Friday, 1 May 2026

CONTENT *(Highlights)*

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UPCOMING EVENTS

Webinar

USDM Life Sciences Summit 2026

Accelerating Digital Trust & Intelligent Transformation in Life Sciences

Virtual Event Overview

Life sciences organizations are entering a new era—one defined by AI adoption, rising cyber threats, rapid workflow automation, and unprecedented talent shortages. In this environment, success depends on one defining capability: the ability to move fast while staying compliant.

Why Watch

This summit is essential for life sciences professionals who want to:

- Understand the biggest regulatory, cybersecurity, and AI forces shaping 2026
- Learn how leading companies are deploying AI responsibly in GxP environments
- See practical examples of automation, platform modernization, and workflow acceleration
- Get ahead of talent scarcity with modern workforce models
- Build a digital roadmap that integrates people, processes, and platforms into a unified compliance ecosystem

Who Should Watch

Industry Types: Pharma, Biopharma, Biotechnology, Medical Device, CRO/CMO, and any regulated life sciences organization.

Roles: CIO, CTO, CISO, Quality leaders, Regulatory leaders, IT Infrastructure, Cloud, GxP Apps, R&D and Lab leaders, Clinical Operations, and more.

Watch Now

DEALS AND FUNDING

Sun Pharma buys US-based Organon in $12bn all-cash deal

MSN, 28 April 2026

In its boldest move yet, Sun Pharma, India's largest pharma company, has struck the biggest-ever overseas pharma deal, acquiring US-listed Organon & Co for $11.8 billion (Rs 98,000 crore) in an all-cash transaction.

The deal broadens Sun Pharma's therapeutic breadth and geographic reach in one sweep, adding over 140 high-growth markets including China, and a portfolio around innovative therapies, including women's health, biosimilars, and legacy brands.

Sun Pharma will pay $14 per share, a premium of over 24% to Organon's last closing price on April 24 in one of the largest M&A deals by an Indian company. On Monday, Sun Pharma shares closed 7% higher at Rs 1,734 on BSE.

Once completed, the acquisition will double Sun Pharma's revenue to $12.4 billion and its EBITDA to $3.7 billion, ranking it among the top 25 global pharmaceutical companies.

Organon, spun off in 2021 from Merck (known as MSD outside US and Canada), brings portfolio of over 70 products across women's health, general medicines and biosimilars, along with six manufacturing facilities worldwide.

The deal follows Sun Pharma's proven M&A playbook from the landmark Ranbaxy acquisition in 2014 to a string of in-licensing deals, which have strengthened its innovative portfolio and delivered a 14% revenue CAGR between FY10 and FY25.

Sun chairman Dilip Shanghvi said: "We are debt-averse, but we are never risk-averse. Biosimilars is a segment where building capabilities organically would take years; Organon gives us that platform immediately."

The deal positions Sun Pharma as the top 3 player in women's health, after German firms Merck and Bayer, and the seventh-largest biosimilars company in the world -- two of the fastest-growing segments. "Sun Pharma's proposed deal with Organon, valued around 6x EBITDA, appears financially disciplined, supported by steady cash flows," Vishal Manchanda analyst at Systematix said.

Sun Pharma buys US-based Organon in $12bn all-cash deal

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Lilly to buy biopharma company Ajax Therapeutics to advance outcomes for patients with myelofibrosis and polycythemia vera

PharmaBiz, 28 April 2026

Eli Lilly and Company, a medicine company, and Ajax Therapeutics, Inc. (Ajax), a biopharmaceutical company developing next generation JAK inhibitors for patients with myeloproliferative neoplasms (MPNs), announced a definitive agreement for Lilly to acquire Ajax. Ajax's lead asset, AJ1-11095, is an investigational, once-daily oral, first-in-class Type II JAK2 inhibitor currently being evaluated in a phase 1 clinical trial, AJX-101, in patients with myelofibrosis who have previously been treated with a Type I JAK2 inhibitor.

All approved JAK2 inhibitors for patients with MPNs, including myelofibrosis and polycythemia vera, bind the Type I confirmation of JAK2. While these JAK2 inhibitors provide clinical and symptomatic relief, many patients often discontinue Type I JAK2 treatment due to a lack of durable benefit or loss of response. AJ1-11095 was designed as a selective Type II JAK2 inhibitor to not only deliver deeper and more durable efficacy than existing JAK2 inhibitors but also to provide a novel treatment option for those patients who become resistant to Type I JAK2 inhibitors. The phase 1 clinical trial of AJ1-11095 began in late 2024 and dose selection for future clinical development is expected in 2026.

"As a founding strategic investor in Ajax, Lilly has long believed in the approach and is excited about the potential for AJ1-11095 to deliver deeper and more durable efficacy than available treatments with a tolerability profile that would allow for patients to remain on therapy longer and be used across both the first- and second-line settings," said Jacob Van Naarden, executive vice president and president of Lilly Oncology and head of corporate business development. "We look forward to the presentation of clinical proof-of-concept data later in 2026, rapidly advancing AJ1-11095 into registrational clinical trials, and using our expertise in blood cancer to hopefully deliver another important new medicine to patients and haematologists."

"We started Ajax to build on the work of its five scientific founders, including Ross Levine, MD, chief scientific officer at Memorial Sloan Kettering Cancer Center and chair of Ajax's scientific advisory board, who sought to develop a novel class of selective and more potent JAK2 inhibitors to address the significant unmet need of patients with MPNs," said Martin Vogelbaum, co-founder and chief executive officer of Ajax Therapeutics. "With a small but highly motivated team, we have successfully applied this work to the design and development of our highly selective, first-in-class Type II JAK2 inhibitor, AJ1-11095. We now look forward to Lilly advancing AJ1-11095 through the clinic and

providing a much-needed new therapy for patients with MPNs. It has been an honour working with our employees and scientific advisors and we're grateful to our clinical investigators, and most importantly, the patients who have participated in our ongoing phase 1 study, AJX-101."

Under the terms of the agreement, Lilly will acquire Ajax and Ajax shareholders could receive up to $2.3 billion in cash, inclusive of an upfront payment and subsequent payments upon the achievement of certain clinical and regulatory milestones.

Lilly to buy biopharma company Ajax Therapeutics to advance outcomes for patients with myelofibrosis and polycythemia vera

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Nutrition Supplements Marketplace HyugaLife Raises ₹100 Cr

Inc 42, 28 April 2026

Summary

The funding round was led by IvyCap Ventures, with participation from First Bridge Fund

The startup will use the capital to strengthen AI-driven personalisation features for users, expand its dark store network and establish an offline presence

HyugaLife operates an ecommerce marketplace for health and wellness products such as herbal supplements, sports nutrition, weight management and fitness accessories

Protein and supplements marketplace HyugaLife has raised ₹100 Cr ($10.6 Mn) in its Series A funding round led by IvyCap Ventures, with participation from First Bridge Fund.

The startup said it will use the capital to strengthen AI-driven personalisation features for users, expand its dark store network, and establish an offline presence.

Founded in 2021 by Sachin Parikh, Anvi Shah and Neehar Modi, HyugaLife operates an ecommerce marketplace for health and wellness products such as herbal supplements, sports nutrition, weight management, fitness accessories, among others.

The startup claims to offer more than 10,000 products across nine different categories from over 450 brands, catering to a broad spectrum of consumers, including athletes, professionals, and families.

"We're doubling down on our authenticity guarantee by expanding lab tested offerings, while investing in AI-driven smart, personalised technology that meets consumers at their specific life stage and fitness phase, and enabling faster access through dark stores and

offline," HyugaLife cofounder and CEO Parikh said.

HyugaLife also offers a "H-Tested" programme that assures authenticity of products listed on its platform, through third-party labs adhering to NABL and FSSAI standards to assess their protein and nutrient values.

The startup also sells self-manufactured products like creatine, whey protein, among others, under the Hyuga brand.

Without disclosing the capital raised so far, HyugaLife claimed that it is backed by Peak XV and Spring Marketing Capital, alongside cricketer KL Rahul since its inception.

The development comes at a time when there is a heightened consumer demand for wellness products in the market, benefitting brands operating in the health and wellness space. Since the start of this year, investors have backed brands like Mosaic Wellness, Fullife Healthcare and Dhun Wellness betting on this growing demand.

Nutrition Supplements Marketplace HyugaLife Raises ₹100 Cr

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XTL Biopharmaceuticals to Acquire Psyga Bio, Establishing a Leading Psychedelic Biotechnology Platform with Advanced Clinical Pipeline, Licensed GMP Manufacturing and Proprietary Psilocybin

Business Insider, 29 April 2026

Transaction Positions XTL at the Forefront of the Rapidly Expanding Global Psychedelic Therapeutics Market Following Major U.S. Regulatory Momentum

Seven Approved Phase 2a Human Clinical Trials Expected to Begin Patient Enrollment in the Near Future

Licensed GMP-Ready Pharmaceutical Facility for Botanical and Synthetic Psilocybin Manufacturing Creates Strategic Commercialization Advantage

Milestone-Based Structure Provides Significant Additional Long-Term Value Creation

XTL Biopharmaceuticals Ltd. announced today that it has entered into a definitive share purchase agreement to acquire 100% of the issued and outstanding share capital of Psyga Bio Ltd., an advanced biotechnology company focused on the research, development and commercialization of proprietary products derived from psychedelic and functional mushrooms, including clinically researched therapeutic candidates, microdosing solutions and wellness-focused formulations.

Psyga operates a licensed, GMP-ready pharmaceutical manufacturing facility designed for the cultivation, extraction, isolation, formulation and production of pharmaceutical-grade botanical and synthetic psilocybin, Ibogaine and other psychedelic active pharmaceutical ingredients (APIs), in accordance with applicable international pharmaceutical manufacturing standards. It has developed a proprietary library of more than 180 unique mushroom strains, including differentiated high-potency and bioactive strains, which support pharmaceutical development, product consistency, future intellectual property protection and scalable commercial manufacturing capabilities. In addition, Psyga is advancing a clinical pipeline consisting of seven (7) approved Phase 2a human clinical trials, which are expected to commence patient enrollment in the near future, across multiple indications, including mental health disorders, neurological conditions, trauma-related disorders, addiction treatment and additional central nervous system indications. Several of these programs are fully funded and are expected to be conducted in collaboration with leading academic institutions and medical centers.

XTL Biopharmaceuticals to Acquire Psyga Bio, Establishing a Leading Psychedelic Biotechnology Platform with Advanced Clinical Pipeline, Licensed GMP Manufacturing and Proprietary Psilocybin... | Markets Insider

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PHARMA & BIOLOGICS

SMALL MOLECULES

Insilico's Rentosertib Inhalation Solution Receives IND Clearance for the World's First AI-Driven Candidate to Enter Direct-to-Lung Clinical Study

MedIndia, 29 April 2026

Insilico Medicine, a clinical-stage, generative AI–driven drug discovery company, today announced that the inhalation solution of Rentosertib (ISM001-055), the company's first-in-class drug candidate with AI-identified novel target and AI-developed molecule structure, received IND clearance from CDE. Notably, Rentosertib inhalation solution is the 13th program from Insilico's AI-driven pipeline to receive IND clearance, further demonstrating how Pharma.AI could reproducibly drive the discovery and development of novel molecules from preclinical development to clinical validation.

The IND clearance supports a Phase I study to evaluate the safety, tolerability, and pharmacokinetic (PK) profiles of Rentosertib inhalation solution. The study will consist of two parts: (1) a randomized, double-blind, placebo-controlled Phase I trial in healthy participants involving single ascending dose (SAD) and multiple ascending dose (MAD)

cohorts; and (2) a non-randomized, open-label evaluation in patients with Idiopathic Pulmonary Fibrosis (IPF) receiving multiple doses. Approximately 80 subjects are expected to be enrolled.

"We are pleased to receive CDE IND approval for Rentosertib inhalation solution." says Feng Ren, Ph.D., Co-CEO and CSO of Insilico Medicine. "In prior clinical studies, oral Rentosertib showed good tolerability, a favorable PK profile, and dose-dependent efficacy trend, strengthening our confidence in its mechanism and clinical potential. We look forward to seeing the Rentosertib inhalation solution deliver positive clinical results again in both healthy volunteers and patient populations. The inhalation solution is designed for targeted lung delivery, with the goal of achieving higher pulmonary exposure and faster onset at lower doses while reducing systemic exposure and optimizing the benefit–risk profile. In parallel, we continue to advance the oral Rentosertib program and remain on track to initiate Phase III trials in the second half of this year."

Insilico's Rentosertib Inhalation Solution Receives IND Clearance for the World's First AI-Driven Candidate to Enter Direct-to-Lung Clinical Study

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Ascletis Completes Enrollment in U.S. Phase II Study of ASC30, an Oral Small Molecule GLP-1R Agonist, for the Treatment of Diabetes

Med India, 26 April 2026

13-week U.S. Phase II study is evaluating the efficacy, safety and tolerability of oral small molecule GLP-1R agonist ASC30, a once-daily tablet, in 100 participants with diabetes.

Ascletis Pharma Inc. (HKEX: 1672, "Ascletis") announces today completion of enrollment in its 13-week U.S. Phase II study (NCT07321678) evaluating ASC30, an oral small molecule GLP-1 receptor (GLP-1R) agonist, for the treatment of type 2 diabetes mellitus (T2D). T2D is the second indication for ASC30, following its first indication of obesity. Topline data from the Phase II study for the treatment of T2D are expected in the third quarter of 2026.

"ASC30 has potential to be the best-in-class oral small molecule GLP-1 for obesity, evidenced by its efficacy and tolerability demonstrated by the U.S. Phase II study in participants with obesity or overweight," said Jinzi Jason Wu, Ph.D., Founder, Chairman and CEO of Ascletis, "Expanding ASC30's clinical development into the large diabetes treatment market is a logical next step that provides us with another chance to highlight ASC30's potential best-in-class profile as a once-daily oral treatment option for patients. We look forward to sharing topline data from the Phase II study in diabetes participants

in the third quarter of 2026."

Dr. Wu added, "Based on the positive clinical results announced in December 2025 from our 13-week U.S. Phase II study of ASC30 in participants with obesity or overweight, the Company expects to obtain the clearance from the U.S. Food and Drug Administration and initiate Phase III trials in the U.S. for obesity indication by the end of the third quarter 2026."
ASC30 was discovered and developed in-house at Ascletis as a first and only investigational small molecule GLP-1R fully biased agonist that can be dosed once daily orally and once monthly to once quarterly subcutaneously for the treatment of obesity, diabetes and other metabolic diseases.

Ascletis Completes Enrollment in U.S. Phase II Study of ASC30, an Oral Small Molecule GLP-1R Agonist, for the Treatment of Diabetes

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Crinetics Pharmaceuticals Announces the European Commission Approval of PALSONIFY® (Paltusotine) for the Treatment of Acromegaly in Adults

Globe Newswire, 27 April 2026

PALSONIFY is the first once-daily, oral therapy approved to treat acromegaly in the European Union

Approval based on strength of data from two pivotal Phase 3 studies studying PALSONIFY in both medical naïve and previously treated patients with acromegaly

Crinetics' first regulatory approval outside of the U.S., with first launch planned for Germany and Austria

Crinetics Pharmaceuticals, Inc. today announced that the European Commission (EC) has approved PALSONIFY® (paltusotine), the first once-daily, oral, selectively-targeted somatostatin receptor type 2 nonpeptide agonist, for the treatment of adult patients with acromegaly.

"The European Commission's decision to approve Palsonify reflects the strength of the clinical data and marks a pivotal step toward bringing this important therapy to even more people living with acromegaly," said Scott Struthers, Ph.D., Founder and Chief Executive Officer of Crinetics. "This approval represents another exciting milestone for Palsonify as it accelerates to become the new standard in acromegaly care in the U.S., and soon abroad. This is also a notable achievement for Crinetics in pursuit of our vision to become the global leader in endocrinology."

The EC approval is supported by positive results from the pivotal data from

the PATHFNDR-1 and PATHFNDR-2 Phase 3 trials, which evaluated PALSONIFY's safety and efficacy in previously treated and medically untreated adults with acromegaly. Across both trials, PALSONIFY consistently demonstrated rapid onset, reliable biochemical control, and sustained efficacy. PALSONIFY also has Orphan Drug Designation in the EU.

Participants also reported significant reductions in signs and symptoms associated with acromegaly – including headaches, joint pain, sweating, fatigue, weakness, swelling, and/or numbness/tingling – as measured by the Acromegaly Symptom Diary (ASD), a validated patient-reported outcome tool developed to capture the symptoms that matter to people living with acromegaly.

Crinetics Pharmaceuticals Announces the European Commission Approval of PALSONIFY® (Paltusotine) for the Treatment of Acromegaly in Adults | Markets Insider

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Newleos Announces Dosing of First Participant in Phase 1b Study of NTX-2001 for Alcohol Use Disorder

Le lizard, 29 April 2026

Newleos Therapeutics, Inc., a clinical-stage biotechnology company developing innovative treatments for neuropsychiatric disorders, today announced that the first participant has been dosed in its Phase 1b study of NTX-2001, the company's novel partial agonist of trace amine-associated receptor 1 (TAAR1), which is being developed as a potential first-in-class therapeutic for alcohol use disorder (AUD). The Phase 1b study is a randomized, double-blind, placebo-controlled clinical trial conducted in collaboration with Yale School of Medicine to measure reductions in alcohol consumption and cravings within an observational setting, as well as safety, tolerability and pharmacokinetics of NTX-2001 in individuals with AUD.

"With the last drug approval for alcohol use disorder nearly two decades ago, the urgency for novel, efficacious pharmacotherapeutic interventions could not be greater," noted Stephanie O'Malley, Ph.D., clinical advisor to Newleos. "There is mounting evidence across addictive disorders, including AUD, that supports the biological rationale for TAAR1 agonists. I am optimistic about the opportunity that this drug class presents and pleased to be collaborating with the Newleos team as they advance this important clinical study."

"As the first time a TAAR1 partial agonist has been evaluated in the clinic for alcohol use disorder, this study of NTX-2001 represents an important milestone for Newleos and for the field of addiction medicine," commented Federico Bolognani, M.D., Ph.D.,

Newleos' Co-founder and Chief Medical Officer. "TAAR1 partial agonists are well-suited as potential treatments for alcohol use disorder by modulating reward pathways in the brain. Demonstrating early signs of efficacy in this NTX-2001 study would provide clinical support that the TAAR1 mechanism may reduce alcohol use in individuals with AUD. Because addiction almost always involves dopamine dysregulation, success in this Phase 1b study would also be a critical first step in the development of a drug that could treat a wider array of addictive disorders."

The launch of Newleos' Phase 1b study builds on robust preclinical and clinical data supporting the TAAR1 mechanism and NTX-2001 specifically. NTX-2001 was previously studied in eight clinical trials involving healthy volunteers and individuals with schizophrenia or schizoaffective disorder designed to assess efficacy, safety, tolerability, pharmacokinetics and pharmacodynamics. NTX-2001 was studied in multiple formulations at multiple dosing regimens, with approximately 645 participants receiving the study intervention (either NTX-2001 or placebo). Across all these studies, NTX-2001 was consistently safe and well tolerated.

Newleos Announces Dosing of First Participant in Phase 1b Study of NTX-2001 for Alcohol Use Disorder

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Zealand Pharma and Roche to advance petrelintide, an amylin analog, to Phase 3 trials for chronic weight management

TMT Newswire, 30 April 2026

- *Phase 3 trials for chronic weight management planned for initiation in the second half of 2026*
- *Petrelintide demonstrated double-digit weight loss with placebo-like tolerability in the ZUPREME-1 Phase 2 trial*
- *Zealand Pharma and Roche aim to unlock the full value potential of petrelintide providing a highly tolerable option for people living with overweight and obesity*

Zealand Pharma A/S, a biotechnology company transforming the future of metabolic health, today announced formal endorsement to advance petrelintide, an amylin analog for chronic weight management, into Phase 3 trials with its partner Roche. The initiation is planned for the second half of 2026.

Adam Steensberg, President and Chief Executive Officer of Zealand Pharma, said,

"Advancing petrelintide into Phase 3 marks an important step for the program and our collaboration with Roche. By delivering exceptional tolerability and desired weight loss without disrupting daily life, we aim to redefine the weight management experience for people living with overweight and obesity."

The Phase 3 program for petrelintide is designed to evaluate the efficacy, safety, and tolerability of petrelintide as a once-weekly subcutaneous treatment in adults living with obesity or overweight with weight-related comorbidities. Petrelintide has the potential to address significant unmet needs in chronic weight management by providing a highly tolerable alternative that promotes long-term adherence, a critical factor for sustained health outcomes.

Zealand Pharma and Roche to advance petrelintide, an amylin analog, to Phase 3 trials for chronic weight management | The Manila Times

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LARGE MOLECULES

Pfizer's ELREXFIO Significantly Improves Progression-Free Survival for Double-Class Exposed Patients with Relapsed or Refractory Multiple Myeloma

Le lizard, 29 April 2026

Pfizer Inc. (NYSE: PFE) today announced positive topline results from the Phase 3 MagnetisMM-5 study evaluating ELREXFIO® (elranatamab) as monotherapy in adults with relapsed or refractory multiple myeloma (RRMM) who received at least one prior line of treatment. The study demonstrated a statistically significant and clinically meaningful improvement in the primary endpoint of progression?free survival (PFS), as assessed by blinded independent central review (BICR), versus standard-of-care daratumumab plus pomalidomide and dexamethasone (DPd). The safety and tolerability of ELREXFIO was consistent with its known safety profile.

The PFS results exceeded the pre-specified interim analysis target hazard ratio for efficacy, with most ELREXFIO-treated patients remaining progression-free. The trial remains ongoing to assess overall survival, a key secondary endpoint, which was not yet mature at the time of this interim analysis. These data will be discussed with global health authorities, and detailed results from MagnetisMM-5 will be submitted for presentation at a future medical congress.

Multiple myeloma is an aggressive and currently incurable blood cancer that affects plasma cells made in the bone marrow:

- It is the second most common type of blood cancer worldwide, with over 36,000 new cases each year in the United States and over 187,000 globally.[1,2,3]
- Despite treatment advances, most patients relapse and develop relapsed or refractory disease, often requiring multiple lines of therapy, with approximately 40% not surviving beyond five years.[2,4]
- Multiple myeloma can significantly impact quality of life, with immune suppression increasing susceptibility to infection, and symptoms such as fatigue, bone pain, and psychological distress making everyday activities more difficult.[5-7]

"Effective intervention earlier in the course of disease represents a critical opportunity to improve outcomes for people living with multiple myeloma," said Jeff Legos, Chief Oncology Officer, Pfizer. "ELREXFIO has already helped address a significant unmet need in heavily pre?treated patients, delivering deep, durable, and clinically meaningful responses. The MagnetisMM-5 results reinforce our confidence in ELREXFIO's potential to benefit patients earlier in their treatment journey and support our comprehensive strategy to evaluate ELREXFIO both as monotherapy and as part of combination approaches across multiple lines of therapy."

Pfizer's ELREXFIO Significantly Improves Progression-Free Survival for Double-Class Exposed Patients with Relapsed or Refractory Multiple Myeloma

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REGULATORS AND REGULATORY ACTIONS

Alembic Pharmaceuticals Incorporates Germany Subsidiary To Expand European Market Presence

The free press journal, 24 April 2026

Alembic Pharmaceuticals has incorporated a wholly owned subsidiary, Alembic Pharmaceuticals GmbH, in Germany with a share capital of 25,000 euros. Announced on April 23, 2026, the move aims to expand the company's footprint in Europe by promoting and distributing its pharmaceutical products, marking a strategic step to explore new business opportunities in the region.

Alembic Pharmaceuticals is taking a direct route into Europe, setting up a new entity in Germany to strengthen its international reach and tap into fresh growth opportunities.

Establishes New Subsidiary

Alembic Pharmaceuticals has incorporated Alembic Pharmaceuticals GmbH as a wholly owned subsidiary in Germany, holding 100 percent ownership. The entity has been set up with a share capital of EUR 25,000, divided into 25,000 shares of EUR 1 each, marking the company's formal entry into a new geographic market.

The primary objective behind the incorporation is to explore business opportunities in Germany and the broader European region. The subsidiary will focus on promoting, selling, and distributing Alembic's pharmaceutical products, aligning with the company's strategy to strengthen its presence in regulated international markets.

Early Stage Operations

As a newly incorporated entity, Alembic Pharmaceuticals GmbH has not yet commenced operations and currently reports no turnover. The disclosure indicates that the subsidiary is in its initial phase, with future activities expected to build gradually as the company establishes its presence in the region.

Alembic Pharmaceuticals Incorporates Germany Subsidiary To Expand European Market Presence

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Dr. Reddy's Laboratories Secures Health Canada Approval For Diabetes Treatment Injection Launch In Canada

The free press journal, 29 April 2026

Dr. Reddy's Laboratories has received Health Canada approval for its generic Semaglutide injection, marking its entry into the Canadian diabetes treatment market. The approval, granted on April 29, 2026, enables commercialization of both 2 mg and 4 mg pen versions. The company becomes the first to secure such authorization for a generic version in Canada.

Dr. Reddy's Laboratories has taken a significant step in expanding its global footprint by securing regulatory approval in Canada for its generic Semaglutide injection. The approval, granted by Health Canada's Pharmaceutical Drugs Directorate on April 29, 2026, allows the company to commercialize the product across the country. This includes both 2 mg per pen and 4 mg per pen formats, aligning with existing treatment standards for diabetes care.

Notice of Compliance Confirmation

The authorization comes in the form of a Notice of Compliance, which confirms that the product meets all regulatory requirements for safety, quality, and efficacy. With this clearance, Dr. Reddy's gains the ability to manufacture, sell, and distribute the drug in Canada without a defined expiry period on the approval. The company also highlighted that the approval was received ahead of Health Canada's target review timeline, indicating a smooth regulatory process.

This development positions Dr. Reddy's as the first company to secure marketing authorization for a generic Semaglutide injection in Canada. The move is particularly relevant given the growing prevalence of diabetes in the country. A significant portion of the adult population is affected by the condition, driving demand for effective and accessible treatment options. Semaglutide, a GLP-1 receptor agonist, is widely used to improve glycemic control and support weight management in patients with type 2 diabetes.

Dr. Reddy's Laboratories Secures Health Canada Approval For Diabetes Treatment Injection Launch In Canada

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Dr Reddy's wins nod to sell generic Ozempic, check cost of weight-loss drug

MSN, 29 April 2026

Indian pharma major Dr Reddy's Laboratories has received regulatory approval from Health Canada to sell the first generic version of Novo Nordisk's blockbuster diabetes-cum-weight-loss drug Ozempic (semaglutide).

Health Canada said it authorised a semaglutide injection developed by Dr Reddy's after a full review of safety, efficacy and quality. The approval covers the same once-weekly treatment for Type-2 diabetes as the branded Ozempic.

Canada becomes the first G7 country to clear a generic semaglutide product, marking a milestone in efforts to make GLP-1 therapies affordable. The generic launch comes after patent protections on semaglutide expired earlier this year in Canada, opening the door for competition. Analysts say this is a key test case for how generics might challenge branded peptides.

Dr Reddy's is expected to supply millions of doses once commercialised. Following the approval, Dr Reddy's stock came in focus. At the time of publishing this report, Dr Reddy's stock was trading at Rs 1,339.90, down by 0.8 per cent. The move follows earlier generic

approvals in India and other emerging markets.

The entry of Dr Reddy's generic is triggering a price battle among pharmaceutical companies worldwide.

In Canada, generic semaglutide prices are expected to be 45-90 per cent cheaper than the original Ozempic, according to Health Canada norms. More generic applications are under review, suggesting a crowded market ahead.

Dr Reddy's wins nod to sell generic Ozempic, check cost of weight-loss drug

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IGC Pharma Secures Psilocybin Research Authorization, Expanding Focus on Neuropsychiatric Symptoms in Dementia

Access Newswire, 24 April 2026

IGC Pharma, Inc., a clinical-stage biotechnology company developing therapeutics for Alzheimer's disease, today announced that on April 9, 2026, it received authorization in Colombia to synthesize, formulate, and conduct development activities involving psilocybin at its research and development facility in Bogotá.

The authorization, granted under the oversight of the Fondo Nacional de Estupefacientes (FNE), provides IGC Pharma with a regulated capability to work with psilocybin, positioning the Company within an expanding area of scientific and investor interest. The Company believes it is among a limited number of organizations in Colombia with this type of authorization.

This capability allows the Company to evaluate potential applications of psilocybin, for example in neuropsychiatric symptoms (NPS) associated with dementia, including depression and anxiety, conditions affecting a large portion of Alzheimer's patients and representing a significant and underserved market opportunity.

Potential Engine of Growth

Neuropsychiatric symptoms affect about 80% of Alzheimer's patients and broad and heterogeneous, including agitation, depression, anxiety, and mood-related conditions. While IGC Pharma's lead candidate, IGC-AD1, is advancing through a Phase 2 clinical trial targeting agitation, additional symptom domains such as depression and anxiety represent a substantial and largely unaddressed segment of the disease burden.

IGC Pharma Secures Psilocybin Research Authorization, Expanding Focus on Neuropsychiatric Symptoms in Dementia | Ap | rutlandherald.com

Novartis, PTC push Huntington's drug into Phase 3, mum on accelerated approval

Biospace, 29 April 2026

Phase 2 data from PTC Therapeutics showed that the Novartis-partnered Huntington's disease asset slowed progression by more than 50%. Analysts say the decision to initiate a last-stage trial reflects a lack of confidence in an accelerated FDA nod.

Following encouraging mid-stage data, Novartis and PTC Therapeutics have decided to advance their Huntington's disease candidate into late-stage development—a move that analysts say demonstrates the partners' confidence in the program but also their apprehension around the likelihood that the FDA will grant accelerated approval based on existing data.

The decision to start Phase 3 development was driven by an interim readout from the long-term extension phase of the mid-stage PIVOT-HD study presented on Tuesday.

A 5-mg dose of PTC and Novartis' drug, called votoplam, slowed disease progression by 28% at 24 months, as compared with natural history controls. Votoplam's benefits were more pronounced at the 10-mg dose, which reduced worsening by 52%. Prolonged votoplam treatment also kept neurofilament light chain levels suppressed below baseline through 24 months of follow-up.

Bolstered by these data, Novartis said on an earnings call Tuesday that it has launched the Phase 3 INVEST-HD study of votoplam, testing the drug against placebo in patients with Huntington's disease. The trial aims to enroll 770 patients, with a readout expected in 2030, according to the pharma's presentation.

While Novartis will take charge of votoplam's late-stage development, PTC will work with the pharma to discuss existing data and determine next steps for the asset, "including regulatory actions," according to the biotech's Tuesday release.

The initiation of INVEST-HD "conveys continued long-term optimism around the program," analysts at RBC Capital Markets told investors in a Tuesday note, however Novartis and PTC are being "deliberately measured" regarding their regulatory plans, offering no specific mention of accelerated approval.

Novartis, PTC push Huntington's drug into Phase 3, mum on accelerated approval - BioSpace

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Incyte's JAK inhibitor scores phase 3 vitiligo wins but can't quite shake off Rinvoq

Fierce Biotech, 28 April 2026

Incyte's povorcitinib has scored a pair of phase 3 wins for a skin condition, although analysts noted the oral JAK inhibitor didn't quite live up to AbbVie's Rinvoq.

Incyte evaluated 30 mg povorcitinib in two late-stage studies, dubbed STOP-V1 and STOP-V2, in adults with nonsegmental vitiligo. Both trials hit their primary endpoint of a more than 75% reduction in a facial vitiligo score at week 52, according to the company's first-quarter earnings release.

Specifically, 18.9% of povorcitinib-treated patients in both trials hit this 75% mark, compared with 6.8% and 3.1% of patients in STOP-V1 and STOP-V2, respectively.

"Across both studies, statistically significant and clinically meaningful differences were also observed in key secondary endpoint measures," Incyte explained, including a measure of reducing vitiligo across the body by 50% or more.

Safety and tolerability was consistent with previous studies, with "no new safety signals observed," the biopharma added.

Incyte will use the latest phase 3 data to support its vitiligo approval push to regulators, which is currently scheduled for the first half of 2027.

Incyte's vitiligo bet scores ph. 3 wins but can't beat Rinvoq

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Pfizer Reaches Three Settlement Agreements for VYNDAMAX

Business Wire, 28 April 2026

Pfizer Inc. today announced that it has entered into settlement agreements with generic drug manufacturers Dexcel Pharma, Hikma Pharmaceuticals and Cipla Ltd, regarding lawsuits filed in the U.S. District Court for the District of Delaware for infringement of patents relating to VYNDAMAX ® (tafamidis), a treatment for cardiomyopathy transthyretin-mediated amyloidosis (ATTR-CM). These settlements extend the effective U.S. patent expiry date for VYNDAMAX to June 1, 2031, subject to the outcome of other litigation. Pfizer had previously anticipated a significant decline in U.S. revenues for VYNDAMAX beginning in 2029 upon patent expiry. As a result of this settlement, revenues are now expected to remain relatively stable from 2028 through mid-2031.

"We are very pleased by this outcome, both for patients and in recognition of the value of our innovative science and the strength of our patents," said Aamir Malik, Executive Vice President and Chief U.S. Commercial Officer, Pfizer. "Our focus continues to be our unwavering commitment to patients with ATTR-CM. With our market leadership and physician experience, we remain confident in the value and benefits of VYNDAMAX as we work to reach more patients living with this serious and underdiagnosed disease."

VYNDAMAX remains the market leader with 75% of prescription volume within the overall ATTR-CM market. As the only once-daily capsule approved for ATTR-CM with statistically significant reductions in both all-cause mortality and cardiovascular-related hospitalizations with a demonstrated safety profile comparable to placebo, VYNDAMAX is backed by over seven years of market leadership and data from more than 7,000 patients across clinical trials and the largest ATTR-CM registry to date.

Pfizer Reaches Three Settlement Agreements for VYNDAMAX - Las Vegas Sun News

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AidaBREAST Gains FDA Breakthrough Status for Personalized Radiotherapy in Early Breast Cancer

Health & Pharma, 29 April 2026

Key Takeaways

- AidaBREAST® received FDA Breakthrough Device designation as a multi-omic assay for women with stage I–IIa invasive breast cancer.
- The test estimates 10-year locoregional recurrence risk and predicts benefit from adjuvant radiation therapy after breast-conserving surgery, aiming to personalize treatment decisions and reduce both overtreatment and undertreatment in early-stage disease.

Prelude Corporation, also known as PreludeDx, announced that the U.S. Food and Drug Administration has granted Breakthrough Device designation to AidaBREAST®, its early-stage invasive breast cancer assay. The designation marks an important regulatory step for a test intended to support more individualized treatment decisions after breast-conserving surgery.

"AidaBREAST addresses an important need in early-stage invasive breast cancer by providing both recurrence risk assessment and insight into which patients are most likely to benefit from radiation therapy," said Dan Forche, President and CEO of PreludeDx. "With Breakthrough Device designations for both DCISionRT and AidaBREAST, we are

continuing to advance precision diagnostics that support more informed treatment decisions for patients and physicians."

AidaBREAST is designed for women with stage I or IIa invasive breast cancer. The assay provides two clinically relevant outputs: an individualized prognostic assessment of 10-year locoregional recurrence risk and a prediction of the expected benefit from adjuvant radiation therapy. In clinical practice, this type of information could help physicians and patients weigh the potential value of radiation therapy more precisely, particularly in cases where conventional clinicopathologic factors may not fully capture tumor biology.

The company says AidaBREAST uses a next-generation multi-omic platform that combines multiplex protein expression with targeted next-generation RNA sequencing. The assay applies spatial biology technologies and artificial intelligence to integrate these molecular and tumor biology signals into a patient-specific risk assessment. According to PreludeDx, this approach is intended to move beyond traditional measures used in early breast cancer risk evaluation.

AidaBREAST Gains FDA Breakthrough Status for Personalized Radiotherapy in Early Breast Cancer

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MEDTECH

Medtronic wins FDA approval for updated mitral replacement valve

Medtech Dive, 29 April 2026

Surgeons have performed initial implants of the Mosaic Neo valve at centers across the U.S., and the first robotic implantation has also been performed.

Dive Brief:

- Medtronic received Food and Drug Administration approval for its next-generation mitral valve and has launched the device in the U.S., the company said Wednesday.
- Called Mosaic Neo, the bioprosthetic valve is designed to be implanted through sternotomy, which requires separating the breastbone to reach the heart, or through minimally invasive surgery.
- In addition, the first concomitant procedure was performed where the Mosaic valve was implanted alongside Medtronic's Penditure left atrial appendage exclusion device, the company said. The Penditure clip is designed to close the left atrial appendage to help prevent clots from entering the bloodstream.

Dive Insight:

Mitral regurgitation, a common heart valve disease affecting millions of people globally, occurs when the valve does not shut properly, allowing blood to flow back into the heart. The condition causes the heart to work harder than normal and can eventually lead to heart failure.

Medtronic said that nearly 20,000 patients undergo surgical mitral valve replacement in the U.S. each year.

The company's original Mosaic porcine valve received FDA premarket approval in 2000 for replacing malfunctioning native or prosthetic aortic and mitral heart valves. The Mosaic Neo mitral valve builds on the earlier Mosaic platform.

Medtronic wins FDA approval for updated mitral replacement valve | MedTech Dive

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Andhra Pradesh Health Department's AI-driven medtech pilot yields early results; 12,677 patients screened in 37 days

Shortlisted through the MedTech Innovation Challenge, the startups have been piloting their technologies across 18 government hospitals; the best performers will be awarded cash prizes and a ₹1 crore work order.

The Hindu, 24 April 2026

Demonstrations of AI-driven medical technologies in government hospitals across the State are yielding encouraging results, the Department of Health, Medical Education and Family Welfare said on Thursday (April 23, 2026).

Following the launch of the A.P. MedTech Innovation Challenge in November 2025, the department received 297 applications and shortlisted 18 innovators. The startups have been piloting their technologies in government hospitals to improve healthcare delivery.

Between February and the end of March, the startups delivered services to 12,677 patients over 37 days. One startup screened 7,433 individuals and identified early-stage tuberculosis in about 15% to 25% of them.

Andhra Pradesh Health Department's AI-driven medtech pilot yields early results; 12,677 patients screened in 37 days - The Hindu

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INTERESTING MEDICAL NEWS

Omega-3s may affect brain repair: Should you avoid them?

Medical News Today, 29 April 2026

- For many years, we have heard about the potential health benefits of fish oil due in part to their high concentration of omega-3 fatty acids.
- Past studies have linked the consumption of fish oil to possible protection against several health concerns, including brain diseases like dementia and Alzheimer's disease.
- A new study has found that fish oil supplements may not be beneficial for people who have experienced repeated mild traumatic brain injuries.
- Researchers believe the build-up of a specific omega-3 fatty acid could potentially disrupt brain healing and assist with the accumulation of the protein tau in the brain, via both human cell and mouse trials.

For many years, we've heard about the potential health benefits of fish oil due in part to their high concentration of omega-3 fatty acids.

Past studies have linked the consumption of omega-3 fatty acids or fish oil — either through oily fish or fish oil supplements — to possible protection against several health concerns, including cardiovascular disease, type 2 diabetes, rheumatoid arthritis, depression, and neurodegenerative conditions such as Parkinson's disease, Alzheimer's disease, and other forms of dementia.

Now, a new study published in the journal Cell Reports has found that fish oil supplements may not be beneficial for people who have experienced repeated mild traumatic brain injuries (TBI).

Instead, the build-up of a specific omega-3 fatty acid in fish oil could potentially disrupt brain healing and assist with the accumulation of the protein tau in the brain, which is considered to be a hallmark of Alzheimer's disease, via both human cell and mouse trials.

Fish oil and repeated mild traumatic brain injuriess

For this study, researchers used a combination of models, including one with mice and another with human brain microvascular endothelial cells, to examine how long-term fish oil use might impact the brain.

"This project developed over several years and was motivated by a broader question," Onder Albayram, PhD, associate professor in the Department of Pathology and

Laboratory Medicine within the Department of Neuroscience at the Medical University of South Carolina, and lead author of this study, told *Medical News Today*.

"Fish oil is widely used and generally considered beneficial, yet there are also observations in other areas of medicine suggesting that its effects may vary depending on the biological context, particularly during periods of tissue repair," Albayram explained.

"We wanted to understand whether similar context dependent effects might exist in the brain," he detailed. "To do this, we needed a model where the brain is actively engaged in recovery over time. Repeated mild head injury provided a useful framework, because it involves a prolonged and often subtle repair process, with elements of resilience and vulnerability."

"In that sense, the model allowed us to study how dietary factors such as fish oil interact with the brain's recovery mechanisms," he continued. "The study evolved step by step, with the findings guiding the next questions."

EPA linked to reduced brain repair capacity

At the study's conclusion, researchers found that one specific omega-3 fatty acid in fish oil, eicosapentaenoic acid (EPA), was associated with a reduced repair capacity in the brain, potentially interfering with healing after a brain injury.

"This was one of the most important parts of the study because it helped us move from observation to mechanism," Albayram said.

"In the mouse model, several findings pointed toward the neurovascular unit, especially the cerebrovascular endothelial cells, as a vulnerable site after repeated mild brain injury. These cells form the inner lining of the brain's blood vessels and help regulate blood flow, metabolic exchange, barrier function, and tissue repair. The human brain has an enormous vascular network, so even subtle changes in endothelial function can have meaningful consequences over time."

– Onder Albayram, PhD

"Based on the mouse data, we developed an in vitro model using human brain microvascular endothelial cells to ask a more focused question: could EPA directly affect the repair capacity of these cells under conditions that allow fatty acid use?," he continued

"What we found was that EPA, but not DHA, reduced endothelial repair responses, including vascular network formation and wound healing capacity. That was significant because it mirrored the direction of the mouse findings and suggested that EPA may act

directly on the vascular repair machinery, rather than being only a secondary marker of injury," said Albayram.

Long-term fish oil supplementation linked to tau buildup

Additionally, Albayram and his team also correlated long-term fish oil supplementation to vascular-associated accumulation of the protein tau in the cortex, as well as lower neurological and spatial learning.

"We observed vascular associated tau accumulation in the cortex, which is a recognized but still not fully understood feature in conditions such as chronic traumatic encephalopathy," Albayram explained.

"In human postmortem studies, tau often accumulates around blood vessels, but it is difficult to determine how this develops over time or whether the vasculature plays an active role in shaping this pathology. Our findings suggest that the cerebrovascular system, including endothelial cells, may be more directly involved than previously appreciated," he told us.

"Importantly, these vascular changes were accompanied by neurovascular uncoupling, meaning a disruption in the coordination between neuronal activity and blood flow," he continued. "This was observed alongside deficits in spatial learning and memory, indicating that the vascular and metabolic changes were functionally relevant. Ultrastructural analyses further supported this, showing disruption within the neurovascular unit."

"Together, these results suggest that under certain conditions, dietary factors may influence how the brain's vascular system adapts to injury, and that this can be linked to both pathological features, such as tau accumulation, and measurable changes in cognitive function," Albayram added.

Moving beyond one-size-fits-all health advice

MNT had the opportunity to speak with Dung Trinh, MD, internist for the MemorialCare Medical Group and chief medical officer of Healthy Brain Clinic in Irvine, CA, about this research.

Trinh, who was not involved in the study, commented that its findings do not mean that fish oil is broadly harmful, but they do challenge the assumption that all omega-3 supplements are automatically brain-protective.

"For patients with repeated mild head injuries, especially athletes, veterans, or people with recurrent falls, the finding that EPA may interfere with brain vascular repair is clinically important and worth paying attention to," Trinh explained.

"Brain health is complex, and cognitive decline can come from many causes, including Alzheimer's disease, vascular disease, traumatic brain injury, sleep problems, mood disorders, medications, and metabolic conditions. We need continued research so we can move beyond one-size-fits-all advice and develop more personalized strategies to protect memory, thinking, and long-term brain function," he added.

Trinh advised readers not to panic about this study's findings, and not to abruptly stop anything recommended by their physician.

"This study does not prove that fish oil causes brain damage in the general population," he continued. "But if someone has a history of repeated concussions or head trauma, they should talk with their doctor about why they are taking fish oil, what dose they are taking, and whether their supplement is EPA-heavy."

How to follow a brain-healthy diet not dependent on fish oil

Meridan Zerner, MS, RDN, CSSD, LD, CHWC, founder of Meridan Zerner Nutrition in Dallas, TX, offered her top tips on how to follow a brain-healthy diet that is rich in whole foods, without relying on supplements.

"First, I would gently and respectfully encourage people to pump the brakes a bit and have a deeper conversation with their healthcare provider," Zerner said.

"This study does not overturn the previous broader recommendations and research. We do know that omega-3s (preferably from food) support the brain's foundation, but repair is far more complex. It's not one nutrient — it's the whole environment: nutrition, sleep, blood flow, and recovery," she emphasized.

Zerner offered these starter recommendations for eating a brain-healthy diet focused on whole foods:

- **Eat fatty fish 2–3 times per week.** Salmon, sardines, mackerel, herring, and trout are naturally rich in both EPA and DHA in a food matrix that the body may process differently than a concentrated supplement.
- **Load up on colorful produce.** Berries, leafy greens, beets, and cruciferous vegetables provide antioxidants and polyphenols that support the brain's vascular health and help to reduce neuroinflammation.

- **Include walnuts, flaxseeds, and chia seeds.** This is small, but meaningful in that these foods provide ALA, a plant-based omega-3. While the conversion to EPA and DHA is very limited, they contribute to overall anti-inflammatory eating patterns.
- **Follow a Mediterranean or MIND diet pattern.** Both are supported by strong evidence for cognitive health. They emphasize olive oil, beans, whole grains, nuts, fish, fruits, and veggies which supply the brain with multiple protective nutrients.
- **Stay well-hydrated and limit ultra-processed foods.** The brain is roughly 73% water, and ultra-processed foods drive inflammation — the opposite of what we want for brain repair.

"This study […] is a smaller mouse study, which for most health scientists means that it raises excellent questions and definitely validates the need for actual human studies," Zerner said.

"But again, the findings depend a lot on context — this is a rodent study, the effects observed are not universal across all omega-3 fatty acids, the dose of EPA that would create an equivalent dose in human beings is unclear, the number and severity of TBIs isn't clear and all the mice were male," she cautioned.

"I would also defer to the lead researcher himself who said this is not a call for the public to abandon fish oil supplements, emphasizing that 'biology is context-dependent'," she added. "However, if you are an athlete in a contact sport, a military service member, or anyone at elevated risk for repetitive mild TBIs, this research does give us reason to pause and ask more questions."

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