Friday, 3 July 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

Conference

CPHI Milan 2026, the world's leading pharmaceutical exhibition, will be hosted at Fiera Milano from October 6-8, 2026. Celebrating 35 years of connecting the global pharma community, this three-day event is set to welcome over 62,000 participants, 2,400 exhibitors, and 180+ international speakers representing more than 166 countries.

The aim of CPHI Worldwide 2026 at Fiera Milano is to act as the central meeting point for the global pharmaceutical industry, bringing together exhibitors from all sectors to highlight the latest progress in pharmaceuticals, biotechnology, and drug development.

It seeks to provide attendees with opportunities to:

- Explore advanced machinery and equipment, finished dosage formulations, and innovative packaging and drug delivery systems.
- Focus on key areas such as contract manufacturing, APIs, excipients, fine chemicals, natural extracts, and integrated pharma solutions.
- Facilitate the discovery of new products and foster valuable business connections across the international pharma community.

At CPHI Milan 2026, pharma companies and professionals will gain unique opportunities to network with global leaders, SMEs, start-ups, and innovators, explore solutions across the pharma value chain, and engage in expert sessions with 260 speakers across six tracks. The event fosters collaboration, strengthens partnerships, provides insights into global trends and regulations, and enhances brand visibility on the international stage.

Previously, CPHI has successfully hosted its global pharma exhibitions in countries such as Spain, Germany, France, Italy, India and other major international hubs, consistently bringing together the pharmaceutical community from across the world.

REGISTER NOW

DEALS AND FUNDING

Kimball lays out $103M to bolster life sciences CDMO footprint across Europe, India

Fierce Pharma, 01 July 2026

On a quest to bolster its life-sci contracting bona fides, self-described "multifaceted manufacturer" Kimball Electronics is going down the path of M&A.

The Jasper, Indiana-headquartered electronics and medical contract manufacturer is putting up 90 million euros, or roughly $103 million, to acquire European CDMO Helvoet Polymer Technologies. The deal is slated to expand Kimball's production footprint by bringing facilities in the Netherlands and India into the company's fold, according to a July 1 press release.

Across its production facilities in Tilburg, Netherlands and Pune, India, the Dutch firm Helvoet focuses a large portion of its contract manufacturing operations on microfluidics, diagnostics and drug delivery, per Kimball. The CDMO, which was founded back in 1939, recently operated under the wing of Hydratec Industries and generated 2025 sales of roughly $56 million.

More than 70% of Helvoet's haul last year came from medical customers, with Kimball crediting the remaining balance to "other end markets that deliver strong margins and support continued reinvestment in the medical business."

For its part, Kimball already boasts a new biopharma contract manufacturing facility in Indianapolis, Indiana, which the company has kitted out to support product design, sterilization and sterile packaging, cold chain logistics, contract manufacturing and more.

Kimball lays out $103M to bolster life sciences CDMO footprint across Europe, India

★★★★★★★

Abivax nears $11 billion valuation after fundraising eases M&A pressure

ET Pharma, 02 July 2026

Abivax, which is developing treatments for chronic inflammatory diseases including ulcerative colitis and Crohn's disease, has long been viewed by investors and industry executives as a potential takeover target for larger drugmakers seeking to build their inflammation and immunology businesses.

Abivax SA raised $800 million in an expanded share sale on Wednesday after strong investor demand, valuing the French biotechnology company at nearly $11 billion and easing pressure to pursue a near-term sale.

Abivax, which is developing treatments for chronic inflammatory diseases including ulcerative colitis and Crohn's disease, has long been viewed by investors and industry executives as a potential takeover target for larger drugmakers seeking to build their inflammation and immunology businesses.

The company's lead drug candidate, obefazimod, is in late stage, Phase 3 testing. The capital raise is enough to fund research and operations until the second quarter of 2029, the company said in a statement. A sale remains possible, but the financing gives Abivax greater strategic flexibility and removes the time pressure that often accompanies biotech deal talks, a person familiar with the matter said. Abivax increased the size of its offering by a third, from $600 million to $800 million, as orders exceeded the shares available, the company said in a statement.

Abivax nears $11 billion valuation after fundraising eases M&A pressure

★★★★★★★

Ipsen to acquire Kartos Therapeutics, expanding hemato-oncology late-stage pipeline

Ipsen, 29 June 2026

Ipsen and Kartos Therapeutics, announced today they have entered into a definitive merger agreement under which Ipsen has agreed to acquire Kartos Therapeutics. The acquisition adds navtemadlin, an investigational MDM2 inhibitor designed to restore the natural tumor-suppressing function of p53, a critical tumor-suppressor in myelofibrosis. Data show strong therapeutic potential of navtemadlin for intermediate and high-risk TP53 wild-type (wt) myelofibrosis as an add-on treatment for patients with a suboptimal response to standard of care ruxolitinib.

"This acquisition further strengthens our late-stage oncology pipeline and reflects our continued focus on bringing transformational treatments to people living with cancer," said David Loew, CEO, Ipsen. "We are excited by the potential of navtemadlin to define a new treatment paradigm for patients with myelofibrosis who have a suboptimal response to current standard of care, addressing a critical care gap and offering the potential for a new therapeutic option as early as 2028.

- Acquisition adds navtemadlin, a late-stage rare blood cancer asset in Phase III. This hemato-oncology program in myelofibrosis expands Ipsen's growing Oncology portfolio
- Navtemadlin, an oral MDM2 inhibitor, has the potential, through disease modifying activity, to transform suboptimal responses to standard of care ruxolitinib into clinically meaningful responses in patients with myelofibrosis
- Top-line data from the ongoing Phase III registrational trial POIESIS is expected in 2027

Ipsen to acquire Kartos Therapeutics, expanding hemato-oncology late-stage pipeline

★★★★★★★

Backed by top-tier VCs, stealthy biotech bags AlzeCure Alzheimer's asset in $2.2B deal

Fierce Biotech, 01 July 2026

QuantumCell has licensed AlzeCure Pharma's Alzheimer's disease platform and lead asset for $12 million upfront in a heavily back-loaded deal that bags a potentially symptom-relieving drug candidate on the cusp of phase 2.

AlzeCure moved ACD856, the lead candidate from its NeuroRestore platform, into the clinic in 2019. The asset is a positive allosteric modulator of tropomyosin receptor kinase receptors. By stimulating the signaling of neurotrophins involved in normal neuronal function, the small molecule could aid cognition and treat depression, creating potential applications in Alzheimer's and beyond.

QuantumCell is paying $12 million upfront for ACD856 and NeuroRestore. The upfront fee includes a $5 million investment in AlzeCure at a 30% premium to its average share price over the past 10 days. QuantumCell has committed to development and commercial milestones that could exceed $2.2 billion.

AlzeCure published phase 1b data on ACD856 in June, showing that the molecule is safe and tolerable when administered repeatedly at higher doses than previously tested. In May, AlzeCure CEO Martin Jönsson told (PDF) investors that studying higher doses addressed feedback the company received in talks with other pharma firms.

Higher doses could unlock the use of ACD856 in more indications, with Jönsson naming depression as an area where AlzeCure was seeing growing interest. Alzheimer's has remained AlzeCure's lead indication, though. Before outlicensing ACD856, the company

planned to use a European Union grant to start a phase 2 trial in the neurodegenerative condition this year.

Backed by top-tier VCs, stealthy biotech bags AlzeCure Alzheimer's asset in $2.2B deal

★★★★★★★

PHARMA & BIOLOGICS

SMALL MOLECULES

Eli Lilly transfers commercialization rights for breast cancer drug in China

Reuters, 30 June 2026

Eli Lilly (LLY.N), has transferred the mainland China commercialization rights for its breast cancer drug Verzenios to Innovent Biologics, the Chinese drugmaker said on Tuesday, as its U.S. partner grapples with generic competition in the world's second-largest pharmaceutical market. Innovent said in a statement it had entered into an agreement that grants it sole commercialization rights for Verzenios, which Lilly has also called Verzenio, in mainland China, adding that Lilly would continue manufacturing, supplying and developing the drug. It did not give financial terms.

Lilly did not immediately respond to a Reuters request for comment on what would happen to the China sales team for Verzenio, which a post on its official WeChat account said it began supplying in China in 2021.

Verzenios recorded China sales of 1.5 billion yuan ($221 million) in 2025, up from 1.4 billion yuan in 2024, Cui Cui, head of Asia healthcare at Jefferies, told Reuters, citing data provider PharmCube. Lilly's pullback in a country where more than 350,000 patients are diagnosed with breast cancer annually follows local approval of a generic version from a unit of China's Qingfeng Pharmaceutical Group this year.

Eli Lilly transfers commercialization rights for breast cancer drug in China

★★★★★★★

LARGE MOLECULES

FDA approves veligrotug-vvze (Lumvoa) for thyroid eye disease across active and chronic stages

Ophthalmology Times, 27 June 2026

The FDA has approved veligrotug-vvze (Lumvoa; Viridian Therapeutics) for the treatment of thyroid eye disease (TED), regardless of disease activity or duration-making it the first approved therapy in this class to carry labeling that includes data from both active and chronic TED, according to the company. The agency granted the biologics license application Priority Review, and the company announced plans for immediate commercial availability.

The Lumvoa development program was a robust evaluation of the drug across the full spectrum of TED, including both active and chronic disease, showing significant improvements in outcomes that matter to patients and clinicians," said Michael Yen, MD, professor of oculoplastic surgery and ophthalmology at Baylor College of Medicine and an investigator in the THRIVE program. "It's encouraging to see a new treatment for the full spectrum of the disease with data showing rapid onset of proptosis reduction as well as improvements in diplopia.

FDA approval was supported by results from two pivotal phase 3 studies: THRIVE, which enrolled patients with active TED, and THRIVE-2, which enrolled patients with chronic TED. According to the sponsor, both trials met their primary and all secondary end points, with statistically significant and clinically meaningful improvements reported at week 15 across key signs and symptoms of TED.

Patients in both trials received five intravenous infusions administered every 3 weeks over a 12-week course. The sponsor reported that reductions in proptosis were observed as early as week 3. Veligrotug-vvze is described by the company as the first approved TED therapy to demonstrate a statistically significant effect on both diplopia response rate and complete resolution of diplopia in both active and chronic disease populations.

FDA approves veligrotug-vvze (Lumvoa) for thyroid eye disease across active and chronic stages

★★★★★★★

FDA widens Vertex's Casgevy use for paediatric patients

Pharmaceutical Technology, 02 July 2026

The US Food and Drug Administration (FDA) has approved expanded use of Vertex Pharmaceuticals' Casgevy (exagamglogene autotemcel) in children with one of two types of inherited blood disorders, marking the first such treatment authorised in this age group. Vertex's gene therapy was already approved in patients aged 12 years and over for the treatment of either sickle cell disease (SCD) with recurrent vaso-occlusive crises (VOCs) or transfusion-dependent beta thalassemia (TDT). With the FDA label expansion, Casgevy can now be given to children as young as two years for either blood disorder.

Expanding patient use continues a positive commercial journey for Casgevy, a product Vertex co-developed with biotech CRISPR Therapeutics. When the gene therapy was first approved by the FDA in adults in December 2023, it became the first approved medicine to use the CRISPR/Cas9 genome editing technology. The one-time therapy works by using CRISPR to edit genetic material, thereby modifying haematopoietic stem cells from the patient so that more foetal haemoglobin (HbF) is produced, which enhances oxygen delivery. The edited cells are then engrafted into the patient's bone marrow.

SCD is caused by a mutation in the HBB gene that causes red blood cells to become rigid and sticky, which blocks delivery of oxygen to tissue. Thalassemia causes the body to have an abnormally low level of haemoglobin, also resulting in reduced oxygen delivery. "With today's decision, paediatric patients as young as two years of age can now access a critical additional treatment option to treat these debilitating, life-threatening diseases," said Karim Mikhail, acting director of the FDA's Center for Biologics Evaluation and Research (CBER).

FDA widens Vertex's Casgevy use for paediatric patients

★★★★★★★

Orca Bio takes commercial leap with FDA approval for Tregzi

Fierce Pharma, 01 July 2026

Orca Bio has jumped into the commercial market with FDA approval for Tregzi, a first-of-its-kind engineered cell therapy for blood cancer patients requiring transplants.

Tuesday, the FDA approved the allogeneic regulatory T cell (Treg)-based immunotherapy, also known as Orca-T, for use as an alternative stem cell transplant to improve survival free of chronic graft versus host disease (GVHD) in adults with hematological malignancies.

At its core, Tregzi is a re-engineered hematopoietic stem cell transplant (HSCT) graft. Rather than infusing a mix of stem and immune cells from a matched healthy donor directly into a patient, Tregzi reformulates the blood material to include purified Tregs to suppress GVHD, a common and often debilitating complication of transplants.

It also leverages hematopoietic stem and progenitor cells that help patients rebuild their immune system to fight cancer, followed by infusion of conventional T cells to wipe out any residual cancer cells and accelerate recovery against infections.

The FDA's approval for Tregzi is "a significant milestone for the field, for the company & for leukemia patients," Orca Bio co-founder and CEO Nate Fernhoff, Ph.D., said in an interview with Fierce Pharma.

Orca Bio takes commercial leap with FDA approval for Tregzi

★★★★★★★

REGULATORS AND REGULATORY ACTIONS

US FDA declines to approve Unicycive's kidney disease drug

Reuters, 30 June 2026

Unicycive Therapeutics said on Tuesday the U.S. drug regulator has declined to approve its drug to treat elevated phosphate levels in chronic kidney disease patients on dialysis, citing deficiencies at a third-party manufacturing facility. Shares of the company fell more than 44% in early trading.

This marks a second setback for the company, which was seeking approval for its drug, oxylanthanum carbonate (OLC), designed to treat a condition known as hyperphosphatemia in patients with chronic kidney disease. The condition causes a dangerous buildup of phosphorus in the blood when failing kidneys can no longer filter it out.

US FDA declines to approve Unicycive's kidney disease drug | Reuters

★★★★★★★

Glenmark Pharma Goa Plant Receives 6 US FDA Observations

Whalesbook, 30 June 2026

Glenmark Pharmaceuticals received six observations from the US FDA following a manufacturing inspection at its Goa facility. The company noted these findings are procedural, involve no data integrity issues, and are not repeat observations. It expects

no impact on product supply. Investors typically track these regulatory updates, as the company must now submit a corrective action plan to the US regulator.

Glenmark Pharmaceuticals announced that its manufacturing facility in Goa has received six observations from the United States Food and Drug Administration (US FDA). The inspection of the plant was conducted between June 22 and June 30, 2026. The company stated that the observations are procedural in nature and confirmed that none of them relate to data integrity. Additionally, the company clarified that these are not repeat observations, meaning they have not been flagged at this specific facility previously.

Glenmark Pharma Goa Plant Receives 6 US FDA Observations | Whalesbook

★★★★★★★

US FDA accepts Sandoz applications for proposed in-house development of generic tirzepatide GLP-1s

Sandoz, 29 June 2026

Sandoz, the global leader in affordable medicines, today announces that the US Food and Drug Administration (FDA) has accepted for review two Abbreviated New Drug Applications (ANDAs) for generic versions of tirzepatide. The ANDAs seek approval for an in-house Sandoz generic version of the tirzepatide autoinjector, a generic gastric inhibitory polypeptide receptor and glucagon-like peptide-1 (GLP-1) receptor agonist.

Both applications, which were filed under the FDA's generic pathway, address all indications of the reference medicines, Mounjaro®+ and Zepbound® ++. For Mounjaro® +, this would be as an adjunct to diet and exercise to improve glycemic control in adults and paediatric patients 10 years of age and older with type 2 diabetes mellitus. For Zepbound®++, this would be in combination with a reduced-calorie diet and increased physical activity, to reduce excess body weight and maintain weight reduction long term in obese or overweight adults in the presence of at least one weight-related comorbid condition and to treat moderate to severe obstructive sleep apnea (OSA) in adults with obesity[1] for weight management.

US FDA accepts Sandoz applications for proposed in-house development of generic tirzepatide GLP-1s | Sandoz

★★★★★★★

Centre proposes amendments in medical devices rules to streamline, expedite licences

The New Indian Express, 28 June 2026

The initiative is aimed at enhancing the ease of doing business, improving regulatory efficiency, and facilitating the timely availability of quality medical devices in the country, officials said. With the aim to simplify and expedite the licensing process for medical devices, the Union Health Ministry has issued draft notification proposing amendments in the rules, which will also ensure continued compliances with quality, safety and performance requirements.

The proposed amendments in the Medical Devices Rules, 2017, seek to rationalize the timelines for the grant of manufacturing licences for medical devices across different risk categories. Among the devices, which fall under low to moderate risk devices like blood pressure monitors, hypodermic needles and pulse oximeters, the timeline for grant of manufacturing licence has been proposed to be reduced from 140 days to 115 days.

Similarly, for those devices which fall under high-risk devices such as cardiac stents, hip and knee implants, and other orthopaedic implants, the grant of manufacturing licence has been proposed to be reduced from 105 days to 90 days. The initiative is aimed at enhancing the ease of doing business, improving regulatory efficiency, and facilitating the timely availability of quality medical devices in the country, officials said.

The ministry has published the draft notification in the official gazette proposing amendments to the Medical Devices Rules, 2017 and has sought suggestions and feedback from all stakeholders within 30 days. Under the Medical Devices Rules, 2017, medical devices are classified into four risk-based categories- Class A, Class B, Class C and Class D.

Class D comprises the highest-risk devices. The Rules prescribe statutory timelines for processing applications for manufacturing licences for each category. The proposed amendments seek to reduce these timelines, thus enabling faster regulatory approvals while maintaining the established standards of quality, safety and performance.

Centre proposes amendments in medical devices rules to streamline, expedite licences

★★★★★★★

Govt Invites Applications Under Medical Device Manufacturing Scheme with Subsidies of Up to INR 10 Cr

Digital Health News, 01 July 2026

The Department of Pharmaceuticals, under the Ministry of Chemicals and Fertilisers, has invited applications from eligible entities under the Scheme for Strengthening of Medical Device Industry (SMDI) to promote domestic manufacturing and innovation in India's medical devices sector. The selected applicants will be eligible for financial support of up to Rs 10 crore under one of the scheme's key components.

The call for proposals covers two sub-schemes: the Marginal Investment Scheme for Reducing Import Dependence and the Medical Device Clinical Studies Support Scheme (MDCSS). The initiative aims to strengthen domestic manufacturing capabilities, reduce reliance on imported medical devices and components, support innovation, and enhance the country's medical device value chain.

Under the Marginal Investment Scheme, eligible applicants can receive a one-time capital subsidy of up to Rs 10 crore on a reimbursement basis. The support is available for investments in manufacturing key components, raw materials, finished medical devices, and accessories that contribute to reducing import dependence.

According to the Department of Pharmaceuticals, the subsidy is intended to encourage domestic production of critical medical device inputs and finished products, supporting the government's efforts to strengthen local manufacturing capacity. Under the Medical Device Clinical Studies Support Scheme (MDCSS), eligible applicants can receive financial assistance of up to Rs 5 crore, also on a reimbursement basis. The funding will support activities including clinical investigations, clinical performance evaluations, post-market follow-up studies, and animal studies required for medical device development and validation.

Govt Invites Applications Under Medical Device Manufacturing Scheme with Subsidies of Up to INR 10 Cr

★★★★★★★

MEDTECH

Hyperfine launches next-generation Swoop MRI system in Europe

Medical Device Network, 02 July 2026

Hyperfine has commercially launched its next generation Swoop portable magnetic resonance imaging (MRI) system (Model 2) in select European markets. The company stated that this follows both CE mark and UK Conformity Assessed (UKCA) approval for the device. The introduction of Model 2 into Europe aims to support Hyperfine's international commercial objectives and enhance access to brain imaging at the point of care.

Swoop is powered by Hyperfine's updated Optive AI software, featuring improved image quality, workflow efficiency and clinical capabilities compared to previous versions. European clinicians and hospitals can purchase the new system, which joins an initial wave of markets since regulatory clearance was achieved.

In addition, Hyperfine has confirmed that the Swoop system is included in the Union of Hospitals for Procurement (UniHA) listing, enabling a wider presence within the French public healthcare system. The system's initial listing in UniHA occurred in October 2025.

Hyperfine international vice-president Eric Willis said: "The next-generation system delivers significant improvements in image quality, workflow efficiency and clinical capability. We have already seen these advancements accelerate use and adoption of the Swoop system throughout the US.

"We look forward to working closely with our distribution partners to expand access to AI-powered portable MRI across Europe, providing critical neuroimaging that helps clinicians make more timely and more informed patient care decisions." The European launch adds to recent developments for the company, including its inclusion in the Russell 2000 Index. Hyperfine describes its Swoop Portable MR Imaging Systems as ultra-low-field, mobile devices cleared by the US Food and Drug Administration for brain imaging in patients of all ages.

Hyperfine launches next-generation Swoop MRI system in Europe

★★★★★★★

J&J starts pivotal trials of Shockwave IVL device in carotid arteries

Medtech Dive, 29 June 2026

Shockwave is built on technology for delivering acoustic energy to break up calcium in coronary and peripheral arteries. By the time J&J acquired Shockwave for $13.1 billion in 2024, the company was working to expand the use of the IVL technology to carotid arteries and structural heart disease.

Carotid artery disease is defined by the accumulation of plaque in vessels that supply blood to the brain. As the plaque hardens, the arteries can become narrowed or blocked, reducing blood flow and raising the risk of stroke.

Treatments include carotid endarterectomy, a surgical operation that removes plaque from the carotid arteries. However, surgical and endovascular treatments can be technically complex and are associated with increased procedural risk, J&J said. Treatment options for patients deemed too high risk for carotid endarterectomy are limited.

SkyRunner could expand treatment options by removing calcium to prepare carotid arteries for stenting. Physicians have used Shockwave's existing products off-label to modify calcification before placing stents in carotid arteries. J&J optimized SkyRunner for the carotid artery's anatomy by developing vessel-specific sizing and shaft lengths suitable for transcarotid and transfemoral approaches.

The pivotal program features two trials, one transcarotid and one transfemoral. Each trial is enrolling up to 160 patients who are at high risk for complications from carotid endarterectomy. The trials will assess the use of SkyRunner prior to stenting.

Both trials are using a composite assessment of death, stroke and myocardial infarction as the primary endpoint. J&J's secondary endpoints are assessing stent delivery, incidence of stroke up to 60 months post-procedure and other outcomes. The studies have late-2027 primary completion dates on the federal clinical trials databases, although both are forecast to continue through 2032 to collect long-term data.

J&J is working to expand use of Shockwave's technology as competition for its core indications emerges. Boston Scientific, which acquired IVL technology last year in a $664 million deal for Bolt Medical, posted data in coronary artery disease last month. The company plans to use the data to seek approvals.

J&J starts pivotal trials of Shockwave IVL device in carotid arteries

INTERESTING MEDICAL NEWS

GLP-1s for Addiction: Are We There Yet?

Medscape, 02 July 2026

Substance use disorders (SUDs) may become the next therapeutic target for GLP-1 receptor agonists (GLP-1s). Although the evidence remains preliminary, growing preclinical, observational, and early clinical data suggest these drugs may reduce the cravings that drive addiction.

Interest has accelerated over the past few years, fueled by reports that patients taking semaglutide or tirzepatide for diabetes or obesity drink less alcohol, smoke fewer cigarettes, or experience fewer cravings. Those observations have prompted a wave of studies exploring whether these drugs could have a role in treating alcohol, nicotine, opioid, and other SUDs.

More recently, large retrospective analyses have suggested that GLP-1s may be associated with lower rates of overdose, SUD-related mortality, and new-onset SUDs.

At this point, however, much of the evidence comes from animal studies, observational research, and patient reports. Definitive answers will require randomized clinical trials. More than 30 studies are now investigating GLP-1s for alcohol, nicotine, opioid, cocaine, and methamphetamine use disorders, making addiction one of the fastest-growing areas of GLP-1 research.

Key Points

- GLP-1s show preliminary signal for SUDs; strongest data in AUD.
- Semaglutide ↓ alcohol craving, heavy drinking; one trial: NNT 4.3.
- Exenatide AUD trial negative overall; possible benefit in obesity subgroup.
- Evidence for nicotine, opioid, cocaine use disorders remains limited/preclinical.
- Key gaps: durability, optimal dose, safety, comorbidities, additive use, access.

Which AUD phenotypes respond best to GLP-1 therapy?

How do GLP-1s alter mesolimbic dopamine signaling?

Do GLP-1s reduce relapse after treatment discontinuation?

One possible explanation comes from the phenomenon patients describe as "food noise." If GLP-1s dampen the intrusive reward-driven thoughts associated with eating,

researchers are asking whether they might also quiet the compulsive cravings that characterize addiction.

"The leading theory involves the brain's reward circuitry," Alvaro Teixeira Filho, MD, addiction psychiatrist at Yale School of Medicine in New Haven, Connecticut, told Medscape Medical News.

Animal studies suggest GLP-1s blunt the dopamine surge normally triggered by alcohol, nicotine, opioids, and cocaine, reducing both substance use and relapse-like behavior, he noted.

The Biological Rationale

Nancy Shenoi, MD, addiction psychiatrist and assistant professor of psychiatry at Baylor College of Medicine in Houston, said the drugs may influence addiction through several pathways.

GLP-1s may influence addiction through multiple mechanisms. In addition to modulating mesolimbic dopamine signalling, potentially reducing cravings and reinforcement, they may alter hypothalamic pathways involved in satiety and impulse control and regulate gamma-aminobutyric acid release, potentially dampening the excitatory signaling that can trigger addictive behaviours, Shenoi said.

She also noted that chronic substance use has been linked to neuroinflammation and oxidative stress, both of which may be mitigated by the anti-inflammatory and neuroprotective effects of GLP-1 medications.

The strongest clinical evidence to date comes from studies of alcohol use disorder (AUD), where several randomized trials have reported reductions in alcohol craving and heavy drinking with GLP-1s.

Two randomized clinical trials have reported encouraging findings. In one, published in JAMA Psychiatry, semaglutide significantly reduced alcohol consumption, drinks per drinking day, and alcohol craving among adults with AUD.

Similarly, another study showed significant reductions in alcohol craving and heavy drinking with semaglutide in adults with AUD.

However, the evidence has been mixed. In a separate randomized trial, exenatide did not significantly reduce heavy drinking compared with placebo among adults with AUD, although exploratory analyses suggested greater benefit in participants with obesity.

Observational studies, meanwhile, have linked GLP-1s to lower hospitalization rates and reduced return-to-drinking rates among patients with AUD and metabolic comorbidities.

What the Evidence Shows

The evidence is less robust for other SUDs. Small clinical studies and preclinical research suggest potential benefit for cocaine, opioid, and nicotine use disorders, but human data remain limited. Several trials in opioid and cocaine use disorders are underway, while findings in nicotine use disorder have been mixed.

Shenoi characterized the evidence beyond AUD as "preliminary." Filho noted that research on opioid and cocaine use disorders remains largely preclinical, although early clinical findings are beginning to emerge.

"I'd call this the beginning of a paradigm shift," Filho said. "What's genuinely new here is the idea itself: that a drug class designed for metabolism could treat addiction by working through the shared neurobiology of reward."

Shenoi was less definitive, noting that the evidence is "strongest at the mechanistic level and in animal studies, but still early in human studies — so not quite a paradigm shift."

Michael Weaver, MD, professor of psychiatry and medical director of the Center for Neurobehavioral Research on Addiction at UTHealth Houston, said the current evidence provides "intriguing signals," but many questions remain about the role of GLP-1s in treating SUDs. "The research is just beginning, and definitive answers are still a few years away," he told Medscape Medical News.

One of the biggest unanswered questions is whether GLP-1s act on addiction itself or more broadly dampen reward-seeking behavior.

"This is still up for debate, but the evidence leans more toward a broad effect on the reward pathway rather than anything addiction-specific," Filho said.

Consistent with that hypothesis, animal studies show that GLP-1s reduce not only drug-seeking behavior but also consumption of highly palatable foods and other rewarding stimuli. Brain imaging studies also suggest reduced activation in reward-related brain regions in response to both food and drug cues, he noted.

Shenoi said reports of reduced cravings for food, alcohol, drugs, and even gambling behaviors support the idea that GLP-1s act on shared reward pathways. However, she cautioned that "specific targeted anti-addiction pharmacology studies are still emerging."

What Questions Remain

Weaver said another important unanswered question is how selective those effects ultimately prove to be.

"Reward-seeking behavior is very broad," he told Medscape Medical News. It remains unclear whether GLP-1s selectively reduce cravings for addictive substances while preserving motivation for other rewarding activities, such as pursuing personal goals or enjoying everyday experiences.

The distinction has important clinical implications. Researchers are trying to determine whether GLP-1s can reduce pathological reward-seeking without diminishing normal pleasure and motivation.

"Case reports of anhedonia and emotional blunting do exist, but population-level data have been reassuring, as GLP-1s use hasn't been linked to increased depression or suicidality, and some studies even suggest mental health benefits," said Filho.

Despite growing optimism about GLP-1s for addiction treatment, important questions remain. Researchers still need to determine which patients are most likely to benefit, the optimal dose and duration of therapy, whether benefits persist after treatment stops, how GLP-1s interact with psychiatric comorbidities, whether they should be used alone or alongside existing addiction medications, and whether benefits extend beyond individuals with obesity.

"The honest answer is that the literature is not there yet, and it probably depends on the substance, among other factors," Filho told Medscape Medical News.

The likely role of GLP-1s may differ by SUD**.** For opioid use disorder (OUD), add-on therapy may be the most plausible approach, he added. "Methadone and buprenorphine cut mortality by roughly half or more, so any new drug would most likely be added on top, not used in their place."

That approach already has some support. A retrospective study of methadone patients with OUD and comorbid type 2 diabetes showed that GLP-1 use was associated with higher remission rates and lower overdose risk, Filho noted.

The outlook may be different for AUD. Although three FDA-approved medications — naltrexone, acamprosate, and disulfiram — are available, their efficacy is modest and they remain underutilized, Filho said.

He noted that in a trial of semaglutide, the number needed to treat (NNT) was 4.3 for a clinically meaningful reduction in World Health Organization drinking risk level, a standard measure of alcohol consumption, comparing favorably with NNTs of 7 or higher reported for the approved AUD medications.

Where Do GLP-1s Fit?

For cocaine and other stimulant use disorders, the picture may be different. No FDA-approved medications are currently available, meaning a GLP-1, if approved, could become the first pharmacologic treatment option.

Filho noted that addiction varies by substance, disease severity, comorbidities, genetics, and social and environmental factors. Current medications are limited, often have only modest efficacy or are difficult to sustain, and remain underused.

"That's the treatment gap GLP-1s are stepping into. So, before we even know where they'll land — first-line, add-on, or reserved for certain patients — just having more tools and mechanisms to choose from is very important for individualized and comprehensive care."

Where GLP-1s ultimately fit into addiction care — and when that role becomes clear — remains uncertain.

Several randomized trials are expected to report results over the next 1-2 years, but larger and longer studies will be needed to answer questions about durability, safety, and relapse prevention.

"That said, the data have been strong enough that some doctors are already using these drugs off-label for alcohol use disorder," Filho said, particularly among patients who also have obesity or another approved indication.

If GLP-1s ultimately become part of routine SUD treatment, equitable access will be another challenge.

Shenoi noted that studies show there is lower GLP-1 use among Asian, Black, and Hispanic individuals and those with lower incomes and that Medicaid does not cover the medications for obesity. She said evidence-based prescribing guidelines would be needed to help ensure equitable and appropriate use if GLP-1s are adopted for SUDs.

However, even as interest in GLP-1s grows, experts emphasized that the drugs are not ready to replace established addiction treatments.

"Failing to offer FDA-approved medications for addiction is a missed opportunity," Shenoi said, noting that most people with SUDs still do not receive evidence-based treatment.

Filho, Weaver, and Shenoi reported having no relevant disclosures