Friday, 31 July 2026

CONTENT *(Highlights)*

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UPCOMING EVENTS

The 8th Edition of the Biopharma Conclave is scheduled to take place on 13th - 14th August, 2026, at Novotel HICC, Hyderabad. This edition, we are co-located with BioProcess International India, an extension of globally recognized BioProcess International Conference Series, which will deep dive into the bioprocessing ecosystem in India.

The Biopharma Conclave will feature 3 parallel conference sessions over 2 days focusing on Biosimilars & Biologics, Bioprocessing & Manufacturing and Cell & Gene Therapy. The conclave will serve as a platform for sharing knowledge, discussing emerging trends and innovations, and fostering networking opportunities among peers.

It will cover a broad spectrum of topics related to biopharmaceuticals. These include drug discovery and development, regulatory affairs, bio-manufacturing processes, and commercialization strategies. By addressing these critical areas, the event aims to provide valuable insights and facilitate meaningful discussions that can drive progress and innovation in the biopharmaceutical sector.

Track 1: Biosimilar & Biologics	Track 2: Cell & Gene Therapy	Track 3: Bioprocess International India

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DEALS AND FUNDING

Organon Shareholders Approve Sun Pharma Merger, Deal Nears Completion

The company said the shareholder vote marks an important milestone for the transaction, though the acquisition still remains subject to customary closing conditions, including regulatory approvals

Outlook Business, 24 July 2026

- Organon shareholders have approved Sun Pharma's proposal to acquire the US firm at an enterprise valuation of $11.75 billion.
- The deal marks the largest acquisition in Sun Pharma's history and is expected to close by early 2027, subject to regulatory approvals.
- Sun Pharma has lined up 11 banks, including SBI, to finance the acquisition through loan syndication.

Sun Pharmaceutical Industries said on Friday that it has crossed a key milestone in its proposed acquisition of US-based Organon & Co after the latter's shareholders approved the merger.

In an exchange filing on July 24, Sun Pharma said Organon stockholders had approved the proposals related to the previously announced merger, under which Organon will become a wholly owned subsidiary of Sun Pharmaceutical Holdings USA, an indirect wholly owned arm of Sun Pharma.

The company said the shareholder vote marks an important milestone for the transaction, though the acquisition still remains subject to customary closing conditions, including regulatory approvals.

Organon Shareholders Approve Sun Pharma Merger, Deal Nears Completion – Outlook Business

★★★★★★★

Argenx pens $2.2bn deal to buy autoimmune biotech Forte

PharmaPhorum, 27 July 2026

Netherlands- and Belgium-based biotech argenx has agreed to buy US biotech Forte Biosciences for up to $2.2 billion, bolstering its autoimmune disease pipeline.

The $77-per-share deal follows an earlier investment in Dallas, Texas-based Forte by argenx, which participated in the US firm's $150 million public offering in April, and represents an 86% premium to Forte's average share price in recent weeks.

Shares in Forte shot up earlier this month after it reported positive phase 1b results for lead candidate FB102, an anti-CD122 antibody, in vitiligo. The autoimmune skin-lightening disorder is the lead indication for FB102, and it is also being developed for coeliac disease, with phase 2 results due later this year, while studies in other autoimmune indications like alopecia areata are also planned.

FB102 is potentially a first-in-class drug that targets pathogenic T-cell and natural killer (NK) cell activity in autoimmune disorders, and is being billed by both argenx and Forte as a "pipeline-in-a-product."

Funding for the deal will come entirely from argenx's cash reserves, driven by sales of its flagship Vyvgart/Vyvgart Hytrulo (efgartigimod alfa) franchise for generalised myasthenia gravis, a rare neuromuscular autoimmune disorder, and chronic inflammatory demyelinating polyneuropathy (CIDP), revenues of which grew 90% to $4.2 billion last year.

Efforts by the company to expand the indications for FcRn blocker Vyvgart have run into some problems, however, including failed trials in thyroid eye disease, pemphigus, and primary immune thrombocytopenia (ITP), so buying Forte will give argenx the opportunity to advance on a broader front whilst retaining its focus on autoimmunity.

Argenx pens $2.2bn deal to buy autoimmune biotech Forte | pharmaphorum

★★★★★★★

Antengene Signals Major Interim Profit on Oncology Licensing Deals

The Globe and Mail, 28 July 2026

Antengene Corporation Limited has issued an announcement.

Antengene has issued a positive profit alert for the six months ended June 30, 2026, signaling a sharp improvement in financial performance driven by recent licensing deals. The board expects revenue to rise to between RMB490 million and RMB536 million, compared with RMB53.2 million a year earlier, and a turnaround to a profit of RMB195 million to RMB238 million from a prior loss of RMB76.4 million.

The company attributes the surge in revenue and profitability mainly to its out-licensing and collaboration arrangement with UCB for ATG-201, effective from March 2026, and an exclusive out-licensing and collaboration agreement with K2 Therapeutics for ATG-106,

effective from June 2026. These transactions, including a USD60 million upfront payment from UCB, underscore the commercial traction of Antengene's pipeline and may strengthen its financial position and credibility with shareholders and potential investors ahead of the formal release of interim results expected by the end of August 2026.

Antengene Signals Major Interim Profit on Oncology Licensing Deals - The Globe and Mail

★★★★★★★

Merck inks pact with four generic drugmakers in India for HIV drug

The Hindu, 27 July 2026

Pharma major Merck (known as MSD outside of the U.S. and Canada) has signed non-exclusive voluntary licensing agreements with generic drugmakers Aurobindo Pharma, Cipla, Emcure and Viatris in India to enable supply of its investigational, once-monthly oral pill HIV pill Alimatravir.

It has also signed such agreements with three other companies in sub-Saharan Africa. The royalty-free agreements with the seven companies cover both the public and private sectors and will enable supply of generic alimatravir in 129 low- and middle-income countries (LMICs) that account for a substantial majority of new HIV diagnoses globally, Merck said recently.

Separately, Aurobindo Pharma said executing the agreements before Phase 3 trial enrollment is completed is a first in HIV prevention. It is intended to enable the right scale-up where Aurobindo Pharma is licenced to manufacture and supply generic Alimatravir, which will meet internationally recognised standards following regulatory approvals.

"Through this voluntary licensing agreement, we look forward to making alimatravir available across eligible low- and middle-income countries, subject to successful development and regulatory approvals, helping strengthen global efforts towards HIV prevention, Aurobindo's Associate President and Head – Global Access and Licensing Umesh K said.

"We are pleased to be working with Aurobindo and the other manufacturers involved in these voluntary licensing agreements to manufacture generic alimatravir in 129 LMICs, if approved," Senior vice president, Global HIV Marketing of MSD Gregg Szabo said.

Merck inks pact with four generic drugmakers in India for HIV drug - The Hindu

★★★★★★★

Cabinet approves scheme of Chemical Parks "Bharat Audyogik Vikas Yojana Rasayan (BHAVYA Rasayan)

PM India, 24 July 2026

The Union Cabinet chaired by the Prime Minister Shri Narendra Modi has approved Bharat Audyogik Vikas Yojana Rasayan or BHAVYA – Rasayan Scheme for establishing three dedicated Chemical Parks in the country. The Scheme was announced in the Union Budget of FY 2026–27.

The Scheme will have a total financial outlay of Rs.3,030 crore, with Rs.3,000 crore towards meeting the cost of establishing the Common Infrastructure Facilities and Basic Utilities inside the park and Rs. 30 Crores as administrative expenditure. The scheme would run for a period of 5 years from FY 2026-27 to FY 2030-31.

In terms of the said scheme, the Centre would provide a grant of up to Rs.1,000 crore per park. This will be subject to minimum contribution of Rs.500 crore by the concerned State Government.

BHAVYA Rasayan Scheme is expected to bring the following benefits to the economy:

• It will promote development of the Chemical industry along the whole value chains including upstream, downstream and ancillary industries promoting efficient utilization of resources, leading to lower logistics cost.

• Through shared Common Infrastructure Facilities and Basic Utilities, keeping the needs of chemicals industry in mind, it will lead to enhanced cost competitiveness and will make the Indian Industry globally competitive.

• It will help the Indian Chemical industry better integrate in Global Value Chains leading to greater exports and higher import substitution.

• It will promote development of Indian Chemical industry in a sustainable way by creating an environment friendly ecosystem which will consist of centralized facilities such as Common Effluent Treatment Plant, Treatment, Storage, and Disposal Facility, and Hazardous Waste Management infrastructure. It will ensure better compliance management with environmental regulations, thereby promoting development of industry in eco-friendly manner.

• Development of Chemical sector will lead to a cascading effect through enhanced development of downstream sectors of the economy as well, thereby leading to higher employment generation and greater development of the economy, helping achieve the goal of Viksit Bharat @ 2047.

Recognising that this sector produces Chemicals and Petrochemicals which are used in various downstream industries such as Agriculture, Textiles, Pharmaceuticals, Nutraceuticals, Construction, Automobile, Electronics, introducing BHAVYA Rasayan Scheme shall facilitate development of the sector by attracting domestic and foreign investments, enhancing domestic production capacity and generating employment. It will boost the global competitiveness of the sector thereby, promoting Atmanirbharta.

Cabinet approves scheme of Chemical Parks "Bharat Audyogik Vikas Yojana Rasayan (BHAVYA Rasayan) | Prime Minister of India

★★★★★★★

PHARMA & BIOLOGICS

SMALL MOLECULES

FDA approves Otsuka's ADHD drug Simtriyo, teeing up its 'next major CNS launch

Fierce Pharma, 27th July 2026

The FDA has approved Otsuka Pharmaceutical's once-daily extended-release capsule Simtriyo (centanafadine) for attention-deficit/hyperactivity disorder (ADHD) in patients aged 6 years and older.

Approval of the first-in-class norepinephrine, dopamine, serotonin reuptake inhibitor (NDSRI) gives the Japanese drugmaker its "next major CNS launch" and positions the therapy to become a potential blockbuster in a large, under-penetrated market, according to Jefferies analysts in a July 26 note.

Before Simtriyo can launch in the U.S. market, it must clear controlled-substance review by the Drug Enforcement Administration (DEA), a standard, up-to-three-month procedure for all central nervous system stimulants.

How the DEA classifies Simtriyo could determine its commercial potential, the Jefferies team noted. A Schedule II designation like what Adderall and Vyvanse have could restrict uptake, while a lower classification could give Simtriyo a competitive edge in a crowded ADHD market, the analysts said.

During an investor Q&A in April, Otsuka said it was not clear whether a DEA review would be necessary.

The FDA classifies Simtriyo as a stimulant likely because it has dopaminergic effects, the Jefferies team observed in their Sunday note. By inhibiting the reuptake of those

neurotransmitters, Simtriyo works by increasing their availability in attention and behavioral pathways.

A chronic neurodevelopmental disorder characterized by trouble paying attention and controlling impulsive behaviors, ADHD affects about 7 million children in the U.S. and 15.5 million adults, according to the CDC.

Stimulants are the most popular treatments for ADHD, but patients often stop or cycle through different therapies due to a lack of effectiveness, troublesome side effects and changing life demands.

We therefore view the market as capable of supporting multiple treatment classes and believe Simtriyo has an opportunity to expand the overall non-stimulant segment rather than simply take share from existing products such as Qelbree or Strattera, the Jefferies team wrote.

FDA approves Otsuka's ADHD drug Simtriyo, teeing up its 'next major CNS launch

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LARGE MOLECULES

Eris Lifesciences bets on insulin, GLP-1s, and biologics to power next phase of growth; eyes 25% insulin market share

Fortune India, 29th July 2026

After spending over ₹4,300 crore on acquisitions over the past three years, Eris Lifesciences , one of India's fastest-growing pharmaceutical companies, is shifting gears to extract value from its expanded portfolio, betting on insulin, GLP-1 therapies, biologics and manufacturing integration to power its next phase of growth.

"We are now focused on going deeper into what we have already built rather than chasing large acquisitions. Consolidation is complete. The next phase is about extracting greater value from the platform we have created," Krishna Kumar, Executive Director and Chief Operating Officer of Eris Lifesciences, tells *Fortune India*.

The company, which will complete 20 years in January, has transformed itself from a diabetes and cardiology-focused company into a diversified specialty pharmaceutical player through acquisitions in dermatology and biotechnology. As recently as four years ago, diabetes and cardiology accounted for nearly 80% of its business.

"From the beginning, our focus was on chronic care. Over time, this expanded to include patient care, diagnostics and the development of supporting healthcare infrastructure,"

says Amit Bakshi, Chairman and Managing Director, Eris Lifesciences.

The company has come a long way from its early years. Eris recorded a book loss of ₹1.3 crore and a cash loss of ₹1 crore in its first year before turning profitable in its second year with revenue of ₹27 crore and a profit of around ₹1-2 crore. In FY26, the company reported revenue of ₹2,778 crore, up 11% year-on-year, while EBITDA rose 12% to ₹1,026 crore. In the first quarter of FY27, revenue from operations increased 13% to ₹873.25 crore from ₹773 crore a year earlier, while EBITDA grew to ₹296 crore from ₹278 crore.

https://www.fortuneindia.com/business-news/eris-lifesciences-bets-on-insulin-glp-1s-and-biologics-to-power-next-phase-of-growth-eyes-25-insulin-market-share/150871

★★★★★★★

Lilly's triple agonist just became its most powerful obesity drug yet

DDN, 24th July 2026

Positive results in metabolic disease, a possible vaccine to treat the current Ebola outbreak, new cancer drug targets, and more led the news this week.

Eli Lilly, this week, reported positive topline results from TRIUMPH-2 and TRIUMPH-3, two pivotal Phase 3 trials of retatrutide, a once-weekly injectable that activates receptors for GIP, GLP-1, and glucagon simultaneously — a triple mechanism that no approved obesity therapy currently matches. In TRIUMPH-2, adults with obesity and type 2 diabetes lost up to an average of 49.6 pounds, or 20.8 percent of body weight, at 80 weeks on the highest 12mg dose, with A1C dropping by an average of 1.5 percent. In TRIUMPH-3, adults with severe obesity and established cardiovascular disease lost up to an average of 55.8 pounds, or 22.6 percent. Cardiovascular event data from TRIUMPH-3 trended favorably but the trial was not powered to draw conclusions on that endpoint. The drug also produced notable reductions in triglycerides, non-HDL cholesterol, systolic blood pressure, and the inflammatory marker hsCRP. Lilly plans to file a Biologics License Application with the FDA in Q1 2027, with the same data package supporting additional submissions for knee osteoarthritis pain and obstructive sleep apnea. Five consecutive positive Phase 3 readouts across the TRIUMPH program now give Lilly a credible path to fielding three distinct obesity medicines at once.

https://www.drugdiscoverynews.com/lilly-s-triple-agonist-just-became-its-most-powerful-obesity-drug-yet-17377

★★★★★★★

GSK partner Hansoh reports another phase 3 win for priority ADC

Fierce Biotech, 28th July 2026

Hansoh Pharmaceutical has guided its GSK-partnered, B7-H3-directed antibody-drug conjugate (ADC) to another phase 3 win in China.

Weeks after reporting a victory in small-cell lung cancer (SCLC), Hansoh revealed that a phase 3 trial of the ADC in relapsed osteosarcoma was tied to significantly longer progression-free survival than chemotherapy, hitting the primary endpoint. The study compared the ADC, risvutatug rezetecan (ris-rez), to chemotherapy in people who had progressed or relapsed after receiving at least two prior lines of systemic therapy.

Sharing Hansoh's findings, GSK said "consistent benefit" was seen across secondary endpoints, including overall survival, while no new safety signals were identified.

Reflecting on the results during a media call to discuss the company's second-quarter earnings, GSK CEO Luke Miels said: "Any day you do something that helps kids with cancer is a good day."

The partners have yet to share data on any of the endpoints, but Hansoh is confident enough in the results to start preparing a regulatory submission in China. The success of the Chinese clinical trial bodes well for Embold Sarcoma-202, a global phase 1b/2 trial that GSK is running to evaluate ris-rez in previously treated unresectable advanced or metastatic sarcomas, including osteosarcoma.

Osteosarcoma, which mainly affects children and young adults, is a bone cancer with a global incidence of about 3.4 cases per million people per year. Chemotherapy is the established first-line treatment, but options are limited for people who relapse and particularly for people who progress after two lines of therapy.

https://www.fiercebiotech.com/biotech/gsk-partner-hansoh-reports-another-phase-3-win-priority-adc

★★★★★★★

DifGen Pharmaceuticals Receives FDA Clearance to Begin Clinical Development for a Single Injection treatment for Advanced Breast Cancer DFGN-101

PR Newswire, 27th July 2026

DifGen Pharmaceuticals LLC today announced that the U.S. Food and Drug Administration (FDA) has accepted the company's Investigational New Drug (IND) application and issued

a "study may proceed" letter for DFGN-101, an intramuscular injection under development for the treatment of advanced or metastatic breast cancer in women.

DFGN-101 is designed to be administered as a single intramuscular injection, compared with the two separate injections required for the currently marketed reference product. If approved, the product would reduce the number of injections a patient receives at each treatment visit.

Under the agreed development pathway, DifGen will proceed with preclinical toxicology studies in rat and rabbit and a Phase 1 pharmacokinetic study. A clinical endpoint/efficacy study is not required. The Agency's position was supported by the company's Chemistry, Manufacturing and Controls (CMC) data package and by results from a pilot pharmacokinetic study showing a PK profile comparable to that of the reference product.

The clearance reflects DifGen's formulation and clinical development capabilities and its focus on identifying efficient development pathways for technically complex programs.

https://www.prnewswire.com/news-releases/difgen-pharmaceuticals-receives-fda-clearance-to-begin-clinical-development-for-a-single-injection-treatment-for-advanced-breast-cancer-dfgn-101-302835253.html

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REGULATORS AND REGULATORY ACTIONS

Regulatory tracker: AbbVie scores 1st Rinvoq alopecia nod in EU

Fierce Pharma, 29th July 2026

In its quest to scoop up yet another immunology indication for its JAK inhibitor Rinvoq, AbbVie has broken through to treatment of severe alopecia areata.

The med's world-first approval in the hair follicle-attacking autoimmune disease has come by way of Europe, where AbbVie announced Wednesday that the European Commission signed off on Rinvoq to treat both adults and adolescents ages 12 years and up.

Rinvoq is still being assessed in alopecia by the FDA after AbbVie submitted its U.S. approval filing in late April.

The European Commission made its call after reviewing phase 3 data from AbbVie's ongoing UP-AA clinical program. Last August, AbbVie unveiled a series of eye-popping results in alopecia from parallel studies that met their primary endpoint when more than half of patients on the highest Rinvoq dose achieved 80% or more scalp hair coverage at 24 weeks.

Alopecia areata is an autoimmune disease that attacks the body's hair follicles, leading to patchy hair loss that can range from sudden, round bald patches on the scalp, to complete body hair loss.

Also in Europe, the EMA's Committee for Medicinal Products for Human Use (CHMP) has tendered a positive opinion on Amgen's Repatha to reduce cardiovascular risk by lowering cholesterol levels in adults who are at high risk for or have established atherosclerotic cardiovascular disease, as an adjunct to correction of other risk factors.

With the CHMP's thumbs-up, a final European Commission decision in the new indication is expected "in the coming months," Amgen noted in a release.

The positive opinion on Repatha—Amgen's heart and cholesterol blockbuster that was first cleared by the FDA in 2015—hinges on results from Amgen's late-stage Vesalius-CV trial, which showed that Repatha on top of statins or other LDL-C-lowering treatments significantly curbed patients' risk of major adverse cardiovascular events (MACE).

https://www.fiercepharma.com/pharma/fierce-pharma-regulatory-tracker-2026-h2

★★★★★★★

Viatris Receives U.S. FDA Approval for Gwyn Lo™, a Once-Weekly Contraceptive Patch

PR Newswire, 29th July 2026

Viatris Inc. a global healthcare company, today announced that the U.S. Food and Drug Administration (FDA) has approved Gwyn Lo™ (norelgestromin and ethinyl estradiol transdermal system). Gwyn Lo is a new combined hormonal contraceptive (CHC) patch with low-dose estrogen. The patch has demonstrated contraceptive efficacy for women of childbearing potential with a body mass index (BMI) below 30 kg/m² who are appropriate candidates for CHC. The Gwyn Lo dosage is norelgestromin 220 mcg/day and ethinyl estradiol 20 mcg/day.

"Gwyn Lo will provide a discreet option for women seeking a reversible, non-invasive, once-weekly contraception patch with a low dose of estrogen," said Philippe Martin,

Viatris Chief R&D Officer. "Building on our expertise in transdermal drug delivery systems and legacy in women's health, we are pleased that the approved label for this new patch reflects the strength of our clinical program. This includes demonstrated efficacy in women with a BMI of 25 to less than 30 kg/m², with no BMI-based limitation of use in this population."

The approval was granted under the FDA's 505(b)(2) regulatory pathway and was supported by results from the Phase 3 Luminous Study (NCT05139121), which demonstrated contraceptive efficacy, a well-characterized safety profile and robust patch adhesion performance. Key outcomes of the Phase 3 study included:

- The primary efficacy endpoint was the Pearl Index (PI), defined as the number of pregnancies per 100 woman-years of exposure in the efficacy evaluable population (women aged 18 to 35 years), which was 4.14 (95% CI: 2.77 to 5.95).
- The study demonstrated robust patch adhesion under real-world conditions, with only 1.3% of the 39,790 transdermal systems applied during the year-long trial fully detaching.
- The most common adverse reactions (2% or greater) reported during the study were application site irritation (4.8%), application site erythema (3.7%), application site pruritus (3.7%), intercycle bleeding (3.9%), heavy withdrawal bleeding (2.0%), and nausea (2.0%).
- Cycle control improved over time, as rates and duration of unscheduled bleeding or spotting decreased from 34.5% and a mean of 3.2 days in Cycle 1 to 20.0% and 2.4 days by Cycle 13.

https://www.prnewswire.com/news-releases/viatris-receives-us-fda-approval-for-gwyn-lo-a-once-weekly-contraceptive-patch-302837674.html

★★★★★★★

Alembic Pharmaceuticals Limited receives USFDA Final Approval for Prucalopride Tablets

Passionate in Marketing, 29th July 2026

Alembic Pharmaceuticals Limited (Alembic) today announced that it has received final approval from the US Food & Drug Administration (USFDA) for its Abbreviated New Drug Application (ANDA) Prucalopride Tablets, 1 mg and 2 mg.

The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD), Motegrity Tablets, 1 mg and 2 mg, of Takeda Pharmaceuticals USA Inc. Prucalopride tablets are serotonin-4 receptor agonist indicated for the treatment of chronic idiopathic constipation (CIC) in adults. Refer label for a detailed indication.

Prucalopride Tablets, 1 mg and 2 mg, have an estimated market size of US$ 100 million for twelve months ending March 2026 according to IQVIA.

Alembic has a cumulative total of 245 ANDA approvals (225 final approvals and 20 tentative approvals) from USFDA.

https://www.passionateinmarketing.com/alembic-pharmaceuticals-limited-receives-usfda-final-approval-for-prucalopride-tablets/

★★★★★★★

FDA advisers recommend relaxing US rules on compounding peptides

Reuters, 24th July 2026

Outside advisers to the U.S. Food and Drug Administration recommended broader access to six unapproved peptides, capping a two-day review that backed most of the compounds despite the health regulator's staff concerns about limited safety and effectiveness data.

Over the course of the meeting held on Thursday and Friday, the panel voted to recommend the FDA allow compounding pharmacies to manufacture six out of seven peptides being considered for patients with a prescription, reversing Biden-era restrictions criticized by Health Secretary Robert F. Kennedy Jr.

This was against the guidance of FDA staff, who argued there is not sufficient evidence to support loosening the rules on compounding.

On Friday, a narrow majority asked the agency to allow compounding of the unapproved peptides Epitalon and Semax, used to support aging and treat migraines, respectively, after recommending on Thursday that pharmacies be permitted to make four other unapproved compounds.

The panel's support for the treatments marks a victory for Health Secretary Robert F. Kennedy Jr., who has said he has used peptides and in April described a black market of unregulated products that still make their way into the United States. The Biden administration in 2023 found that nearly 20 peptides raised safety concerns and barred their legal compounding.

https://www.reuters.com/legal/litigation/fda-advisers-weigh-relaxing-rules-three-more-peptides-widen-access-2026-07-24/

★★★★★★★

MEDTECH

Total Flow Medical earns FDA nod for femoral arterial cannula for cardiopulmonary bypass

Mass Device, 30th July 2026

Total Flow Medical announced today that it received FDA 510(k) clearance for its TFA femoral arterial cannula device.

Vancouver-based Total Flow Medical's TFA cannula received clearance for extracorporeal circulation during cardiopulmonary bypass procedures for up to six hours.

Femoral arterial cannulation, a commonly used technique for establishing extracorporeal circulation, circulates blood outside the body during cardiac surgery. However, the company says maintaining blood flow to the cannulated limb remains an important consideration.

Total Flow Medical designed the TFA cannula with this challenge in mind. The device incorporates a balloon at its distal tip to allow blood flow to the cannulated limb. According to the company, it provides clinicians with an option that can integrate into existing surgical workflows as well.

With clearance, Total Flow Medical has preparations underway for a U.S. market release. It plans to work with cardiac surgery centers to support early clinical adoption.

"FDA clearance for the TFA cannula represents a pivotal milestone for Total Flow Medical," said CEO Hillary Pierce. "This device is the product of close collaboration among perfusionists, engineers and cardiac surgeons who set out to reimagine how cardiac surgery teams approach extracorporeal circulation — starting with femoral arterial cannulation. Receiving FDA clearance marks the start of our commercial journey, and we look forward to introducing the TFA cannula to hospitals across the United States.

Total Flow Medical gets FDA nod for femoral arterial cannula device

★★★★★★★

MiMedx to acquire Sanara MedTech for $350M

Mass Device, 30 July 2026

MiMedx Group (Nasdaq: MDXG) will acquire all of Sanara MedTech (Nasdaq: SMTI) in a cash-and-stock transaction valued at $35 per Sanara share.

The deal, announced yesterday, has a total enterprise value of approximately $350 million.

Sanara develops and commercializes regenerative products for surgical markets. In addition to Sanara's CellerateRX Surgical Powder, Biasurge Advanced Surgical Solution and additional soft tissue and musculoskeletal products, the company is working towards a 2027 commercial launch of its OsStic BioAdhesive Advanced Bone Fixation, which has FDA Breakthrough Device designation.

MiMedx CEO Joseph H. Capper said in a news release: "Over the last several years, MiMedx has demonstrated the ability to drive strong, double-digit growth in surgical end markets. With Sanara, we will accelerate this effort and meaningfully expand our reach across several subspecialties. On a combined basis, 2027 total revenue is expected to be well in excess of $400 million with an adjusted EBITDA margin expected to be over 20%."

Under the terms of the agreement, Sanara shareholders will receive $33.00 in cash and 0.4735 shares of MiMedx common stock for each share of Sanara common stock they own, which represents a value of $2.00 per share, calculated based on the average closing price of MiMedx common stock of $4.22 for the last five consecutive trading days through and including July 28, 2026. The merger consideration represents a premium of 46% to Sanara's 30-day volume-weighted average share price as of July 28, 2026.

MiMedx to acquire Sanara MedTech for $350M

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MoU signed to boost innovation in medical robotics

The Hindu Bureau, 26 July 2026

The Technology Innovation Hub Foundation for IoT and IoE (IHFC) at IIT Delhi and AIC-AMTZ MediValley at Andhra Pradesh MedTech Zone (AMTZ) on Sunday signed a Memorandum of Understanding (MoU) to accelerate innovation in medical robotics and intelligent healthcare technologies.

The partnership brings together Technology Innovation hub's (IHFC) expertise in artificial

intelligence, robotics, cyber-physical systems and autonomous technologies with AMTZ's integrated MedTech manufacturing and innovation ecosystem. By combining advanced research with world-class manufacturing capabilities, the collaboration aims to accelerate the development, testing and translation of next-generation medical robotic solutions into real-world healthcare applications.

"India has the talent to lead the world in medical robotics. What we need is an ecosystem that transforms ideas into life-saving technologies. At AMTZ, we are building that

ecosystem by bringing together innovation, manufacturing and entrepreneurship," said AMTZ MD Jitendra Sharma.

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"India has the talent to lead the world in medical robotics. What we need is an ecosystem that transforms ideas into life-saving technologies. At AMTZ, we are building that ecosystem by bringing together innovation, manufacturing and entrepreneurship," said AMTZ MD Jitendra Sharma.

MoU signed to boost innovation in medical robotics - The Hindu

★★★★★★★

INTERESTING MEDICAL NEWS

Two Global Reports Point to a Widening Cancer Survival Gap

Medscape, 30 July 2026

Where a person with cancer lives increasingly dictates their survival more than the biology of their disease, and the disparities between high- and low-/middle-income countries are widening, even with the existence of tools to mitigate them.

These were the among the conclusions of two new global reports on cancer incidence, mortality, and disparities by geography, income levels, and modifiable risk factors among men vs women.

One of these reports, the World Health Organization's (WHO's) *Global Status Report on Cancer 2026: The Future We Choose Together*, addresses policies and progress related to cancer, and infectious causes of the disease. The other, which was published in *CA: A Clinical Journal for Clinicians,* focuses primarily on epidemiology. Both reach similar conclusions from different data, including what oncologists can do to improve patient outcomes.

"The starkest take-home message is that the global cancer crisis is no longer defined by a gap in scientific knowledge or treatment innovation, but by a massive implementation gap," said Julie Gralow, MD, Chief Medical Officer at the American Society of Clinical Oncology, in an interview with *Medscape Medical News*. "The WHO report makes it clear that while 82% of countries have National Cancer Control Plans, a staggering number of these plans remain completely unfunded and unimplemented on the ground."

The WHO report notes the large scope of the cancer burden, with 92% of people worldwide affected by cancer directly or through a family member or caregiver at least once in their lifetime. It "made visible how cancer is now a near-universal life experience, deeply shaping families, communities and health systems everywhere," Isabelle Soerjomataram, MD, PhD, Deputy Head of the WHO's International Agency for Research on Cancer (IARC) Cancer Surveillance Unit, told *Medscape Medical News*.

The other report, which is based in the IARC GLOBOCAN database, reveals that 1 in 5 people globally will develop cancer before they turn 75. Also, there were nearly 21 million new cases and almost 10 million deaths from cancer globally in 2024.

Incidence of Individual Cancer Types

Lung cancer remained the most commonly diagnosed (12.8%) and the leading cause of cancer death in 2024 (19.1%), the GLOBOCAN findings reveal. The next most common diagnoses were female breast, colorectal, prostate, and stomach cancers. The deadliest cancers after lung cancer were colorectal, liver, female breast, and stomach cancers.

The WHO report links moderate progress on tobacco control to implementation of the MPOWER initiatives around the world. The organization reports a 27% reduction in tobacco use worldwide from 2010 to 2025. A total of 155 countries now deploy one or more best practices from the MPOWER measures. This figure is up from 44 countries in 2007.

In terms of disparities, WHO estimated that the 5-year net survival for breast cancer is more than 85% in high-income countries like the US compared with less than 45% in low-income countries. Earlier detection in high-income countries contributes to this difference, the authors noted.

In addition, for colorectal cancer, high-income countries reached 63% 5-year survival compared with 54% in upper-middle-income and 39% in lower-middle-income countries from 2000 to 2014. For prostate cancer in the same period, the split was 90% (high) vs 80% (upper-middle) vs 59% (lower-middle), the WHO reported.

About 10% of new cancer cases in 2022 were linked to infections, predominantly viruses including *H pylori*, hepatitis B and C, human papillomavirus (HPV), and Epstein-Barr, the WHO noted, citing a study published in *Nature Medicine*. WHO credits its Cervical Cancer Elimination Initiative with "substantial progress" in reducing these infection-associated cancers, especially those linked to HPV. However, by 2020 only four countries had achieved the goal of 90% of girls being fully vaccinated against HPV by age 15, other researchers reported in *BMC Medicine*.

The IARC provided country-level data in the GLOBOCAN report. For example, the US fact sheet reveals that 2,462,729 new cases and 632,166 deaths from cancer occurred in 2024. The lifetime risk of developing cancer before age 75 was 33.9%, with an associated 8.4% risk for death. The age-standardized incidence of all cancers was 358.5 per 100,000 Americans with a mortality rate of 80 per 100,000.

How US Oncologists Can Make a Difference

Experts called for oncologists to focus on trying to reduce the cancer burden beyond US borders and act to promote greater equity in diagnosis and treatment.

"US oncologists have a powerful voice and a professional responsibility to help bridge these disparities through structural, system-wide solutions," Gralow said. "ASCO members and global oncology members can actively participate in bridging this gap by decentralizing clinical research, investing in the global workforce capacity, and fostering global health equity in policies."

"The WHO report points out that simple, high-impact interventions like HPV vaccination coverage, stuck at just 31% globally, and basic diagnostic workups are entirely out of reach for billions," she added. "The report challenges us to shift our collective mindset toward value-based adoption frameworks, ensuring that innovation is measured by actual patient outcomes and universal access worldwide, a core focus of the ASCO Center for Global Impact."

The 31% figure is an improvement over the 17% HPV vaccination rate WHO estimated in 2019, but this "moderate progress" still falls well short of the 90% goal by 2030, the authors of the report noted.

"Every healthcare provider contributes to an ecosystem that must place people at the center, recognizing the devastating, long-lasting, and far-reaching effects of a cancer diagnosis," the WHO wrote. "As providers, we should measure progress and innovation not only by the effect on tumors but by whether we can deliver interventions, such as patient navigation, that make good care more efficient and more equitable."

Modifiable Risk Factors

The paper published in *Nature Medicine* pointed out that almost 38% of the 18.7 million cancer cases diagnosed in 2022 globally were associated with modifiable factors, including tobacco smoking, consuming alcohol, having a high BMI, and engaging in a low level of physical activity. A higher proportion of cancers in men was linked with these risk factors, 45%, compared with 30% of new cancer cases among women.

In terms of mortality, the GLOBOCAN report estimates that 48% of global cancer deaths are potentially avoidable by combining prevention through modifiable risk factors (33%) with early detection and improved access to treatment (15%).

Reducing tobacco use; treating *H pylori*, hepatitis B, and HPV infections; and reducing rates of obesity and alcohol use are among the targeted recommendations for cancer prevention, in the WHO report.

A Mixed Outlook

The WHO reported that between 2000 and 2019, premature mortality rates from cancer declined in 75% or 138 out of 183 countries. Its projections up to the year 2050 suggest a continued but unequal reduction across countries by income level, with the lowest decline in low- to middle-income nations.

The authors of the GLOBOCAN report predicted an increase in cancer incidence that will reach 34.4 million by 2050, up 67% from 2024, with the largest proportional increases in lower Human Development Index countries.

Soerjomataram and Gralow reported having no relevant financial relationships. Hyuna Sung reported being employed by the American Cancer Society, which receives grants from private/corporate foundations for research outside the submitted work.

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