierceBiotech, 1 October 2024

The FDA has granted a de novo clearance to Pi-Cardia's ShortCut device, designed to open up previously implanted heart valves and clear a path for blood to flow into the coronary arteries, allowing patients to undergo a successive transcatheter aortic valve replacement procedure.

As some structural heart implants are only rated to last for a number of years, many patients with severely narrowed valves may one day require a replacement procedure—with a new valve placed within the confines of their prior valve. That need may also increase in the future, whether due to older patients living longer or with implants being placed in a comparatively younger population.

However, a problem may arise when the new implant expands and pushes aside the old leaflets—forcing them up against the walls of the heart's outflow tract and covering up the entrances to the coronary arteries.

https://www.fiercebiotech.com/medtech/fda-clears-pi-cardias-leaflet-splitting-device-valve-valve-tavr-procedures

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INTERESTING MEDICAL NEWS

Rickets on the Rise: The Growing Concern of Vitamin D Deficiency
ETHealthworld, 2 October 2024

With the world's largest population, and children (0-14 years) constituting 18.6% of the population, India is facing a massive health issues 46% of children aged 0-10 years are prone to rickets. While the government is yet to come up with a national survey, a clinical study by K Ashwin Reddy in 2020, confirmed this alarming number. This is a major cause of concern since rickets leads to the softening and weakening of bones, stunted growth and, in severe cases, skeletal deformities.

https://health.economictimes.indiatimes.com/news/industry/rickets-on-the-rise-the-growing-concern-of-vitamin-d-deficiency/113815004#:~:text=With%20the%20world's%20largest%20population,years%20are%20prone%20to%20rickets.

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Patients With Long-COVID Show Abnormal Lung Perfusion Despite Normal CT scans

Manuela Callari, September 12, 2024

VIENNA — Some patients who had mild COVID-19 infection during the first wave of the pandemic and continued to experience postinfection symptoms for at least 12 months after infection present abnormal perfusion despite showing normal CT scans. Researchers at the European Respiratory Society (ERS) 2024 International Congress called for more research to be done in this space to understand the underlying mechanism of the abnormalities observed and to find possible treatment options for this cohort of patients.

Laura Price, MD, PhD, a consultant respiratory physician at Royal Brompton Hospital and an honorary clinical senior lecturer at Imperial College London, London, told *Medscape Medical News* that this cohort of patients shows symptoms that seem to correlate with a pulmonary microangiopathy phenotype.

"Our clinics in the UK and around the world are full of people with long-COVID, persisting breathlessness, and fatigue. But it has been hard for people to put the finger on why patients experience these symptoms still," Timothy Hinks, associate professor and Wellcome Trust Career Development fellow at the Nuffield Department of Medicine, NIHR Oxford Biomedical Research Centre senior research fellow, and honorary consultant at Oxford Special Airway Service at Oxford University Hospitals, England, who was not involved in the study, told *Medscape Medical News*.

The Study

Researchers at Imperial College London recruited 41 patients who experienced persistent post-COVID-19 infection symptoms, such as breathlessness and fatigue, but normal CT scans after a mild COVID-19 infection that did not require hospitalization. Those with pulmonary emboli or interstitial lung disease were excluded. The cohort was predominantly female (87.8%) and nonsmokers (85%), with a mean age of 44.7 years. They were assessed over 1 year after the initial infection.

Exercise intolerance was the predominant symptom, affecting 95.1% of the group. A significant proportion (46.3%) presented with myopericarditis, while a smaller subset (n = 5) exhibited dysautonomia. Echocardiography did not reveal pulmonary hypertension. Laboratory findings showed elevated angiotensin-converting enzyme and antiphospholipid antibodies. "These patients are young, female, nonsmokers, and previously healthy. This is not what you would expect to see," Price said.

Baseline pulmonary function tests showed preserved spirometry with forced expiratory volume in 1 second and forced vital capacity above 100% predicted. However, diffusion capacity was impaired, with a mean diffusing capacity of the lungs for carbon monoxide (DLCO) of 74.7%. The carbon monoxide transfer coefficient (KCO) and alveolar volume were also mildly reduced. Oxygen saturation was within normal limits.

These abnormalities were through advanced imaging techniques like dual-energy CT scans and ventilation-perfusion scans. These tests revealed a non-segmental and "patchy" perfusion abnormality in the upper lungs, suggesting that the problem was vascular, Price explained.

Cardiopulmonary exercise testing revealed further abnormalities in 41% of patients. Peak oxygen uptake was slightly reduced, and a significant proportion of patients showed elevated alveolar-arterial gradient and dead space ventilation during peak exercise, suggesting a ventilation-perfusion mismatch.

Over time, there was a statistically significant improvement in DLCO, from 70.4% to 74.4%, suggesting some degree of recovery in lung function. However, DLCO values did not return to normal. The KCO also improved from 71.9% to 74.4%, though this change did not reach statistical significance. Most patients (n = 26) were treated with apixaban, potentially contributing to the observed improvement in gas transfer parameters, Price said.

The researchers identified a distinct phenotype of patients with persistent post-COVID-19 infection symptoms characterized by abnormal lung perfusion and reduced gas diffusion capacity, even when CT scans appear normal. Price explains that this pulmonary

microangiopathy may explain the persistent symptoms. However, questions remain about the underlying mechanisms, potential treatments, and long-term outcomes for this patient population.

Causes and Treatments Remain a Mystery

Previous studies have suggested that COVID-19 causes endothelial dysfunction, which could affect the small blood vessels in the lungs. Other viral infections, such as HIV, have also been shown to cause endothelial dysfunction. However, researchers don't fully understand how this process plays out in patients with COVID-19.

"It is possible these patients have had inflammation insults that have damaged the pulmonary vascular endothelium, which predisposes them to either clotting at a microscopic level or ongoing inflammation," said Hinks.

Some patients (10 out of 41) in the cohort studied by the Imperial College London's researchers presented with Raynaud syndrome, which might suggest a physiological link, Hinks explains. "Raynaud's is a condition of vascular control or dysregulation, and potentially, there could be a common factor contributing to both breathlessness and Raynaud's."

He said there is an encouraging signal that these patients improve over time, but their recovery might be more complex and lengthy than for other patients. "This cohort will gradually get better. But it raises questions and gives a point that there is a true physiological deficit in some people with long-COVID."

Price encouraged physicians to look beyond conventional diagnostic tools when visiting a patient whose CT scan looks normal yet experiences fatigue and breathlessness. Not knowing what causes the abnormalities observed in this group of patients makes treatment extremely challenging. "We need more research to understand the treatment implications and long-term impact of these pulmonary vascular abnormalities in patients

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Ozempic and Suicide: What the Real-World Data Reveal

F. Perry Wilson, MSCE, MD, DISCLOSURES | September 04, 2024

This transcript has been edited for clarity.

Welcome to *Impact Factor*, your weekly dose of commentary on a new medical study. I'm Dr F. Perry Wilson of the Yale School of Medicine.

In July of 2023, the European Medicines Agency released a statement that threatened to put the brakes on what had been the runaway success of the new weight loss drugs, GLP-1 receptor agonists like semaglutide (Ozempic) and tirzepatide (Mounjaro).

The agency announced that it was conducting a formal review into reports that the use of these drugs could increase the risk for suicide and suicidal thoughts.

The reason for the review? The Icelandic Medicines Agency had received reports of up to 150 people who took the drugs and experienced suicidal thoughts or self-injury.

The easiest way to prove that a drug might increase the risk for death from suicide is to look at randomized trial data: If individuals randomized to a GLP-1 receptor agonist die from suicide at a higher rate than those randomized to placebo, you've got your causality signal. But suicide is rare — occurring in about 14 per 100,000 people in the United States— and people who enrol in randomized trials are often heavily screened to ensure that they don't have any psychological issues at baseline. It's no surprise, then, that the randomized trial data have not shown a psychiatric safety risk for the new weight loss drugs.

Which means, if you really want to figure out whether this risk is real, you must use real-world data. And real-world data are like crude oil: hard to come by, difficult to extract, and messy. Fortunately for us, we have Scandinavia.

They say that countries like Sweden and Denmark have some of the happiest populations in the world. I suspect that this is driven largely by epidemiologists, who are thrilled to have access to medical datasets that basically encompass every person in the entire country for their whole life.

You can use those datasets for some pretty impressive things, like trying to figure out whether Ozempic causes suicide. This is exactly what researchers did in an analysis appearing in *JAMA Internal Medicine.*

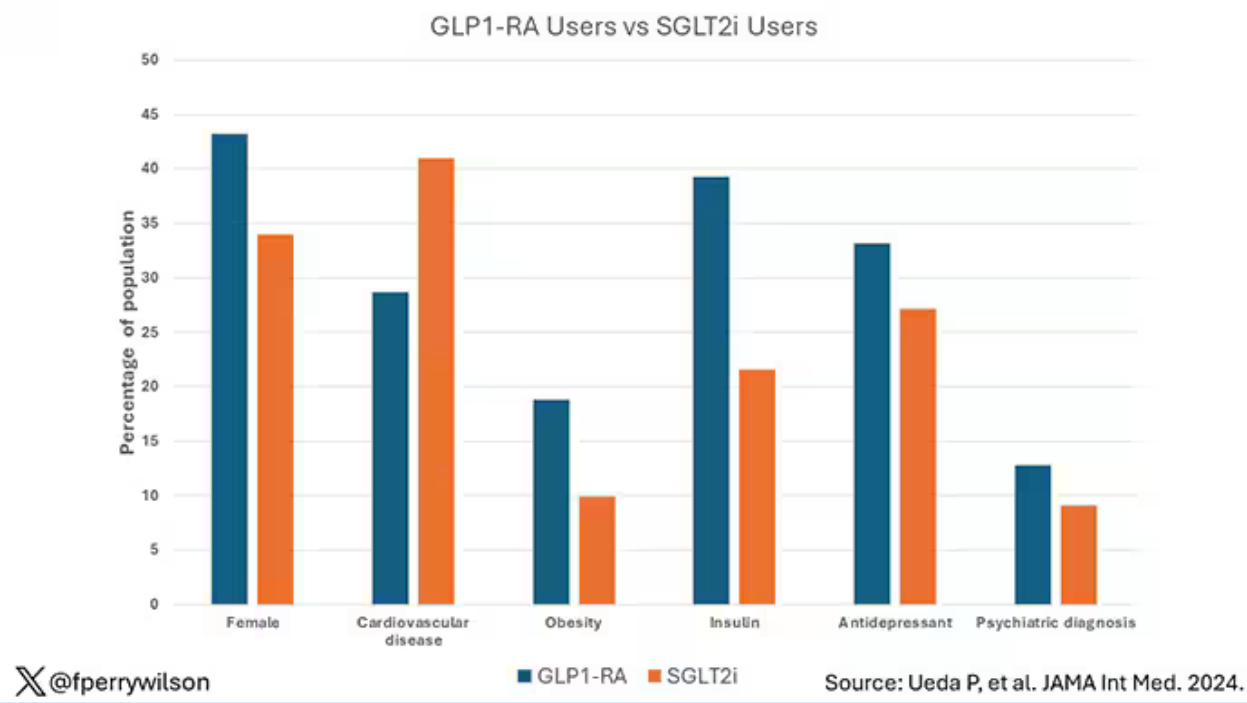
But first things first. Is it even biologically plausible that Ozempic could lead to suicide? I think it is, actually. First off, we know that the GLP-1 receptor agonists act on receptors in the brain; any drug that can get across the blood-brain barrier, in theory, can have

adverse (or positive) psychiatric effects. Also, as I discussed recently, these drugs can have pretty dramatic effects beyond their ability to curb appetite for food: decreasing compulsive gambling and shopping, reducing alcohol intake, and helping to quit smoking. These are all good things, of course, but you wonder whether they could be having some effect on psychological reward systems, and maybe disrupting that, in some people, could lead to despair.

To figure it out, the researchers identified everyone in Sweden and Denmark who started taking semaglutide or liraglutide for diabetes from 2013 to 2021. As a control group, they identified everyone with diabetes who started taking an SGLT2 inhibitor in the same timeframe. Both drug classes are used for diabetes treatment, but it is worth noting that SGLT2 inhibitors don't have much effect on weight.

In any case, 124,517 adults were prescribed Ozempic or an Ozempic-like drug, and 174,036 started taking an SGLT2 inhibitor.

This is not a randomized trial, of course. People who took Ozempic were different from those who took SGLT2 inhibitors. The Swedish data show that those taking Ozempic were more likely to be female, less likely to have cardiovascular disease, more likely to have a diagnosis of obesity, and more likely to be taking insulin.

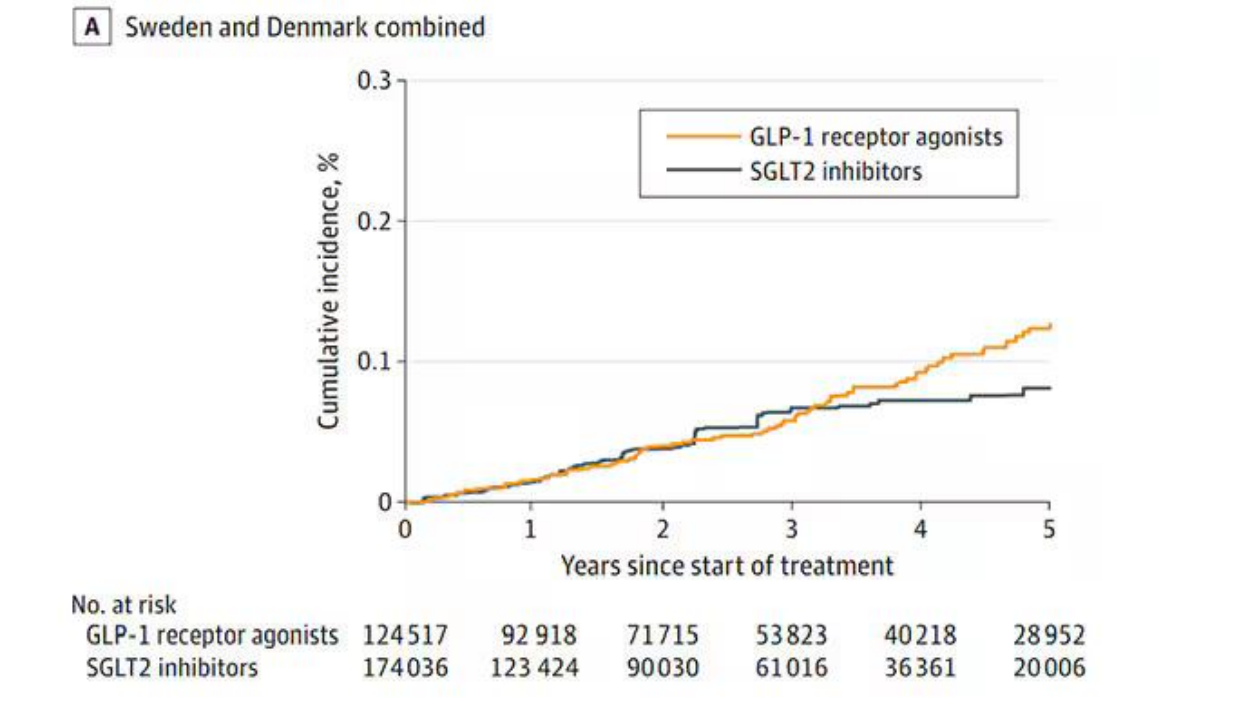


From a psychiatric standpoint, prior to starting the drugs, those who were prescribed Ozempic were more likely to be using or to have previously used antidepressants and to have had an outpatient visit for a psychiatric diagnosis.

The authors controlled for these important differences using propensity scores, which I've covered before, if you want a little primer. After that process, the groups were much more balanced.

That done, they looked forward in time to see who would die from suicide, suffer nonfatal self-harm, or — among those without a prior psychiatric diagnosis — develop a new diagnosis of anxiety or depression.

The topline results show that 77 new Ozempic users died from suicide (6 out of 10,000 people) as did 71 new SGLT2 inhibitor users (4 out of 10,000 people).



After accounting for the differences between the two groups at baseline, the authors calculated an overall risk for suicide that is 25% higher for the GLP-1 receptor agonist users, though the margin of error is large here, ranging from a 17% reduction in risk to an 88% increase (hazard ratio [HR], 1.25; 95% CI, 0.83-1.88).

When death from suicide and nonfatal self-harm were combined, GLP-1 receptor agonists appear to be protective (HR, 0.83; 95% CI, 0.07-0.97)

Looking at new psychiatric diagnoses associated with GLP-1 receptor agonists, it seems to be a total wash (HR, 1.01; 95% CI, 0.97-1.06).

What have we learned here? At the top, I explained how randomized trials are not ideal for detecting differences in rare events such as suicide, and we need to depend on real-world data.

And yet here it is: more than 100,000 users of Ozempic with a reasonable control group, and the outcome is equivocal. The headline is certainly "There is no significant association between Ozempic and suicide." The results of this study are 100% consistent with that statement, because it's clear that you could see results like this due to chance alone; that's why the 95% confidence interval of risk crosses 1.

Negative results are tricky, however. You can conclude that no relationship was evident from these data — which is the case here — but it's harder to conclude that there is no risk whatsoever. To do that, you need to look at the range of the effect estimate, and the data from this high-quality, large, population-based study are consistent with Ozempic and sister drugs preventing suicide, or increasing the rate significantly.

I should point out that this is not the only study of this type. This one, in *Nature Medicine*, looked at more than a million patients and found that the use of Ozempic and similar drugs might substantially *decrease* the rate of death from suicide.

And, of course, suicide is a product of multiple interacting factors: the individual's psychological state, the services available to them, the culture they are immersed in, and so on. Scandinavia, with its high national happiness rate and paradoxically high suicide rate, may not be comparable to the United States.

For now, the weight of evidence does not suggest a major risk here. But it's not a bad idea to remember, whether prescribing these drugs or taking them, that they do affect the brain — that is how they work — and to be on the lookout for any changes, positive or negative, that might result from that interaction.