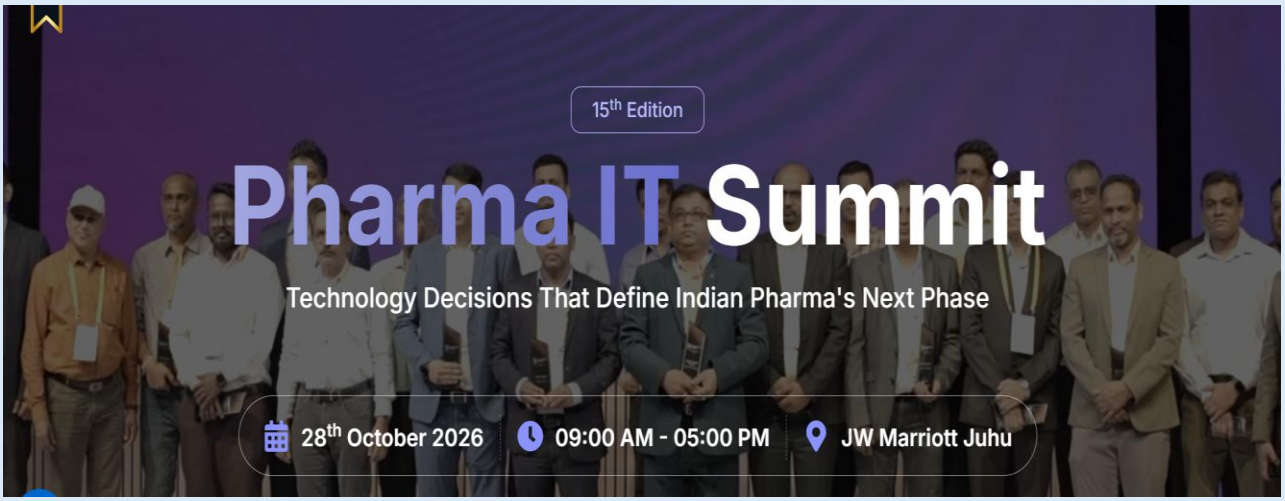
Friday, 4 September 2026

CONTENT *(Highlights)*

A-601, Marathon Innova, Opp. Peninsula
Corporate Park, Off Ganpatrao Kadam Marg,
Lower Parel (W), Mumbai 400 013, India.

Tel.:+91-22-6673 6800,
Fax: 91-22-66399727
web: www.sidvim.com

UPCOMING EVENTS



Why Attend?

The Pharma IT Summit brings together technology leaders, pharmaceutical executives, and solution providers to explore the technologies transforming the life sciences industry. Through expert-led discussions, real-world case studies, and peer collaboration, the summit delivers practical insights into AI, cloud, cybersecurity, digital manufacturing, ERP modernization, data, and regulatory compliance.

Who Should Attend?

- Chief Information Officer (CIO)
- Chief Technology Officer (CTO)
- Chief Digital Officer (CDO)
- Chief Data Officer (CDO)
- Chief Information Security Officer (CISO)
- Head of IT Strategy
- Head of Technology Innovation
- Head of Data Science
- Head of Cybersecurity
- Director of IT Infrastructure
- Director of Software Development
- Director of Data Analytics
- Director of Information Security
- Director of IT Governance
- Director of Cloud Computing
- Senior IT Architect
- Head of Digital Transformation

REGISTER NOW

DEALS AND FUNDING

India's largest drugmaker Sun Pharma inks deal with US govt to supply cheaper medicines to Americans

2nd September 2026, Hindustan times

India's largest drugmaker Sun Pharmaceutical Industries has reportedly signed an agreement with the US government to extend affordable medicines to American patients. According to a report by news agency *PTI*, the Mumbai-based pharma company entered into a deal to provide 'Most Favoured Nation' (MFN) pricing to state Medicaid programmes in the United States. Under the MFN pricing, a buyer can avail the lowest price possible for a medicine.

In a regulatory filing on Tuesday, Sun Pharma said the agreement to provide MFN pricing will also apply to the company's future innovative medicine launches in the US market. The US government has delayed the imposition of tariffs under Section 232 on Sun Pharma's innovative products by over two years as the deal acknowledges the company's investment in the country. Further details of the deal were not revealed by the company.

Sun Pharma's North America CEO Rick Ascroft, who represented the firm at the White House, said the United States was a crucial area of investment and expansion across clinical development, sales and marketing, and both Active Pharmaceutical Ingredient (API) and finished products manufacturing.

India's largest drugmaker Sun Pharma inks deal with US govt to supply cheaper medicines to Americans

★★★★★★★

BioMarin Announces Global Settlement with Ascendis Pharma A/S; Ascendis Will Pay Royalties to BioMarin on Yuviwel Sales in U.S., EU, Brazil and South Korea

31st August 2026, PR Newswire

BioMarin Pharmaceutical Inc. today announced that it has entered into binding terms with Ascendis Pharma A/S, resolving the patent and ancillary disputes pending globally, including before the U.S. International Trade Commission (ITC) concerning Ascendis's Yuviwel. As part of the agreement, Ascendis will pay BioMarin a royalty equal to 20% of net sales of Yuviwel in the U.S., retroactive to the first commercial sale, and 18% of net sales in the European Union, Brazil and South Korea until May 2030.

"This outcome incentivizes companies like BioMarin to keep investing in the kind of long-term innovation that is critical to bringing breakthrough treatments to the people who need them," said Alexander Hardy, President and Chief Executive Officer of BioMarin. "We have spent decades focused on understanding the underlying biology of rare genetic conditions, building the deep scientific expertise that led to our development of six first-in-disease medicines for patients. We look forward to continuing to innovate, bringing forward the next generation of medicines for people with serious genetic conditions, and building on our ongoing momentum for children with achondroplasia."

The scope of the settlement includes a license for BioMarin's patents that relate to Yuviwel for all current and potential indications, including achondroplasia and hypochondroplasia. It also covers the use of Yuviwel in combination with other medicines. Under the terms of the agreement, BioMarin will dismiss the pending Section 337 investigation before the ITC and the parties will resolve all claims relating to the asserted intellectual property, including litigation pending in Brazil, Denmark, Germany, South Korea and the Northern District of California.

Reaching this agreement recognizes the value of BioMarin's pioneering innovations in C-type natriuretic peptide (CNP) technology, including the development of VOXZOGO® (vosoritide), while providing a framework that enables continued access to medicine for children with achondroplasia around the world.

BioMarin Announces Global Settlement with Ascendis Pharma A/S; Ascendis Will Pay Royalties to BioMarin on Yuviwel Sales in U.S., EU, Brazil and South Korea

★★★★★★★

Nxera Pharma to Receive $8.6 Million Milestone Payment from Centessa Pharmaceuticals Following Late-stage Development Progress

3rd September 2026, Yahoo Finance

Nxera Pharma Co., Ltd. ("Nxera" or "the Company"; TSE 4565) today announces that Centessa Pharmaceuticals Limited ("Centessa"), a wholly-owned subsidiary of Eli Lilly and Company ("Lilly"), has achieved a late-stage development milestone associated with its selective orexin receptor 2 (OX2R) agonist portfolio. This milestone triggers a payment of US$8.6 million to Nxera pursuant to its research collaboration with Centessa. The milestone payment will be recognized as revenue in the third quarter of the fiscal year ending 31 December 2026.

On 24 June 2026, Lilly announced that it had completed the acquisition of Centessa. Through this acquisition, Lilly gained ownership of Centessa's OX2R agonist pipeline, currently comprising clinical-stage molecules designed to treat a broad range of diseases associated with sleep-wake regulation and related neurological disorders. Nxera retains rights to receive future development and commercialization milestones, as well as royalties, related to the programs.

Christopher Cargill, President and CEO of Nxera Pharma, commented: "We are very pleased to see progress in the clinic and more broadly across the OX2R agonist pipeline. This is a very exciting portfolio with great potential to address major unmet needs across a broad range of disorders, and we look forward to announcing further updates that impact Nxera as key milestones are reached."

Nxera Pharma to Receive $8.6 Million Milestone Payment from Centessa Pharmaceuticals Following Late-stage Development Progress

★★★★★★★

Cipla and SBP Group sign exclusive licensing agreement for potential best-in-class HER2 bispecific ADC Rolditamig Deuderuxtecan (TQB2102)

31st August 2026, Cipla

Cipla Limited and Sino Biopharmaceutical Limited today announced that SBP Group's subsidiary, Chia Tai Tianqing Pharmaceutical Group Co., Ltd. ("CTTQ"), has entered into an exclusive license and supply agreement with Cipla for Rolditamig Deuderuxtecan, also known as TQB2102, a potential best-in-class HER2 bispecific antibody-drug conjugate ("ADC").

Under this agreement, Cipla will receive exclusive rights to develop and commercialise TQB2102 in India, South Africa and 5 other emerging markets. Cipla will be responsible for local clinical development, regulatory activities, and commercialisation in the licensed territories, while CTTQ will continue to manufacture and supply TQB2102.

TQB2102 is being evaluated across HER2-expressing cancers and has demonstrated encouraging clinical potential in HER2-low advanced breast cancer. The collaboration brings together SBP Group's differentiated late-stage oncology asset and development and manufacturing capabilities with Cipla's established regulatory, medical, market access and commercial presence across India, South Africa, and other emerging markets. The partnership is intended to accelerate local development and regulatory approvals, enabling patient access across licensed countries, subject to applicable approvals.

Commenting on the partnership, Achin Gupta, Managing Director and Global Chief Executive Officer, Cipla said, "At Cipla, innovation is central to our mission of expanding access to therapies that address unmet patient needs. Breast cancer remains a significant healthcare challenge, and this agreement strengthens our oncology portfolio with a promising HER2-targeted antibody-drug conjugate. Through our partnership with SBP Group and CTTQ, we aim to accelerate development and, subject to regulatory approvals, expand access to this innovative treatment across licensed territories."

"Expanding global access to medicines developed by SBP Group is a central part of our strategy," said Eric Tse, CEO, SBP Group. "TQB2102 has demonstrated encouraging clinical potential across different HER2-expressing breast cancer populations. Cipla's scale, local expertise and commitment to patient access make it a strong partner to help bring this treatment to patients across India, South Africa and other emerging markets."

Cipla and SBP Group sign exclusive licensing agreement for potential best-in-class HER2 bispecific ADC Rolditamig Deuderuxtecan (TQB2102)

★★★★★★★

RPG Active Pharma acquires API business of Raghava Life Sciences for ₹135 crore

3rd September 2026, The Hindu business line

RPG Life Sciences Ltd has made a second acquisition in two months in the active pharmaceutical ingredients (API) segment. The company's wholly-owned subsidiary, RPG Active Pharma Ltd (RPGAP) has entered into a Business Transfer Agreement to acquire the API and intermediates business of Raghava Life Sciences Private Ltd on a going-concern basis through a slump sale, for a consideration of up to ₹135 crore, it said.

Last month, RPGLS agreed to transfer its API business to RPG Active Pharma Ltd, even as it has announced plans to acquire Actis Generics Private Ltd – a Visakhapatnam-based API manufacturing company. The latest acquisition is the next step in RPGAP's consolidation based on a buy-and-build strategy to bolster growth and create an integrated, scaled API focused organisation, it said. Following the recent acquisition of Actis Generics, this transaction broadens RPGAP's manufacturing base, product portfolio, regulatory capabilities and customer access across geographies, it added. The acquisition will be funded in line with the recent equity raise announced by RPGAP.

Raghava operates a modern API manufacturing facility near Hyderabad, spread across approximately 9 acres, with around 300 KL of installed capacity and a dedicated research set-up, RPG said.

"The facility is WHO-GMP and EU-GMP approved with significant investment towards capacity expansion in recent years. Its established regulatory approvals, meaningful installed capacity and chemistry capabilities provide RPGAP with a high-quality manufacturing presence," it added.

The business has developed a portfolio of high-growth APIs, comprising 22 commercialised products and seven development-stage assets across diabetes, cardiovascular, CNS and other therapeutic segments. The portfolio includes commercially attractive molecules and has multiple international regulatory credentials, besides a broad basket of commercialised and pipeline APIs, it added. The acquisition will be funded in line with the recent equity raise announced by RPGAP.

The transaction includes business with revenues of about Rs 19 crore in FY26 (unaudited), along with manufacturing facilities, R&D facility and a portfolio of 29 API molecules, of which 22 are commercialised and 7 are under development. "No shares are being purchased in any entity and no entity is being acquired," the company told the stock exchange. Quillan Partners acted as the legal advisors, o3 Capital acted as the financial advisors and Deloitte acted as the Financial Due Diligence partner to RPG Active Pharma Ltd, the note said.

RPG Active Pharma acquires API business of Raghava Life Sciences for ₹135 crore

★★★★★★★

PHARMA & BIOLOGICS

SMALL MOLECULES

PMV Pharma's Rezatapopt Achieves 44% Response Rate in TP53 Y220C Ovarian Cancer

2nd September 2026, The Clinical Trial Vanguard

A 44% objective response rate in heavily pretreated ovarian cancer patients is the number PMV Pharmaceuticals is betting its regulatory future on. Updated interim data from the Phase 2 pivotal portion of the PYNNACLE trial, with a May 14, 2026 data cutoff, show rezatapopt monotherapy delivering that response rate in patients whose tumors carry a TP53 Y220C mutation, a genetically defined subset that has historically had few targeted options and is typically managed with chemotherapy until progression. That figure, in a single-arm registrational cohort, is the direct evidence base PMV will carry into an FDA discussion about whether this data package supports accelerated approval.

The clinical logic here is unusually clean for an oncology program. Rezatapopt is an orally available small molecule that binds a hydrophobic pocket created specifically by the Y220C mutation, refolding misshapen p53 protein back toward functional conformation. Because the drug's target is the mutation itself rather than a downstream pathway, patient selection is binary: tumors either carry Y220C or they do not. That precision cuts enrollment noise and, critically, gives regulators a biomarker-defined population in which to interpret single-arm response data without a randomized comparator arm. The registrational design across five tumor-type cohorts in PYNNACLE reflects PMV's read that the FDA is receptive to this framework in genomically selected populations.

What the interim data do not yet resolve is durability. Response rate in a snapshot dataset tells you tumors shrank; it does not tell you for how long. The ovarian cancer cohort in a single-arm trial will face scrutiny on progression-free and overall survival curves before any label claim about clinical benefit can be made definitive. PMV is betting that the Y220C selection is tight enough, and the unmet need deep enough in this line of therapy, to clear an accelerated pathway on response alone while confirmatory data mature. That is a reasonable bet, but it is still a bet. The number to track from here is not the response rate itself but the duration of response in the May cutoff dataset. If the median duration of response in the ovarian cohort holds above six months in the full data package submitted to FDA, the accelerated approval argument becomes substantially harder to dismiss.

PMV Pharma's Rezatapopt Achieves 44% Response Rate in TP53 Y220C Ovarian Cancer

★★★★★★★

LARGE MOLECULES

Cipla licenses China's Qilu Pharmaceutical Keytruda biosimilar US rights

Pembrolizumab, marketed by US giant Merck (known as MSD in India) under the brand name Keytruda is world's top selling immunotherapy, which clocked over $31 billion in 2025.

ET Pharma, 4th September 2026

Joining its peers in race to market a biosimilar alternative of blockbuster cancer drug Keytruda, pharma major Cipla has in-licensed exclusive rights to market Qilu Pharmaceutical's "QL2107" in the US.

Under the agreement, China-based Qilu will be responsible for development, regulatory registration and supply of the product while Cipla will oversee its commercialization across the country. The deal's financial terms are not disclosed by the company.

"This partnership reflects Cipla's confidence in the long-term potential of biosimilars and supports our strategy to build a strong oncology-focused portfolio," said Achin Gupta, MD and Global CEO, Cipla.

"With our established commercial capabilities, we are well-positioned to successfully launch QL2107, subject to regulatory approval, and help ensure it reaches patients in need while lowering the cost of treatment." Marc Falkin, CEO, Cipla North America added.

Pembrolizumab, marketed by US giant Merck (known as MSD in India) is world's top selling immunotherapy which clocked over $31 billion in 2025.

The novel biologic, which works by blocking the PD-1 pathway to help the immune system attack cancer cells, is approved for more than 40 indications. However, as the brand nears its patent cliff, several drugmakers are gearing to enter the market with lower-cost biosimilar alternatives.

Among Indian drugmakers eyeing the opportunity is Ahmedabad-based Zydus Lifesciences, which has partnered with Formycon AG to market its biosimilar FYB206. Hyderabad-based Dr Reddy's Laboratories has also teamed up with Alvotech to develop another Keytruda biosimilar.

Meanwhile for Cipla, the deal marks its second licensing pact with a Chinese drugmaker in a week, highlighting its growing appetite to build a biosimilars portfolio as its internal R&D initiatives are focused around small molecules.

Earlier this week, the Mumbai-based drugmaker struck a deal with China-based Sino Biopharmaceuticals to commercialise its novel bispecific antibody-drug conjugate "rolditamig deruxtecan", in select markets including India.

Cipla Secures US Rights for Keytruda Biosimilar from Qilu Pharmaceutical, ETPharma

★★★★★★★

Roche inks $1.53B deal for Simcere's B-cell-targeting antibody

Fierce Biotech, 1st September 2026

Roche is paying oncology-focused Simcere Zaiming $75 million upfront for global rights to a preclinical trispecific antibody targeting B-cell-mediated diseases.

Under the deal, Roche will gain exclusive global rights to develop, manufacture and commercialize the asset, SIM0660. Simcere Zaiming is eligible to receive up to $1.53 billion in total payments, including the upfront fee, as well as tiered royalties of up to double digits on future net sales, according to the release.

"This agreement with Simcere Zaiming reflects our commitment to partnering with innovative companies to advance and deliver new therapeutic options for patients in need. SIM0660 represents a potential advancement for patients with B-cell-mediated diseases," Boris L. Zaïtra, Roche head of corporate business development, said in the release.

SIM0660 is a preclinical trispecific antibody designed to target CD79a, CD19 and CD3. The molecule combines a CD3-engaging arm that binds to T cells with domains that target the B-cell antigens CD79a and CD19. The approach is designed to trigger T cell-mediated killing of target cells while limiting cytokine release, according to Simcere.

The dual targeting of CD79a and CD19 could give SIM0660 therapeutic potential across B-cell-mediated diseases, including in patients previously treated with CD20- or CD19-directed therapies. Simcere also sees potential for the antibody in B-cell-mediated autoimmune diseases.

Simcere Zaiming was founded in 2023 as an oncology-focused subsidiary of Simcere Pharmaceutical Group, which dates back to 1995. The Chinese biopharma previously partnered with G1 Therapeutics to sell Cosela, a therapy designed to reduce chemotherapy-induced bone marrow damage, in China, Hong Kong, Macau and Taiwan. Simcere also markets the biliary tract cancer treatment Enweida in China.

Roche inks $1.53B deal for Simcere's B-cell-targeting antibody

★★★★★★★

GSK wagers up to $1.3B on a different kind of cancer drug

With its latest foray into China, GSK acquired rights from Hutchmed to an "antibody-targeted therapy conjugate" impacting two well-known cancer drivers, EGFR and KRAS.

BiopharmaDive, 3rd September 2026

GSK is spending up to $1.3 billion on a first-of-its-kind cancer therapy slated to enter the clinic this year.

In a deal announced Thursday, GSK agreed to pay Hutchmed $110 million up front, and potentially roughly $1.19 billion more in milestone payments and royalties, for a majority of the rights to a treatment known as HMPL-A830. That treatment is what Hutchmed refers to as an "antibody-targeted therapeutic conjugate," and could potentially address multiple tumor types.

Typical antibody-drug conjugates, or ADCs, link a targeting antibody to a toxin. They've become a pillar of cancer care in recent years, but still have limitations restricting their reach.

Many drug developers have been working on new ways to improve the technology.

HMPL-A830 is one example. The therapy links an antibody targeting the well-studied EGFR protein to a small-molecule payload designed to block another popular cancer driver, KRAS. Hutchmed claimed the approach has produced "synergistic anti-tumor activity" and "durable" responses in preclinical testing, as well as shown the potential to outperform a traditional antibody or small-molecule drug.

EGFR and KRAS are each the focus of many marketed medicines. EGFR mutations are observed in about 10% to 15% of lung tumors, while KRAS is mutated in a large percentage of colorectal, pancreatic and lung cancers. In its statement, Hutchmed noted that a significant portion of these tumors that lack a "safe and durable" KRAS therapy, a need HMPL-A830 is "designed to address."

GSK wagers up to $1.3B on a different kind of cancer drug | BioPharma Dive

★★★★★★★

Novartis, Bristol Myers pause autoimmune CAR-T trials due to safety concerns

The deaths of three study participants led Novartis to halt development of rap-cel in multiple indications, while "transient" side effects pushed Bristol Myers to pause its own program.

BiopharmaDive, 31st August 2026

Novartis and Bristol Myers Squibb have paused multiple trials evaluating their respective cell therapy programs against autoimmune conditions after observing inflammatory side effects in testing, the companies confirmed Monday afternoon.

Novartis, which is testing a personalized cell therapy called rap-cel in a handful of autoimmune studies, found three cases of immune effector cell-associated hemophagocytic syndrome, a rare and possibly life-threatening reaction. Complications from those events led to "fatal outcomes," according to a company spokesperson.

Novartis said it initiated holds on those trials — which are evaluating rap-cel in lupus, myasthenia gravis, multiple sclerosis and more — on Aug. 24. Novartis is "engaged" with regulators and is reviewing the findings, the spokesperson wrote in an email to BioPharma Dive.

"The temporary halt will allow for a more comprehensive review of the evolving clinical and safety data across the program," the spokesperson added.

Bristol Myers has also voluntarily paused enrollment in autoimmune trials evaluating its own CAR-T treatment zolacabtagene autoleucel, or zola-cel. In an email to BioPharma Dive, a company spokesperson said the move was made "out of an abundance of caution" to "review clinical data across our zola-cel program," noting that Bristol Myers detected "transient and reversible inflammatory events" during routine safety surveillance. The company aims to complete the evaluation and resume testing "as quickly as possible."

Novartis, Bristol Myers pause autoimmune CAR-T trials due to safety concerns | BioPharma Dive

★★★★★★★

REGULATORS AND REGULATORY ACTIONS

Delhi High Court Rejects Reddy Pharmaceuticals' Review Plea In 'REDDY' Trademark Dispute With DRL

31st August 2026, Livelaw biz

The Delhi High Court on 14 August dismissed a review petition filed by Reddy Pharmaceuticals Ltd., refusing to revisit its earlier judgment upholding a permanent injunction restraining the company from using the mark "REDDY" and directing removal of its registered trademark from the Register of Trade Marks.

A Division Bench of Justice C. Hari Shankar and Justice Om Prakash Shukla held that none of the errors alleged by Reddy Pharmaceuticals (RPL) constituted an "error apparent on the face of the record", the limited ground on which a review may be sought. The dispute arose from a 2003 suit filed by Dr. Reddy's Laboratories (DRL) against Reddy Pharmaceuticals over the use of "REDDY" in the pharmaceutical trade.

DRL sought an injunction against passing off, besides reliefs for copyright infringement, rendition of accounts and damages. A Single Judge decreed the suit in DRL's favour in 2013 and granted a permanent injunction against RPL. RPL challenged the judgment before the Division Bench.

During the pendency of the appeal, DRL also succeeded in rectification proceedings before the Intellectual Property Appellate Board (IPAB), which ordered removal of RPL's registered "REDDY" mark from the Register.

Delhi High Court Rejects Reddy Pharmaceuticals' Review Plea In 'REDDY' Trademark Dispute With DRL

Ionis Pharma's drug becomes first FDA-approved treatment for rare brain disorder

Reuters, 4th September 2026

The U.S. FDA on Thursday approved Ionis Pharmaceuticals' (IONS.O), therapy to treat a rare disease that affects the brain's white matter, making it the first treatment to get the nod for the genetic disorder.

Ionis' injectable drug zilganersen, branded as Zanvastro, can be used to treat adults and pediatric patients with Alexander disease, a neurological disorder that damages brain cells and causes problems with movement, speech and swallowing, often starting in early childhood.

The condition affects fewer than 1,000 people in the U.S., according to the National Institutes of Health.

"Today's approval is a landmark moment for this community, offering the first therapy that addresses the underlying cause of this rare and serious disease," said Emily Freilich, director of the Food and Drug Administration's neurology division that reviews treatments for rare genetic and neuromuscular diseases.

Ionis did not immediately respond to a Reuters request for comment on pricing details.

In an early-to-late-stage study, patients who got a 50 mg dose of Zanvastro showed a statistically significant improvement in gait speed as assessed by a 10-meter walk test at 61 weeks.

Ionis Pharma's drug becomes first FDA-approved treatment for rare brain disorder | Reuters

★★★★★★★

EMA launches data sharing pilot to gain confidence in NAMs, reduce animal testing

Regulatory Affairs and Professionals Society, 3rd September 2026

The European Medicines Agency (EMA) has launched a voluntary data submission (VDS) pilot to allow drug developers to share data generated by new approach methodologies (NAM), which regulators say may help reduce the need for traditional animal studies during drug development. The announcement follows other efforts by global regulators to reduce reliance on animal testing.

"This pilot is part of EMA's efforts to foster the regulatory acceptance of NAMs by enabling regulators to gain experience with these approaches and assess their scientific value in a regulatory context," said EMA. "NAMs can include complex in vitro systems such as organoids and microphysiological systems, computational models, as well as a combination of multiple methodologies.

"Ultimately, this initiative aims to strengthen the future use of scientifically robust alternatives to animal testing in regulatory decision-making," the agency added. "It builds on EMA's longstanding commitment to the 3Rs principles – to replace, reduce and refine the use of animals in medicines development and regulation."

EMA noted that NAMs are increasingly being used in research and early drug development, but the data generated from their use typically aren't shared with regulators. The agency said that the lack of information sharing by NAMs is limiting regulators' opportunities to build confidence in their use in regulatory applications.

EMA launches data sharing pilot to gain confidence in NAMs, reduce animal testing | RAPS

★★★★★★★

Tavneos no longer available for new patients in UK as Amgen awaits FDA hearing

Biospace, 2nd September 2026

CSL Vifor holds the marketing authorization for Tavneos in the U.K., where the drug is marketed as Avacopan Vifor. It continues to be sold on the U.S. market by Amgen despite concerns raised by the FDA.

The U.K. has stopped allowing the use of rare autoimmune disease therapy Tavneos in new patients, becoming the latest major health regulator to act on concerns about the drug's benefit-risk profile.

Tavneos is sold as Avacopan Vifor in the U.K. and is marketed there by CSL Vifor. The drug was originally developed by ChemoCentryx and won FDA approval in 2021 for ANCA-associated vasculitis, a systemic disease that can lead to organ damage and failure. Amgen acquired ChemoCentryx for $3.7 billion in 2022, and the pharma remains Tavneos' owner in the U.S.

In a media release on Tuesday, the U.K.'s Medicines and Healthcare products Regulatory Agency (MHRA) said that the decision to suspend Avacopan Vifor was driven by an assessment of all available evidence for the drug, as well as concerns raised by patients and healthcare professionals regarding "the integrity and reliability of data from the

pivotal clinical study underpinning the medicine's authorization."

Amgen expressed disappointment with the MHRA's decision. "We disagree with the MHRA's decision to withdraw Tavneos from the U.K. market and are deeply concerned about the impact this decision may have on rare disease patients," a company spokesperson told *BioSpace* in an email.

"We are disappointed that the MHRA's interpretation of the data fails to appropriately recognize the totality of evidence supporting the effectiveness and favorable benefit-risk profile of Tavneos," the spokesperson added, pointing to real-world studies and secondary-endpoint data.

Tavneos no longer available for new patients in UK as Amgen awaits FDA hearing - BioSpace

★★★★★★★

MEDTECH

MiniMed submits new patch pump for FDA clearance

1st September 2026, Medtech Dive

Following the debut of its smallest insulin pump, diabetes tech firm MiniMed is planning more device launches next year. The company, which spun out of Medtronic earlier this year, said Tuesday that it has filed a Food and Drug Administration submission for its first patch pump, with a planned launch next summer. CEO Que Dallara told investors on an earnings call that the company is preparing for a commercial launch of the patch pump, called MiniMed Fit. Currently, Insulet leads the U.S. market for insulin patch pumps, but competitors including MiniMed and Tandem Diabetes Care have been working on their own versions of the technology.

Dallara said that Fit would have a 300-unit insulin reservoir, larger than other devices on the market today, and would accommodate up to seven days of wear time. This could better support people with Type 2 diabetes, who may require more insulin and benefit from fewer device change-outs, the CEO said. MiniMed also completed enrollment of a pivotal trial for a fully closed loop algorithm, which would calculate the amount of insulin a person needs throughout the day, even if they don't announce meals or count carbohydrates. MiniMed also plans to launch the feature later next year.

Finally, MiniMed is working on a new glucose sensor with a longer wear time. The company received an investigational device exemption that would allow it to start a pivotal trial this fall. MiniMed has not yet shared what features the sensor will have or

how long of a wear time it is targeting. Its current sensor, Simplera Sync, has a six-day wear time, while competing devices have wear times ranging from 10 to 15 days. MiniMed partnered with Abbott in 2024, with Abbott agreeing to offer a version of its glucose sensors that works exclusively with MiniMed's devices. Dallara said that continuous glucose monitors have "been our Achilles' heel for a very long time," and that the new sensor has helped drive insulin pump growth.

MiniMed submits new patch pump for FDA clearance

★★★★★★★

MicroPort's covered stent system receives special review in China

2nd September 2026, Mass Device

MicroPort Coronary announced that its FireShield coronary covered stent system will undergo the National Medical Products Administration (NMPA) special review procedures in China.

The special review procedures aim to accelerate review for innovative medical devices that meet criteria for domestic originality, technical novelty and clinical value. (The FDA Investigational Device Exemption program plays a similar role in the U.S.)

The FireShield system is a "designed for the management of coronary artery perforation or rupture during percutaneous coronary intervention," MicroPort said. FireShield is composed of a single-layer cobalt-chromium alloy stent frame covered in an expanded polytetrafluoroethylene (ePTFE) membrane. The device is currently undergoing a pre-market clinical study, which completed enrollment in July 2025.

The FireShield's design "is intended to reduce the system's overall outer diameter and enhance deliverability and lesion-crossing capability," the company stated in a press release. This is MicroPort's sixth medical device to enter this special review process. If approved, FireShield would enter into a category defined globally by Abbott's GraftMaster and Biotronik's PK Papyrus. Similarly to FireShield, GraftMaster also features an ePTFE membrane, while PK Papyrus is polyurethane covered. FireShield's single-layer design, however, is closer to Papyrus.

MicroPort's covered stent system receives special review in China

★★★★★★★

INTERESTING MEDICAL NEWS

Depression May Mask Early Cognitive Decline

Medscape, 2nd September 2026

Key Takeaways

- Distinguishing between depression and early-stage dementia is not always easy during the initial evaluation, and according to a recent literature review, the key lies in long-term follow-up.
- Early detection of cognitive impairment — which is frequently associated with depression in older adults — is a critical factor in prognosis, and general practitioners play a decisive role in this process.
- To ensure that early-stage neurodegenerative diseases are not overlooked, a US research team is calling for routine assessment of cognitive function whenever depression is diagnosed or suspected.

Cognitive impairment and depression are common conditions among older adults; they influence one another and are linked by shared pathophysiological mechanisms. According to a recent literature review, depression is found in 30%-50% of individuals with Alzheimer's disease, and the prevalence is even higher among those with Lewy body dementia or vascular dementia. The diagnosis is not always straightforward during the initial evaluation in primary care as depression can present alternately as a risk factor, a prodrome, or a differential diagnosis for mild cognitive impairment or early-stage dementia. Only standardized longitudinal monitoring of mood and cognitive function, including use of the Montreal Cognitive Assessment in collaboration with a neurologist, can help clarify the clinical picture. A major depressive episode can lead to reversible impairments in memory, attention, and executive functions. In contrast, a progressive cognitive decline observed over several months despite improvement in the depressive episode raises suspicion of an underlying neurodegenerative disease.

Early Detection and Prognosis

The primary care physician is on the front lines when it comes to identifying cognitive impairments and influencing prognosis. Early detection improves patient care through faster access to both treatments and nonpharmacologic interventions, as well as through management of modifiable risk factors and better planning of care and life goals. More broadly, early detection is also associated with a reduction in clinical and social impact, both in terms of hospitalizations and falls and in terms of the burden on caregivers.

Conversely, the later the detection, the more likely patients are to enter the care pathway at an advanced stage, with a loss of independence already established.

Systematic screening of at-risk individuals — including those older than 55 years, patients taking multiple medications, and those reporting subjective memory complaints — could support earlier detection and allow clinicians to adjust treatment, including psychotropic drugs, anticholinergics, and other contributors to polypharmacy, in an effort to prevent further cognitive decline.

Depression and Cognitive Impairment

A systematic review of nearly 200 studies underscores the significant role comorbidities play in the relationship between depression and cognitive decline. Major depressive episodes are linked to a higher risk of developing or worsening a range of conditions, particularly neurodegenerative diseases such as Alzheimer's and Parkinson's, as well as cardiovascular disease, diabetes, and metabolic disorders.

More recently, an American study conducted in primary care settings among individuals aged 55 and older went even further in demonstrating the intertwining of these two conditions. It shows that depression and cognitive impairments frequently coexist in this older population. Furthermore, depression appears to be closely associated with the presence of preexisting, undetected cognitive impairments, and the severity of these impairments increases with the severity of the depression. Consequently, the authors call for the systematic assessment of cognitive function whenever depression is diagnosed or suspected, as well as for screening for depression whenever cognitive impairments have been identified.

Quarter of Over-40s Unaware of Dementia Risk Factors

Around one in four people in the UK over the age of 40 are unable to name one habit or health condition that can increase the risk of developing dementia, according to a survey.

The lack of awareness is depriving millions of people of the chance to take simple steps to protect their brain health, the Alzheimer's Society warned.

It is estimated that there are around 982,000 people with dementia in the UK, although a third do not have a formal diagnosis. The figure is expected to rise to 1.4 million by 2040.

The lifestyle habits that increase the risk of developing dementia include high blood pressure, obesity, smoking, lack of exercise and drinking too much alcohol, along with conditions such as hearing loss, depression, and type 2 diabetes.

However, the poll of 1393 people in the UK, conducted on behalf of the Alzheimer's Society, found 26% could not name one of these risk factors. Fewer than a third (32%) knew that high blood pressure can increase dementia risk, while 24% identified high cholesterol as a risk.

Meanwhile, just one in five (21%) were aware of growing evidence that 45% of dementia cases may be linked to factors that can be prevented or treated.

Michelle Dyson, chief executive at the Alzheimer's Society, said: "These new findings show that many people are not aware of the factors they can influence to help reduce their risk of developing dementia, the UK's biggest killer. As a result, millions of people are missing the chance to take simple steps today that could help protect their brain health tomorrow, from getting their hearing checked to managing their blood pressure."

Hearing Loss and Blood Pressure Among Overlooked Risk Factors

The survey found over-40s could be living with potential risk factors. Four in 10 told the poll their hearing had worsened in the last 5 years, while only a third had had their hearing checked in that time.

Dyson added: "By helping people to understand their risks and the actions they can take, we have a meaningful opportunity to reduce the number of people affected by dementia in the future."

Ian Maidment, professor in clinical pharmacy at Aston University, said: "Many people understandably live in fear of dementia. But there are many things that we can do to reduce the risk of dementia including exercise, not smoking, alcohol in moderation and managing diseases such as high blood pressure and a raised cholesterol.

"The key message is: what is good for the heart is good for the head. This message needs to be communicated in accessible ways to a diverse audience; social media has a key role."

David Thomas, head of policy and public affairs at Alzheimer's Research UK, said: "These findings from the Alzheimer's Society confirm what our own research found earlier this year: the UK has a dementia awareness gap, and too many people still see dementia as an inevitable part of ageing.

"The question is no longer whether awareness is too low — that's been established — but what can be done to help people understand how to keep their brains healthy and reduce their risk of dementia.

"We are calling on the government to introduce a national dementia risk reduction campaign delivered through the NHS, so people can access clear, evidence-based information about protecting their brain health."

★★★★★★★