Friday, 3 April 2026

CONTENT *(Highlights)*

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UPCOMING EVENTS

Join us at the **2nd MedTech Meets AI Conference** in **Barcelona on October 1 & 2**, hosted by **UBIQ Events**. This premier **MedTech summit** will bring together senior leaders and innovators from across the **medical device**, **medical technologies**, and **life sciences** sectors to explore the cutting edge of artificial intelligence in healthcare. The conference will feature real-world case studies, practical applications, and expert insights into how AI is being implemented across diagnostics, imaging, robotics, data analytics, and more. Key focus areas include:

1 - Transforming Diagnostics with AI: The Future of Disease Detection
2 - AI-Driven Imaging: The New Frontier of Medical Imaging and Radiology
3 - From Data to Diagnosis: The Role of AI in Medical Big Data
4 - AI-Powered Robotics in Medicine: Advancing Surgical Precision
5 - Ethical and Regulatory Considerations for AI in Healthcare
6 - The Future of AI in MedTech: Challenges, Innovations, and Impact

Whether you're a MedTech executive, healthcare innovator, or AI strategist, this **conference** offers a unique opportunity to connect with peers, discover emerging trends, and gain actionable insights that are reshaping the future of **medical technology**.

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DEALS AND FUNDING

Eli Lilly To Buy Centessa Pharma For Up To $7.8 Billion; Centessa Shares Skyrocket

Investors Business Daily, 31 March 2026

Eli Lilly announced what an analyst called an "incredibly smart" acquisition Tuesday, maneuvering into the sleep-wake disorders space with the takeover of Centessa Pharmaceuticals for up to $7.8 billion.

Centessa stock surged 44%, closing at 39.72, while Lilly shares jumped 3.7% to 919.77.

The small biotech company is working on treatments for narcolepsy and idiopathic hypersomnia. Its drugs are in the orexin space, a next-generation approach to sleep disorders. These drugs work on orexin receptors in the brain to promote wakefulness.

Evercore ISI analyst Umer Raffat called the deal "incredibly smart," saying Lilly management is "thinking several chess moves ahead."

"I think Lilly may have just landed a flagship molecule for the next mass market beyond GLP-1," Raffat said in a client note, referencing Eli Lilly's highly successful type 2 diabetes and weight-loss drugs. "And I'm not talking narcolepsy alone."

In addition to its sleep-wake disorders pipeline, Centessa is also working on treatments for neurological, neurodegenerative and neuropsychiatric disorders. Raffat sees a peak sales potential "that could easily top" $5 billion and perhaps run up to $10 billion for Centessa's products.

Eli Lilly's Game Of Chess

The initial deal values Centessa at $6.3 billion. But Lilly agreed to pay an additional $9 per share in a contingent value right, or CVR, tied to a handful of regulatory approvals. The CVR bumps the total deal value up by $1.5 billion.

Leerink Partners analyst David Risinger says the deal is "compelling for both companies." Lilly will gain a portfolio of potential blockbuster candidates at a 38% premium, with an additional 24% premium tied to the CVR. The deal is expected to close in the third quarter.

Centessa isn't the only game in the orexin space.

Last month, Alkermes (ALKS) wrapped its $2.4 billion takeover of Avadel

Pharmaceuticals. The deal bolsters Alkermes' pipeline of drugs to treat sleep-wake

disorders. Takeda Pharmaceutical (TAK) recently asked the Food and Drug Administration to approve its twice-daily orexin-targeting pill for narcolepsy type 1. That drug could win approval in the third quarter.

"LLY is making a disciplined move into the next-generation sleep pharmacology that fills a clear portfolio gap and signals renewed confidence in (central nervous system) innovation," RBC Capital Markets analyst Trung Huynh said in a report.

He noted Eli Lilly has a growing presence in depression, pain and neurodegeneration, but the company has "lacked a credible insomnia position." In this "high-unmet need" space, orexin biology is driving differentiation, he added.

https://www.investors.com/news/technology/eli-lilly-centessa-pharmaceuticals-acquisition-narcolepsy-insomnia/

★★★★★★★

Koye Pharma next on Warburg's health play

The Economic Times, 31 March 2026

Global private equity fund Warburg Pincus is nearing a deal to buy Koye Pharma. The Mumbai-based drugmaker focuses on women's health, respiratory care, and anti-diabetes drugs. This acquisition, valued at approximately ₹300 crore, marks Warburg Pincus's third investment in India's growing medicine market. Koye Pharma has shown strong growth recently, with sales around ₹160 crore.

Mumbai: Global private equity fund Warburg Pincus is in advanced discussions to acquire Mumbai-based Koye Pharma, a drugmaker that has built its presence across women's health, respiratory care, and anti-diabetes drugs, besides consumer health and medical devices.
"The deal for Koye may be signed at roughly ₹300 crore," a person aware of the development told ET.

Currently, Koye is owned by Aries Holdings, a healthcare-focused fund launched by Chinta Bhagat, the former Asia head of L Catterton.

https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/koye-pharma-next-on-warburgs-health-play/articleshow/129934812.cms?utm_source=contentofinterest&utm_medium=text&utm_campaign=cppst

★★★★★★★

Royalty Pharma, Johnson & Johnson in $500 Million Autoimmune Drug Funding Pact

Market Watch, 30 March 2026

Royalty Pharma has inked a $500 million research-and-development co-funding agreement with Johnson & Johnson to support development of a proposed drug for autoimmune diseases.

Royalty Pharma, a New York biopharmaceutical royalties investor, on Monday said it will provide the funding in 2026 and 2027 to advance the development of Johnson & Johnson's JNJ-4804 drug candidate.

JNJ-4804 is currently in Phase 2 studies for the autoimmune diseases ulcerative colitis, psoriatic arthritis and Crohn's disease.

New Brunswick, N.J., pharmaceutical giant J&J last month struck a deal under which asset manager Blackstone will help fund the development of its bleximenib drug candidate for the blood cancer acute myeloid leukemia.

Royalty Pharma, Johnson & Johnson in $500 Million Autoimmune Drug Funding Pact - MarketWatch

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Merck buying Terns in $6.7B deal to bolster its cancer portfolio before key Keytruda patent expires

Business, 25 March 2026

Merck is buying oncology company Terns Pharmaceuticals in a deal valued at approximately $6.7 billion as the pharmaceutical giant works on beefing up its cancer portfolio before a key patent on its cancer drug Keytruda expires in two years.

Merck received accelerated approval for Keytruda from the Food and Drug Administration in September 2014 to treat advanced or unresectable melanoma. The drug has since been approved to treat more than 15 types of cancers and has been a key contributor to Merck's revenue.

Terns of Foster City, California, is currently developing a drug to treat certain patients with chronic myeloid leukemia, which is a slow growing type of blood cancer that leads to an overproduction of white blood cells that accumulate in the blood and bone marrow, disrupting the production of healthy blood cells.

A Merck subsidiary will pay $53 per share in cash for each Terns share.

Terns' stock rose more than 5% in early trading Wednesday. Merck shares were up less than 1%.

Both companies' boards have approved the transaction, which is expected to close in the second quarter. The deal is subject to a majority of Terns' stockholders tendering their shares in a tender offer that will be initiated by a Merck subsidiary.

Rahway, New Jersey-based Merck said it will book a charge of about $5.8 billion, or approximately $2.35 per share, related to the acquisition in its second-quarter and full-year results.

Merck buying Terns in $6.7B deal to bolster its cancer portfolio before key Keytruda patent expires | WWTI - InformNNY.com

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Neion Bio Emerges from Stealth with Multi-Product Biosimilar Partnership Leveraging Its Cutting-Edge Genetic Engineering Platform

Globe Newswire, 26 March 2026

- Neion Bio's Raptor™ platform utilizes cutting-edge genetic engineering to harness nature's most efficient molecular factories for the production of critical medicines at lower cost, with minimal capital investment, and with a fully localized and resilient supply chain
- Neion Bio has inked a commercial partnership for the co-development and supply of up to three (3) monoclonal antibodies in a deal that includes up-front and milestone payments along with participation in commercial profits
- Neion Bio is led by a multidisciplinary founding team—Demetrios (Dimi) Kellari, Sam Levin, and Sven Bocklandt—and has appointed industry veteran Ming Li to head its commercial operations across the biopharma ecosystem
- Founded in 2024, Neion Bio is backed by leading venture capital firms – its most recent funding round was led by Caffeinated Capital, with significant participation from Basis Set Ventures and Haystack VC, among others

Neion Bio, a biotechnology company revolutionizing the production of biologic medicines, today announced its emergence from stealth and the signing of its first co-development and supply agreement with a major global pharmaceutical company. Neion's Raptor™ platform utilizes the latest genetic engineering tools to produce recombinant biologics in

eggs, enabling scalable and efficient production of virtually any therapeutic protein. This

commercial deal provides Neion with near-term revenue through up-front and milestone payments, along with long-term participation through profit sharing once products are commercialized.

"Biopharma manufacturing has not changed in decades, and has become a major bottleneck in advancing medical breakthroughs, increasing accessibility of existing therapies, and localizing domestic production of critical medicines," said Dimi Kellari, co-founder and CEO of Neion Bio. "Neion Bio's platform removes the capital intensity and process constraints of traditional biomanufacturing enabling highly scalable and resilient production while materially lowering the cost of development and supply."

Neion's Raptor™ platform harnesses nature's most powerful molecular factory – the egg – to create a highly reproducible and consistent manufacturing process. Neion re-engineers these self-contained, naturally sterile vesicles to produce virtually any biological therapeutic at an order of magnitude lower costs. The Raptor™ platform enables consistent protein expression, simplified operations, and a level of manufacturing control that is difficult to achieve in traditional cell-culture-based manufacturing. The platform is made possible by recent advances in precision genome engineering, the availability of large genomic data sets, and the ability to grow avian primordial germ cells ("PGCs").

"Millions of years of evolution have sculpted this system into an extremely prolific producer of complex proteins. By leveraging this natural architecture, we've created a fundamentally superior way to produce biological therapeutics," said Dr. Sam Levin, co-founder and CTO of Neion Bio. "Our platform delivers improved control and scalability versus conventional biomanufacturing without the burden and cost of large steel tanks or disposable plastics. As AI dramatically reduces the time and cost to design breakthrough medicines, we are enabling a pathway to bring these to market far more efficiently and sustainably than traditional manufacturing."

Neion Bio Emerges from Stealth with Multi-Product Biosimilar Partnership Leveraging Its Cutting-Edge Genetic Engineering Platform | Markets Insider

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Whoop raises $575M, adds Abbott as strategic investor

Medtech Dive, 31 March 2026

Dive Brief:

- Whoop, the wearable company that sparked a debate on wellness regulations, has raised $575 million.

- The series G round values Whoop at $10.1 billion, the company said on Tuesday.

  Abbott joined as a strategic investor.

- Whoop plans to put the funds toward its U.S. and international growth, as well as personalized health features.

Dive Insight:

Whoop makes a wearable wristband that tracks metrics such as sleep, heart rate and strain. All of Whoop's devices require an annual membership, with costs ranging from $150 to $360. Certain features, such as electrocardiogram readings and atrial fibrillation detection, are locked behind the pricier membership.

The company added a blood pressure feature last year, which became the subject of a Food and Drug Administration warning letter as regulators said blood pressure measurements should be regulated as a medical device. In January, the FDA changed course, saying in a final guidance that blood pressure features may fall under the agency's wellness exemption. Whoop applauded the changes.

Whoop is undergoing a hiring spree as it raises the funds. In early March, the company said it plans to hire for more than 600 jobs in 2026.

The latest funding round was led by Collaborative Fund, with participating investors including Abbott and Mayo Clinic. Whoop also named sports celebrities among individual investors, including Cristiano Ronaldo and LeBron James.

https://www.medtechdive.com/news/whoop-raises-575m-adds-abbott-as-strategic-investor/816229/

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PHARMA & BIOLOGICS

SMALL MOLECULES

Rusan unveils APOSAN 3ml multi-dose pen for treatment of motor fluctuations

The APOSAN 3ml PEN offers a multi-dose, dial-a-dose mechanism with an enhanced dose-visibility window, thereby enabling accurate and consistent dose administration.

Express Pharma, 31 March 2026

Rusan Healthcare, the marketing and distribution arm of Rusan Pharma, an integrated global pharmaceutical company, has announced the launch of the multi-dose delivery pen device – APOSAN 3ml Pen (Apomorphine Hydrochloride solution for injection in

cartridge)(10 mg/ml)(3 ml pre-filled cartridges) for treatment of motor fluctuations commonly known as 'ON-OFF' episodes in patients suffering from Parkinson's disease (PD).

In 2018, Rusan was the first company in India to launch APOSAN Apomorphine Hydrochloride solution for injection (10 mg/ml) (2ml and 5ml ampoules). Since APOSAN's launch in India, Rusan has observed remarkable clinical impact and consistently positive patient experiences, underscoring Apomorphine's value as a transformative option in Parkinson's management.

The company now offers the complete range of Apomorphine Hydrochloride in different fill volumes, namely – 2ml injection, 3ml in pre-filled cartridge with a 'Multi-dose PEN device', and 5ml for continuous 'Infusion PUMPS' to meet distinct clinical scenarios in PD management, such as rapid rescue from OFF episodes using PEN devices and sustained symptom control using infusion PUMPS.

PD is estimated to affect nearly 10 to 11.7 million people globally, with India accounting for a significant and growing share of the patient population. However, the clinical perception is shifting: Early-Onset Parkinson's Disease (EOPD), defined as diagnosis after the age of 20 years and before 50 years, now represents a growing share of the global burden, with incidence and prevalence tripling between 1990 and 2021, as reported in the Journal of Neurology, Neurosurgery & Psychiatry 2026.

https://www.expresspharma.in/amp/rusan-unveils-aposan-3ml-multi-dose-pen-for-treatment-of-motor-fluctuations/

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Ainnocence's CarbonAI®, a Proprietary AI Engine for De Novo Small-Molecule and PROTAC Design and Optimization

EIN Presswire, 30 March 2026

Platform screens up to 10 billion compounds in hours, delivering wet-lab-ready candidates in weeks without requiring 3D protein structures

Ainnocence, a next-generation AI drug discovery company, announces the commercial availability of CarbonAI®, its proprietary artificial intelligence engine for de novo small-molecule and PROTAC design. CarbonAI® enables pharmaceutical and biotechnology

organizations to advance from target sequence to optimized, wet-lab-ready lead candidates in weeks compressing a process that traditionally spans years.

"The fundamental bottleneck in small-molecule discovery has not been a lack of chemical

matter, it has been the inability to explore vast chemical spaces while simultaneously optimizing for the properties that determine clinical success," said Dr. Lurong Pan, PhD, Founder and CEO of Ainnocence.

"CarbonAI® was designed from the ground to solve that problem. By working directly from sequence, we enable programs that were previously intractable due to missing or unreliable structural data. We are compressing discovery timelines from years to weeks and giving our partners the confidence to advance candidates with strong multi-parameter profiles from day one."

CarbonAI® operates entirely from amino acid sequence input, eliminating the dependency on experimental 3D protein structures that constrains conventional and many AI-driven approaches. The platform screens chemical space at a scale of up to 10 billion compounds within hours to days, simultaneously optimizing across potency, selectivity, ADME/Tox, synthetic accessibility, and IP novelty. Uniquely, CarbonAI® is a pioneer small-molecule engine capable of whole-genome off-target screening in hours enabling safety profiling at a scale that is simply not achievable with conventional docking or structure-based methods.

Ainnocence's CarbonAI®, a Proprietary AI Engine for De Novo Small-Molecule and PROTAC Design and Optimization - The Detroit Free Press

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LARGE MOLECULES

Lilly's Ebglyss delivered up to four years of durable disease control for patients with moderate-to-severe atopic dermatitis

Pharma Biz, 30 March 2026

New long-term data show Eli Lilly and Company's Ebglyss (lebrikizumab-lbkz) delivered durable skin clearance?and?relief from persistent?itch for up to four years for patients with moderate-to-severe atopic dermatitis (eczema) in an open-label extension study offering once-monthly maintenance injection. Interim findings from the first year of the ADlong phase 3b study presented at the American Academy of Dermatology (AAD) Annual Meeting, taking place March 27-31 in Denver.

"These data underscore our unwavering commitment to expanding what people with moderate-to-severe atopic dermatitis can achieve with treatment," said Adrienne Brown, executive vice president and president, Lilly Immunology. "For too long the focus has been around symptom management and many patients struggle to achieve consistent disease control despite cycling through topical treatments. Ebglyss is helping transform this treatment paradigm—allowing people the opportunity to reimagine life without the frequent interruptions caused by flares or topicals applied 2-3 times per day." Ebglyss is an interleukin-13 (IL-13) inhibitor that selectively blocks IL-13 signalling with high binding affinity and slow dissociation rate. The cytokine IL-13 is a primary cytokine in atopic dermatitis, driving the type-2 inflammatory cycle in the skin, leading to skin barrier dysfunction, itch, skin thickening and infection.

In the ADlong study, the majority of patients achieved a high bar of near-complete skin clearance and significant itch relief with up to four years of continuous Ebglyss treatment. Most patients (77%) were on Ebglyss monotherapy, and 80% achieved results without topical corticosteroids. In addition, 80% achieved these outcomes with Ebglyss monthly maintenance dosing during the study.

The safety of Ebglyss in the first year of the ADlong study was consistent with the known profile in patients with moderate-to-severe atopic dermatitis, regardless of dose frequency, and no new safety signals were observed. The majority of adverse events were mild or moderate and did not lead to discontinuation. Reported treatment-related adverse events in the study included conjunctivitis (6.9%) and injection-site reactions (0.6%).
Lilly's Ebglyss delivered up to four years of durable disease control for patients with moderate-to-severe atopic dermatitis

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Rhythm Pharmaceuticals Receives Positive CHMP Opinion for IMCIVREE® (setmelanotide) for the Treatment of Obesity and Control of Hunger in Patients with Acquired Hypothalamic Obesity due to Hypothalamic Injury or Impairment

Globe Newswire, 26 March 2026

Rhythm Pharmaceuticals, Inc., a global commercial-stage biopharmaceutical company focused on transforming the lives of patients living with rare neuroendocrine diseases, today announced that the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) has adopted a positive opinion recommending to expand the current marketing authorization for IMCIVREE® (setmelanotide) to include the

treatment of obesity and the control of hunger in adults and children 4 years of age and above with acquired hypothalamic obesity (HO) due to hypothalamic injury or impairment.

"The positive CHMP opinion with a broad label following closely upon last week's FDA approval validates the quality of the data which supports our filings in acquired HO and further confirms our global approach to drug development," said David Meeker, M.D., Chairman, President and Chief Executive Officer of Rhythm. "Acquired HO represents a significant unmet medical need across geographies and a unique opportunity for Rhythm which we are well positioned to execute on."

"Acquired hypothalamic obesity is a devastating neuroendocrine disease characterized by reduced energy expenditure, hyperphagia (pathological insatiable hunger) and accelerated, sustained weight gain resulting from physical injury or structural abnormality of the hypothalamus. This disease condition is driven by impairment of MC4R pathway signaling and other hypothalamic functional damage, making it exceptionally difficult to manage with existing approaches," said Professor Hanneke van Santen, M.D., PhD., professor of pediatric endocrinology at the Prinses Máxima Center and Wilhelmina Children's Hospital, Utrecht, The Netherlands. "There is a clear and urgent need for a precision medicine that targets the root cause of the disease and offer patients a meaningful path forward."

Rhythm Pharmaceuticals Receives Positive CHMP Opinion for IMCIVREE® (setmelanotide) for the Treatment of Obesity and Control of Hunger in Patients with Acquired Hypothalamic Obesity due to Hypothalamic Injury or Impairment | The Manila Times

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REGULATORS AND REGULATORY ACTIONS

Lipella files for bankruptcy, ending dream of developing mouth inflammation drug

Fierce Biotech, 31 March 2026

Lipella Pharmaceuticals' ambition to develop the first treatment for an inflammatory mouth condition has reached the end of the road, with the biotech filing for bankruptcy.

The Pittsburgh-based company had been working on a liposomal oral rinse of the immunosuppressant tacrolimus to treat symptomatic oral lichen planus (OLP), a chronic inflammatory condition affecting the oral mucosa.

Back in September 2025, Lipella said its candidate, dubbed LP-10, had hit the key safety endpoint in a phase 2a study of 27 patients with OLP. The biotech reported at the time that pain and sensitivity "improved significantly, with patients reporting meaningful reductions on numerical rating scales."

Based on the data, Lipella's plan was to advance LP-10 into a phase 2b study, with the

ultimate goal of scoring the first FDA approval in OLP.

But that dream died yesterday, when the company announced it had filed a voluntary petition for relief under Chapter 11 of the U.S. Bankruptcy Code in the Bankruptcy Court for the Western District of Pennsylvania.

The biotech plans to undergo an asset sale process to "maximize value for creditors," according to a post-market March 30 release. Further, it expects to seek customary "first-day" relief that would allow the business to continue day-to-day operations in the near term.

https://www.fiercebiotech.com/biotech/lipella-files-bankruptcy-ending-dream-developing-mouth-inflammation-drug

★★★★★★★

Crinetics Pharmaceuticals, Inc.: Crinetics Pharmaceuticals Announces Submission of Marketing Authorization Application in Brazil for Palsonify (Paltusotine) in Acromegaly

Globe Newswire, 26 March 2026

Crinetics Pharmaceuticals, Inc. today announced the submission of a Marketing Authorization Application (MAA) to Brazil's National Health Surveillance Agency (ANVISA) for PALSONIFY (paltusotine), the first once-daily, oral, selectively-targeted somatostatin receptor type 2 nonpeptide agonist, for the proposed treatment of acromegaly in adults.

"The submission of our MAA for Palsonify in Brazil represents another important global milestone for this important therapy," said Scott Struthers, Ph.D., founder and chief executive officer of Crinetics. "Once-daily, oral Palsonify is redefining the treatment paradigm as the next generation of acromegaly care in the US, following its approval by the FDA. We now look forward to working with ANVISA as they evaluate our MAA for Palsonify to treat acromegaly in adults in Brazil."

The MAA submission is supported by data from 18 clinical trials, including two Phase 3 trials that evaluated paltusotine for the treatment of acromegaly in medically untreated and treated patients. All primary and secondary endpoints were met in both Phase 3

studies. Treatment with paltusotine was well-tolerated and resulted in statistically significant biochemical control and patient reported symptom control compared to placebo.

Crinetics Pharmaceuticals, Inc.: Crinetics Pharmaceuticals Announces Submission of Marketing Authorization Application in Brazil for Palsonify (Paltusotine) in Acromegaly

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Marksans Pharma gets USFDA nod for generic Benzonatate capsules

This product is bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Tessalon Capsules, 100 mg and 200 mg, of Pfizer Inc

Business line, 1 April 2026

Marksans Pharma Ltd on Wednesday said it has received final approval from the US health regulator for its generic version of Benzonatate capsules indicated for treatment of persistent cough, bronchitis, pneumonia or other lung infections.

The approval by the US Food and Drug Administration (USFDA) is for the company's abbreviated new drug application (ANDA) for Benzonatate capsules of strengths 100 mg and 200 mg, Marksans Pharma said in a regulatory filing.

This product is bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Tessalon Capsules, 100 mg and 200 mg, of Pfizer Inc, it added.

Benzonatate is a non-narcotic antitussive that numbs stretch receptors in the respiratory tract, reducing the cough reflex and relieving persistent cough, bronchitis, pneumonia or other lung infections, the company said.

Marksans Pharma gets USFDA nod for generic Benzonatate capsules - The HinduBusinessLine

★★★★★★★

Alembic Pharma Gets USFDA Nod for Mental Health Tablet

Rediff, 30 March 2026

New Delhi, Mar 30 (PTI) Alembic Pharmaceuticals Ltd on Monday said it has received final approval from the US health regulator for its generic version of Paroxetine extended-release tablets indicated for various mental health conditions.

The approval by the US Food & Drug Administration (USFDA) is for the supplemental Abbreviated New Drug Application (sANDA) of Paroxetine extended-release tablets of strength 12.5 mg, Alembic Pharmaceuticals said in a statement.

The approved sANDA is therapeutically equivalent to the reference-listed drug product Paxil CR Tablets, 12.5 mg, of Apotex Inc, it added.

Alembic Pharma Gets USFDA Nod for Mental Health Tablet: Rediff Moneynews

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Granules Life Sciences' Hyderabad plant gets VAI inspection classification from U.S. FDA

The establishment inspection report (EIR) was issued following a current good manufacturing practice (cGMP) and pre-approval inspection (PAI) of the oral solid dosage manufacturing operations between December 15 and 19

The Hindu, 31 March 2026

Granules Life Sciences (GLS) manufacturing facility in Shamirpet, near Hyderabad, has been classified as voluntary action indicated (VAI) by the U.S. Food and Drug Administration (U.S. FDA) consequent to an inspection in December 2025.

The establishment inspection report (EIR) was issued following a current good manufacturing practice (cGMP) and pre-approval inspection (PAI) of the oral solid dosage manufacturing operations between December 15 and 19. The inspection is now closed and no regulatory action has been recommended, parent company Granules India said on Tuesday (March 31, 2026).

Granules Life Sciences (GLS) manufacturing facility in Shamirpet, near Hyderabad, has been classified as voluntary action indicated (VAI) by the U.S. Food and Drug Administration (U.S. FDA) consequent to an inspection in December 2025.

Granules gets Board nod to raise ₹1,762.5 crore

The development strengthens Granules India's finished dosage manufacturing capabilities by enabling multi-site manufacturing for the approved products, the company said.

Five observations issued

The U.S. FDA had issued five observations on completion of the inspection in December. The observations were related to procedural requirements. None of the observations are associated with data integrity or product safety, the company had then said. Granules

Life Sciences is into manufacturing of pharmaceutical formulation intermediates (PFIs) and finished dosages.

Granules Life Sciences' Hyderabad plant gets VAI inspection classification from U.S. FDA - The Hindu

Government tightens oversight of GLP-1 drugs, flags risks amid rising demand; key details

MSN, 4 April 2026

The Centre has issued a detailed advisory on the use, risks and regulation of GLP-1 receptor agonist drugs, as their popularity grows for treating type 2 diabetes and obesity.

According to PIB, these drugs, commonly prescribed to regulate blood sugar and aid weight loss—must be used strictly under medical supervision due to potential side effects. Authorities stressed that GLP-1 medications are not over-the-counter products and can only be prescribed by qualified specialists such as endocrinologists, internal medicine experts and cardiologists.

The government also announced that it has stepped up regulatory surveillance. The Drug Controller General of India, along with state drug regulators, is conducting inspections and has warned of strict action, including licence cancellation and fines, against any violations in the sale or prescription of these drugs.

The advisory reiterates that diabetes is a chronic condition caused either by insufficient insulin production or the body's inability to effectively use it, leading to high blood sugar levels. If left untreated, it can result in serious complications such as heart disease, kidney failure, stroke and blindness.

Highlighting risk factors, officials noted that obesity, family history and unhealthy diets significantly increase the likelihood of developing type 2 diabetes.

Government tightens oversight of GLP-1 drugs, flags risks amid rising demand; key details

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MEDTECH

Parliamentary Panel recommends decentralisation of approval of all medical devices

Pharma Bizz, 30 March 2026

The Parliamentary Panel on Health and Family Welfare has recommended various significant regulatory changes in the regulation of medical devices, including

decentralisation of approval for all medical devices with the State Drug Authorities, self-financing of the drug control authority using the substantial revenues generated from medical device licensing, and an immediate overhaul of the Central drug regulator's medical devices (MD) online portal to reduce the bottlenecks in approvals.

The Department Related Parliamentary Standing Committee on Health and Family Welfare, in its 172nd report on the Demands for Grants for 2026-27 for the Department of Health and Family Welfare, observed that that present decentralized framework is under which the State Authorities regulate drugs and Class A/B devices, while the Central Drugs Standard Control Organisation (CDSCO) oversee imports and Class C and D devices.
However, it recommended a decentralized framework for imports and Class C/D devices. "The Committee strongly recommends that CDSCO approval for imports be completely decentralized to the State Authorities. Centralization with the DGCI at the Central level has created major bottlenecks and is the biggest hurdle in India being at the forefront of Medical devices manufacturing," said the Panel headed by Member of Parliament Prof. Ram Gopal Yadav.

"The Committee recommends for decentralization of approval for all Medical Devices with the State Drug Authorities to reduce pendency. In this current phase when we are competing with China, Vietnam, Malaysia giving CDSCO approvals for even already approved devices/technologies beyond a period of 45 days resulting in India losing its competitive edge," said the Panel.

It noted with concern that significant administrative bottlenecks hindering the swift clearance of medical devices, particularly the Class C and Class D categories regulated by the CDSCO.

Out of 2,999 manufacturing and import applications processed, approximately 62% were subjected to queries more than twice, and 253 import applications, even those possessing US FDA/CE certifications, have been pending for over 90 days, (most of these import applications are pending at the applicants end for submission of requisite documents as per MDR-2017).

Repetitive query cycles indicate a systemic lack of clarity in the initial submission guidelines and point toward an inefficient, iterative assessment process, it opined. The Panel recommended that the Department immediately overhaul the 'MD Online' portal to include a mandatory, AI assisted pre-submission validation checklist to ensure applications are complete before formal submission.

Parliamentary Panel recommends decentralisation of approval of all medical devices

INTERESTING MEDICAL NEWS

AI-powered stroke tool linked to improved patient outcomes in large clinical trial

Medical News Today, 30 March 2026

- A new study suggests that a stroke clinical decision support system (CDSS), which uses artificial intelligence (AI) assisted imaging, could help to significantly reduce the risk of recurrent vascular events.
- Researchers suggest the AI tool is a safe intervention that provides the added benefits of lower cost and greater sustainability.
- In the large study, the AI-based system improved stroke care and outcomes, supporting its potential as a scalable tool for routine stroke care, particularly in resource-limited settings.

Stroke is a significant global health concern and continues to be a leading cause of disability and death in the United States.

Evidence suggests that more than 795,000 people in the U.S. have a stroke each year, and nearly one in four of those are people who have had a previous stroke.

Clinicians play a critical role in preventing recurrent stroke. Typically, this occurs through implementing effective strategies, such as prevention plans, regular patient reviews, and addressing lifestyle modifications.

To assist with this, clinicians may consider clinical decision support systems (CDSS). These systems can help healthcare institutions analyze data from electronic health records and make recommendations to physicians by sending prompts and reminders in real-time

The potential scope of CDSS to help aid clinicians in complex decision-making processes for preventing stroke is increasing. However, many tools that utilize AI have not been rigorously evaluated, limiting their use.

Now, a large study published in The BMJ suggests an AI-powered CDSS may improve the quality of care and long-term outcomes for people who experience an acute ischemic stroke.

The findings suggest that such systems could offer a scalable and cost-effective way to enhance stroke management, particularly in regions with limited healthcare resources.

Addressing a gap in stroke care

The use of AI technologies has increasingly been explored in healthcare, particularly for diagnosing disease, predicting outcomes, and supporting clinical decision making.

However, many AI tools designed for stroke care have not yet undergone rigorous evaluation in real-world clinical settings, limiting their widespread adoption.

To address this, researchers in China conducted a large trial to assess whether an AI-assisted CDSS could improve care quality and patient outcomes in routine practice.

The system analyzes brain scans to classify stroke causes and combines this with evidence-based treatment recommendations tailored to individual patients.

The research team suggests that the AI-based tool was associated with a significant reduction in subsequent vascular events compared with standard care.

Christopher Yi, MD, board certified vascular surgeon at MemorialCare Orange Coast Medical Center in Fountain Valley, CA, who was not involved in the study, suggests how AI could fit into stroke management.

"This study is the first of its kind to utilize AI for stroke care from being a diagnostic aid to being a tool that can improve care quality and reduce recurrent vascular events," said Yi.

"In this study, the CDSS did more than read images: It integrated AI-assisted imaging, stroke-cause classification, reminders for needed evaluations, and guideline-based treatment recommendations," he added.

"The biggest takeaway is that a well-integrated CDSS can help clinicians deliver more consistent evidence-based stroke care. It also helps guide interventionalists to better outcomes by improving stroke care quality and decreasing long term vascular events." – Christopher Yi, MD

Large-scale trial across 77 hospitals

The large study involved more than 21,000 participants with acute ischemic stroke admitted to 77 hospitals across China within 7 days of symptom onset. The individuals had an average age of 67, and just over one-third were female.

Between January 2021 and June 2023, 11,054 people received treatment at 38 hospitals supported by the AI-based CDSS. The other 10,549 participants at 39 hospitals received usual medical care.

Physicians in the intervention group were trained to use the system. The CDSS incorporated a range of patient-specific factors, including age, medical history, lifestyle, and hospital characteristics, when generating recommendations.

Fewer vascular events observed

The study found that participants whose care was supported by the CDSS experienced fewer new vascular events at multiple follow-up points. This included recurrent stroke, heart attack, or related death.

At 3 months, 2.9% of those in the intervention group (320 of 11,054) experienced a new vascular event, compared with 3.9% in the control group (416 of 10,549), representing a 26% relative reduction.

This benefit persisted at 12 months, with event rates of 4% in the intervention group (440 of 11,054) versus 5.5% in the control group (576 of 10,549), representing a 27% reduction.

The research team also found that care quality measures were slightly higher in the intervention group, with performance scores of 91.4% compared with 89.8% in the usual care group.

Notably, the researchers add that the use of the AI system did not appear to increase risks. There were no significant differences between the groups in terms of disability, overall mortality, or bleeding complications at 3, 6, or 12 months.

When asked how clinically meaningful these improvements in care quality measures are, Yi told us: "Modest overall, but meaningful in the domains that matter most. The composite quality score improved from 89.8% to 91.4%, which by itself is not dramatic."

"But several individual measures improved more substantially, including dual antiplatelet use, anticoagulation for atrial fibrillation, dysphagia screening, and DVT prophylaxis," he noted. "Those are not trivial process metrics; they are directly tied to secondary prevention and complication avoidance."

"The fact that recurrent vascular events fell from 3.9% to 2.9% at 3 months makes the quality gains feel clinically real rather than cosmetic," Yi emphasized.

Limitations and future potential

The authors note that the trial randomized hospitals rather than individual patients. This means that differences in care practices and follow-up outside the hospital could have influenced the results.

Despite this, the researchers emphasize that the system was easy to integrate into existing hospital infrastructure and required relatively minimal training.

"The biggest barriers are likely to be workflow integration, interoperability, imaging standardization, technical support, and clinician adoption," Yi told *Medical News Today*.

"This system was integrated into the hospital information system, EMR [electronic medical record], and PACS [picture archiving and communication system], and physicians received training before rollout, which takes infrastructure and organizational commitment," he continued.

"The paper also notes that hospitals already struggle with insufficient resources and heavy physician workloads, which are exactly the settings where implementation can be hardest even if the tool is potentially valuable," said Yi.

"The next challenge is not proving that AI can help, but making it portable, explainable, affordable, and easy to trust across different practice environments," he added.

The researchers suggest that AI-powered CDSS could serve as a comprehensive management tool, supporting both in-hospital care and secondary prevention strategies.

They add that it could represent a promising approach to delivering high-quality stroke care at scale, particularly in resource-constrained settings with a high burden of cerebrovascular disease.

As healthcare systems continue to explore the possible role of AI, studies like this indicate that such tools may deliver measurable benefits in real-world clinical practice.

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