Friday, 03 October 2025

INSIGHTS

Healthcare Newsweekly For You

CONTENT *(Highlights)*

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UPCOMING EVENTS

Conference

11-12 November, London

By Financial Times

300+	45+	320+	20+
Attendees	Speakers	Companies represented	Countries

Few Interesting Panel Discussions

- Rare diseases – Brilliant breakthroughs vs. systemic gaps
- AI in pharma – From trial and error to business as usual
- Policy volatility and pharma – Strategies for a fragmented world
- Global health security – Steering progress on pandemic readiness
- Beyond CRISPR – Developing fully programmable, adaptable gene therapies

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DEALS AND FUNDING

Genmab to acquire closely watched cancer drug in $8B Merus buyout

Biopharma Dive, 29 September 2025

The deal hands Genmab a drug that showed the potential in earlier testing to extend survival in head and neck cancer when added to Merck's widely used immunotherapy Keytruda.

Dive Brief:

- Antibody drug specialist Genmab on Monday agreed to acquire Dutch biotechnology company Merus in an $8 billion deal centered around a drug that's shown potential treating head and neck cancer.
- Per deal terms, Genmab will pay $97 per share in cash to acquire Merus, representing a 41% premium to the biotech's closing price on Friday of about $68.
- The deal hands Genmab a drug called petosemtamab and that's in late-stage testing for head and neck cancer. Phase 2 data presented at the American Society of Clinical Oncology meeting in May showed that the drug helped extend survival when used alongside Merck & Co.'s immunotherapy Keytruda, a result that boosted shares and suggested it could change care for those tumors.

Dive Insight:

Merus had already seen its share value jump by more than 50% since late May, when its ASCO presentation showed that petosemtamab kept nearly 80% of study participants with advanced head and neck squamous cell carcinoma alive for at least a year.

Genmab to acquire closely watched cancer drug in $8B Merus buyout | BioPharma Dive

★★★★★★★

Amgen to invest $650m in US manufacturing network expansion

Pharmaceutical Technology, 29 September 2025

The investment aims to scale up the production of drugs at the company's Juncos' biologics production facility.

Global biotechnology company Amgen has revealed a significant investment plan, earmarking $650m to enhance its manufacturing operations in the US.

The investment aims to scale up the production of drugs at the company's Juncos' biologics production facility in Puerto Rico.

The company will also use the planned investment to incorporate the latest technologies across operational workflow and generate 750 new jobs, including positions in construction and specialised manufacturing sectors.

Amgen CEO and chairman Robert Bradway stated: "This expansion underscores Amgen's commitment to US biomanufacturing and to strengthening the resilience of our global supply chain.

Pharmaceutical Technology

★★★★★★★

Natco Pharma mulls demerger of agro business

The Hindu, 25 September 2025

Generic drugmaker Natco Pharma is considering spinning off its agro business, a move for which it got an in-principle approval from the board on Thursday.

The board of directors has given in-principle approval to evaluate the demerger of the agro business of the into a separate entity. The management is of the opinion that the move will enable value unlocking of the core pharmaceuticals business and enhance long-term growth. Further, the demerger is also expected usher in operational flexibility, pave way for a focused and dedicated management for the businesses as also help different brand positioning for each legal entity, Natco Pharma said in a filing.

The company said as a part of the proposed reorganisation, it may retain a small minority stake in the resulting company as a measure to support the entity in terms of common services such as research and development and patents.

https://www.thehindu.com/business/natco-pharma-mulls-demerger-of-agro-business/article70094763.ece

★★★★★★★

Korea's Boryung looks to stir up new value in Sanofi's legacy chemo Taxotere with $205M rights buy

Fierce Pharma, 30 September 2025

South Korea-based Boryung Corporation is boosting its global oncology foothold with a deal to take on Sanofi's time-honored chemotherapy Taxotere (docetaxel) in nearly 20

markets for up to 175 million euros ($205 million).

The deal, which includes potential milestone payments worth 14 million euros ($16 million), encompasses Sanofi's Taxotere business in 19 countries, including Korea, Germany, Spain and China.

Boryung will manufacture the drug at its plant in Yesan, South Korea, and sell it to the global market, allowing the company to emerge as a "global pharmaceutical company with a strong portfolio of legacy cytotoxic anti-cancer drug," Boryung said in a Sept. 30 release.

"While the paradigm of anti-cancer treatment is evolving toward targeted and immuno-oncology therapies, the cytotoxic anti-cancer drug remains an essential foundation of anti-cancer treatment," a Boryung official said in the company's release.

The drugmaker hopes to maintain a "stable global supply chain" to ease recurrent shortages and supply disruptions of the med that can impact treatment.

Boryung picks up Taxotere rights in deal worth up to $205M

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Vaxcyte strikes up to $1B deal for fill-finish space at Thermo Fisher's N.C. production facility

Fierce Pharma, 2 October 2025

As North Carolina's biopharma hotbed enjoys an onshoring investment rush, clinical-stage vaccine developer Vaxcyte is the latest company to put down manufacturing roots in the state.

As with other drugmakers who've embarked on North Carolina production projects in recent months, Vaxcyte plans to leverage the extensive CDMO capacity offered there.

Vaxcyte is paying Thermo Fisher Scientific up to $1 billion to access vaccine fill-finish capacity at the CDMO's production facility in Greenville, North Carolina. Vaxcyte positioned the deal—which covers the biotech's pipeline of broad-spectrum pneumococcal conjugate vaccines (PCV)—as a "long-term U.S. commercial manufacturing commitment."

Vaxcyte has yet to win any FDA approval, specifying in a press release this week that the Thermo Fisher pact forms part of its long-term commercial supply strategy.

https://www.fiercepharma.com/manufacturing/vaxcyte-strikes-1b-deal-fill-finish-space-thermo-fishers-nc-production-facility

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Roche commits $1.9 bn investment in India over next 5 yrs

Financial Express, 2 October 2025

Swiss healthcare giant Roche Pharma announced a major expansion, committing 1.5 billion Swiss francs ($1.9 billion) investment in India over the next five years, cementing the country's status as a key growth and innovation hub.

Swiss healthcare major Roche Pharma said on Wednesday it will invest 1.5 billion Swiss francs (approximately $1.9 billion) in India over the next five years, marking a significant expansion as the country becomes a key growth and innovation hub for the pharmaceutical giant.

Roche's long-term commitment and scale in India

Announcing the investment at the India-European Free Trade Association Prosperity Summit organised on the day of Trade and Economic Partnership Agreement (TEPA) coming into force, Roche Pharma area head CEETRIS (Central Eastern Europe, Turkiye, Russia and Indian Subcontinent) Francois du Toit said the company's investment underlines a long-term commitment to the Indian market.

https://www.financialexpress.com/business/industry/roche-commits-1-9-bn-investment-in-india-over-next-5-yrs/3996063/

★★★★★★★

PHARMA & BIOLOGICS

SMALL MOLECULES

US FDA approves another generic version of abortion pill

Reuters, 3 October 2025

The U.S. Food and Drug Administration has approved Evita Solution's generic version of the abortion drug, mifepristone, the regulator said.

The FDA said in a letter dated September 30 it has approved Evita's generic version of Danco Laboratories' mifepristone, which is used to terminate pregnancy at up to 10 weeks.

The drug is manufactured by the privately held company that describes its mission as being to "normalize abortion" and make it "accessible to all."

GenBioPro, another private company, also sells a generic version of Danco Labs' mifepristone.

The approval comes amid heightened scrutiny of abortion drugs, with the FDA currently reviewing the safety of mifepristone following pressure from conservative lawmakers and state attorneys general.

U.S. Health Secretary Robert F. Kennedy Jr. said in a post on X that "the Biden administration removed mifepristone's in-person dispensing rule without studying the safety risks. We are filling that gap."

"U.S. FDA only approved a second generic mifepristone tablet because federal law requires approval when an application proves the generic is identical to the brand-name drug," he added.

https://www.reuters.com/business/healthcare-pharmaceuticals/us-fda-approves-generic-version-abortion-drug-2025-10-02/

★★★★★★★

Pfizer's new prize Metsera touts 14% weight loss, 'class-leading tolerability' for lead GLP-1 drug

Fierce Biotech, 30 September 2025

The GLP-1 agonist at the center of Pfizer's upfront $4.9 billion buyout of Metsera last week has been tied to 14.1% weight loss at 28 weeks as well as "potentially class-leading tolerability," according to the biotech.

The injectable candidate, dubbed MET-097i, was the main attraction from the pipeline of obesity drugs that Pfizer secured as part of its acquisition. Metsera kicked off the year by tying MET-097i to weight loss of up to 11.3% after 12 weeks and unveiled longer-term data yesterday.

Specifically, the phase 2b Vesper-1 study assessing weekly dosing of MET-097i demonstrated a mean placebo-subtracted weight loss of 14.1% after 28 weeks for the 54 patients who were overweight or with obesity who received the highest, 1.2-mg, dose of the drug.

https://www.fiercebiotech.com/biotech/pfizers-new-prize-metsera-touts-141-weight-loss-lead-glp-1-drug

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LARGE MOLECULES

Jazz Pharma, Roche's combination therapy for lung cancer gets US approval

Reuters, 3 October 2025

The U.S. Food and Drug Administration has approved Jazz Pharmaceuticals and Roche's combination therapy as a maintenance treatment for adult patients with a type of lung cancer, the regulator said on Thursday.

Jazz's drug, Zepzelca, in combination with Roche's Tecentriq, is now approved for patients with extensive-stage small cell lung cancer (ES-SCLC), whose disease has not progressed after initial chemotherapy.

This is an aggressive form of lung cancer that may spread to other parts of the body, including the bone marrow.

"This approval marks the first and only combination therapy for the first-line maintenance treatment of ES-SCLC, a highly aggressive disease for which treatment options have been limited," Roche said in a statement.

Zepzelca is already approved as a second-line treatment — to be administered when the initial treatment fails — for the illness.

"With the FDA approval, the combination will be eligible for reimbursement," Jazz Pharma told Reuters. Zepzelca's list price is $8,110, according to the company website as of January 14. Jazz Pharma noted that the cost does not change per indication.

https://www.reuters.com/business/healthcare-pharmaceuticals/us-fda-approves-jazz-pharmas-therapy-lung-cancer-2025-10-02/

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REGULATORS AND REGULATORY ACTIONS

Global drugmakers rush to boost US presence as tariff threat looms

Reuters, 1 October 2025

Global drugmakers are scrambling to shore up their U.S. manufacturing capacity and domestic inventory as the Trump administration moves ahead with a 100% tariff on imported branded and patented drugs, starting October 1.

The sweeping measure has triggered a flurry of activity across the industry, including fast-tracking U.S. manufacturing projects, price cuts and direct-to-consumer sales.

Here's what drugmakers are doing to mitigate supply-chain risks and reassure investors:

Pfizer

Pfizer reached a deal with President Donald Trump on September 30 to invest $70 billion in research and development and domestic manufacturing, and received a three-year grace period exempting its products from the pharmaceutical-targeted tariffs.

GSK

The London-based drugmaker plans to invest $30 billion in U.S. research and development and supply chain infrastructure over five years.

Eli Lilly

The U.S. drugmaker said in September it will invest $5 billion to build a manufacturing facility in Virginia. The facility is the first of four new U.S. plants planned under its $27 billion expansion over the next five years.

https://www.reuters.com/business/healthcare-pharmaceuticals/global-drugmakers-rush-boost-us-presence-tariff-threat-looms-2025-09-26/

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CDSCO clarifies regulatory pathway for combi-pack approvals of Lyophilized injections & diluents

Express Pharma, 30 September 2025

The Central Drugs Standard Control Organization (CDSCO) has issued a clarification concerning the regulatory approval process for combi-pack products comprising lyophilized dry powder for injection or intravenous (I.V.) infusion, along with diluents used for reconstitution, such as Sterile Water for Injection or Sodium Chloride Injection.

The organization had received several representations seeking guidance on the appropriate regulatory pathway for such combinations. After a detailed examination of the matter, CDSCO has outlined the applicable procedure for granting permission for these combi-pack products.

According to the clarification, if the lyophilized dry powder for injection or I.V. infusion has been approved by CDSCO for more than four years and is already being used with a specific diluent as per its prescribing information, then a combi-pack that includes the same approved diluent will not be considered a new drug. In such cases, the State Licensing Authority (SLA) may grant the manufacturing or marketing license without requiring additional approval from CDSCO.

However, the notice also mentioned, if the approved injection or infusion is proposed to be combined with a different diluent not originally specified in its prescribing information, such a product will be treated as a new drug under Rule 2(1)(w) of the New Drugs and Clinical Trials (NDCT) Rules, 2019. In these instances, the applicant must obtain prior approval from CDSCO before a license can be issued by the SLA.

https://www.expresspharma.in/cdsco-clarifies-regulatory-pathway-for-combi-pack-approvals-of-lyophilized-injections-diluents/

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Lilly wins European Alzheimer's approval for Kisunla after regulatory setbacks

European Pharmaceutical Review, 26 September 2025

The anti-amyloid monoclonal antibody is part of the class of medicines representing the first disease-modifying therapies for the neurodegenerative disease.

In March European Medicines Agency (EMA) advisors refused to back its approval, believing its benefits were not enough to outweigh the risk of potentially fatal events due to amyloid-related imaging abnormalities (ARIA), involving swelling and potential bleeding in the brain.

After re-examining the drug the EMA's committee for Medicinal Products for Human Use (CHMP) recommended Kisunla for approval, but only for a subset of the patient population.

Consequently, the monoclonal antibody is now indicated for adults with mild cognitive impairment and individuals with mild dementia stages of Alzheimer's, but only for those that do not have a copy of the ApoE4 gene, a certain form of the gene for the protein apolipoprotein E, or people who have only one copy of the gene.

https://www.europeanpharmaceuticalreview.com/news/265972/lilly-wins-european-alzheimers-approval-for-kisunla-after-regulatory-setbacks/

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MEDTECH

EssilorLuxottica wins FDA OK for myopia-slowing eyeglass lenses

MedtechDive, 29 September 2025

Investigators saw a 71% reduction in myopia progression in children who used the lenses

for two years.

Dive Brief:

- The Food and Drug Administration has authorized a spectacle lens from EssilorLuxottica for use in children with nearsightedness.
- EssilorLuxottica, which announced the de novo authorization on Thursday, linked the lenses to a 71% reduction in the progression of nearsightedness in a 24-month study.
- CooperVision already sells contact lenses in the U.S. to manage nearsightedness. The FDA said EssilorLuxottica's eyeglass lens is a lower-risk device that is suitable for use in younger children.

Dive Insight:

Myopia, the medical term for nearsightedness, affects around 40% of the U.S. population and prevalence is increasing rapidly among children and adolescents, the FDA said. When the chronic disease progresses to high myopia, people are at greater risk of sight-threatening complications such as retinal detachment, myopic maculopathy, glaucoma and cataracts later in life.

The Essilor Stellest eyeglass lenses are designed to slow myopia progression in children. The lenses have a clear 9mm diameter area in the center. Rings of tiny raised dots surround the clear center to defocus peripheral light. Studies suggest blurring side vision may slow eye growth and limit myopia.

https://www.medtechdive.com/news/essilorluxottica-fda-myopia-slowing-eyeglasses/761330/

★★★★★★★

FDA seeks feedback on monitoring real-world performance of AI devices

MedtechDive, 1 October 2025

The agency is looking for ways to detect, assess and mitigate changes to the performance of AI-enabled devices over time.

Dive Brief:

- The Food and Drug Administration is seeking public feedback on how to measure and evaluate the real-world performance of artificial intelligence-enabled medical devices.

- In the consultation, which began Tuesday, the FDA has posed six sets of questions about ways to perform ongoing, systematic performance monitoring to see how AI behaves in clinical settings.
- With the rate of AI submissions accelerating, the FDA is wary of the potential for "data drift" to cause devices to perform worse in the real world than in tests run to support authorization.

Dive Insight:

The FDA's call for feedback is informed by evidence that the performance of AI-enabled medical devices can change over time. As the agency explained in its request for comment, factors such as changes in clinical practice, patient demographics, data inputs and healthcare infrastructure can affect devices. User behavior, workflow integration and changes to clinical guidelines may also impact performance.

Commonly called data drift, the tendency for AI-enabled devices to change over time can degrade performance, cause bias or reduce reliability. The phenomenon sets AI-enabled devices apart from traditional products, the performance of which should remain constant.

In a January draft guidance, the FDA recommended that developers have a post-market monitoring plan in place for AI-enabled devices because their performance can degrade over time.

https://www.medtechdive.com/news/fda-comment-real-world-performance-ai-devices/761553/

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Siemens Healthineers sees FDA Class I recall over ice buildups in MRI scanners

Fierce Biotech, 1 October 2025

The FDA is amplifying a recall effort underway at Siemens Healthineers related to several of its MRI machines, linked to their helium containment and the potential for a dangerous rupture.

The company began notifying operators and healthcare providers in late August about the possibility of ice buildups within the supercooled magnet's venting systems.

This ice can form blockages that—in the event of an emergency shutdown known as a quench, where liquid helium is rapidly boiled off into a gas—could cause pressure to spike

and ultimately leak helium into the scanning room, raising the risks of suffocation.

The issue spans more than a dozen of Siemens Healthineers' internationally distributed models, including across its Magnetom family and its line of Biograph combination MR/PET scanners. This week, the FDA handed down a Class I recall designation to the problem, its most serious.

https://www.fiercebiotech.com/medtech/siemens-healthineers-sees-fda-class-i-recall-over-ice-build-ups-mri-scanners

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INTERESTING MEDICAL NEWS

Even small amounts of alcohol may increase dementia risk, study finds

Medical News Today, 25 September 2025

- Alcohol consumption, particularly heavy alcohol use, is linked to many health conditions, including an increased risk of dementia.
- However, studies have suggested that consuming small amounts of alcohol might actually decrease the risk of developing dementia.
- Now, a study has found that low alcohol consumption may not have the suggested protective effect.
- The study, which used both observational and genetic analysis, suggests that any alcohol consumption may increase a person's risk of dementia, with the risk increasing as alcohol intake increases.
- According to the World Health Organization, consuming any alcohol can affect a person's health in some way. Alcohol consumption is linked to at least seven types of cancer, including cancers of the breast and bowel, as well as high blood pressure, heart disease, and liver disease.
- Consumption of high levels of alcohol can also increase a person's risk of dementia, but many observational studies suggest that consuming small amounts of alcohol will not increase the risk and may even reduce it.
- A new genetic analysis has found that although the risk of dementia increases with increased alcohol intake, even low alcohol intake can increase a person's risk of developing the condition.

The study, published in BMJ Evidence-Based Medicine, used both observational and genetic analyses. While the observational analysis found that moderate drinkers had a

lower dementia risk than abstainers, the genetic analysis found that any alcohol intake was linked to an increased risk.

"This is a highly important and influential finding. It challenges decades of observational research suggesting that light-to-moderate alcohol consumption may protect against dementia. By incorporating genetic analyses, which are less susceptible to confounding and reverse causation, the study demonstrates a likely causal relationship between alcohol and increased dementia risk at all levels of intake. This has direct implications for public health messaging and dementia prevention strategies."

— Dr. Steve Allder, consultant neurologist at Re:Cognition Health, who wasn't involved in the study

Alcohol's effects on the brain

The effects of heavy drinking on the brain are well known. According to the National Institute on Alcohol Abuse and Alcoholism , alcohol affects areas of the brain that control balance, memory, speech, and judgment, resulting in a higher likelihood of injuries and other negative outcomes.

Allder explained how alcohol damages the brain:

"Alcohol is neurotoxic: it damages neurons, promotes brain atrophy, disrupts neurotransmitter systems, and accelerates vascular injury. Chronic use can impair thiamine metabolism, leading to cognitive deficits, while even lower levels have been linked to adverse brain imaging findings such as reduced gray matter volume."

"Alcohol also increases systemic inflammation and oxidative stress, both of which are implicated in neurodegeneration," he added.

Genetic vs. observational analysis

In this study, the researchers undertook an observational analysis of almost 560,000 people from the UK Biobank and the U.S. Million Veteran Program.

Using questionnaires and the Alcohol Use Disorders Identification Test (AUDIT-C) clinical screening tool, they assessed participants' drinking. They then monitored participants for an average of 4 years, during which time, 14,540 people developed dementia.

In the observational analysis, they found U-shaped associations between alcohol use and dementia risk. Non-drinkers and heavy drinkers both had a higher dementia risk than those who drank fewer than seven drinks a week.

However, the genetic analysis gave different results.

Şebnem Ünlüişler, genetic engineer and chief longevity officer at the London Regenerative Institute, who was also not involved in the study, explained why:

"Studies looking at alcohol and dementia can sometimes give conflicting messages. Observational research often suggests that light drinking might protect the brain, showing a U-shaped pattern where moderate drinkers seem at lower risk than heavy drinkers or abstainers. But this can be misleading. People who drink lightly often lead healthier lives — they may exercise more, eat better, have higher education, or enjoy stronger social connections, all of which reduce dementia risk. At the same time, some people stop drinking because of early health problems or subtle cognitive changes, making abstainers appear at higher risk."

"Genetic studies offer a clearer picture," she told Medic*al News Today*. "By using inherited genetic markers linked to alcohol use, researchers can estimate lifetime exposure without the bias of lifestyle or health differences."

Any alcohol intake increases dementia risk

Lead author, Dr. Anya Topiwala, BM BCh, DPhil, Wellcome Trust Career Development Fellow, Honorary Consultant Psychiatrist, Nuffield Department of Population Health, University of Oxford, UK, explained to *MNT* how the genetic risk for alcohol consumption was actually worked out by another group:

"It's determined using a genome-wide association study (GWAS). They take a huge sample of individuals and ask them how much they drink. They then look across peoples' genomes, and test [whether] each genetic variant is more or less common in people who drink more or not. For alcoholic drinks per week they found [d]ifferent genetic variants that were more or less common with higher alcohol intake. Each only contributes a small effect, but we used these genetic variants to 'proxy' alcohol intake."

They found that, in those of European ancestry, a higher genetic risk for alcohol consumption was associated with an increased risk of all-cause dementia.

Is alcohol harmless?

"These [genetic] analyses consistently show that any alcohol, even in small amounts, raises dementia risk, with no protective effect at low levels. While light drinking may look harmless in some studies, the safest choice for your brain is to minimise or avoid alcohol entirely."

— Şebnem Ünlüişler

Contrary to the observational analysis, the genetic analysis found no U-shaped association between alcohol use and dementia. This analysis found that dementia risk increased steadily with greater predicted alcohol consumption, and that there was no protective effect from low alcohol intake.

Reduce or stop alcohol consumption to minimize risk

Topiwala advised that people should:

"Not to be under the illusion that moderate drinking is likely to reduce your dementia risk. If you want to minimize your risk then minimize your alcohol consumption."

"This study represents a turning point in the debate on alcohol and dementia. It suggests that previously reported benefits of light drinking were likely artefacts of study design rather than true neuroprotection. The public health message should evolve accordingly: reducing alcohol consumption, much like reducing smoking or managing cardiovascular risk factors, may be a powerful strategy in lowering dementia incidence worldwide."

— Steve Allder, MD

https://www.medicalnewstoday.com/articles/even-small-amounts-alcohol-may-increase-dementia-risk-study

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