

# PHARMA NEWS ROUND-UP

Vol 4, Issue 3

Sep - Dec, 2025

## 02<sup>nd</sup> July, 2025



Rinri Therapeutics, a University of Sheffield spinout, has received MHRA approval to begin its first human trial of Rincell-1, an otic neural progenitor cell therapy designed to regenerate damaged auditory neurons in people with sensorineural hearing loss. The Phase I/IIa trial, conducted at three UK hearing research centres, will enrol 20 cochlear implant patients—10 with auditory neuropathy spectrum disorder and 10 with age-related hearing loss. Participants will receive either Rincell-1 plus a cochlear implant or a cochlear implant alone. The study will assess safety and look for improvements in neural health using cochlear implant telemetry, alongside speech perception and patient-reported outcomes. Early proof-of-concept data is expected within 12 months of trial initiation.

## 02<sup>nd</sup> July, 2025

AstraZeneca Pharma India has received regulatory approval from the CDSCO to import and market Durvalumab for two new indications in endometrial cancer, the most common uterine cancer. Endometrial cancer affected more than 400,000 people globally in 2022, including over 17,000 new cases in India, and incidence is expected to rise by more than 20% worldwide and in India. Durvalumab can now be used in combination with carboplatin and paclitaxel as a first-line treatment for adults with primary advanced or recurrent endometrial cancer who are eligible for systemic therapy. For patients with pMMR (mismatch-repair proficient) endometrial cancer, this may be followed by Durvalumab maintenance therapy in combination with Olaparib.

## 07<sup>th</sup> July, 2025

Biocon Biologics has received marketing authorisations from the UK's MHRA for Vevzuo and Evfraxy, its biosimilar versions of Denosumab. Vevzuo is approved for preventing skeletal-related events in adults with advanced cancers involving bone, and for treating adults and skeletally mature adolescents with giant cell tumour of bone that is unresectable or would require highly morbid surgery. Evfraxy is authorised for treating osteoporosis in postmenopausal women and men at increased fracture risk—significantly reducing vertebral, non-vertebral, and hip fractures—as well as for managing bone loss associated with hormone ablation therapy in men with prostate cancer and with long-term glucocorticoid use in adults. Clinical evidence confirms that both biosimilars offer safety and efficacy comparable to the reference product. Additionally, the European Commission has recently granted EU-wide approval for Biocon Biologics' Denosumab biosimilars, enabling their commercialisation across all EU and EEA markets.

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## 10<sup>th</sup> September, 2025

AstraZeneca India has introduced Eculizumab (300 mg, 10 mg/mL concentrate for infusion) to the Indian market following CDSCO approval in January 2025 for its import, sale, and distribution. This marks the first anti-complement therapy authorised in India for treating Paroxysmal Nocturnal Hemoglobinuria (PNH) and atypical Hemolytic Uremic Syndrome (aHUS) in both adults and children. These ultra-rare, life-threatening diseases result from chronic, uncontrolled complement system activation, which can severely affect blood and kidney function. In aHUS specifically, dysregulated complement activity leads to thrombotic microangiopathy (TMA)—the formation of blood clots in small blood vessels—causing progressive and serious complications.

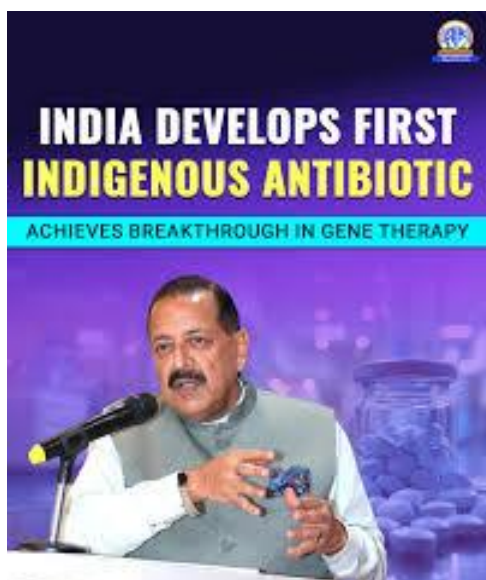
## 03<sup>rd</sup> September, 2025

Lupin Ltd has received approval from the US Food and Drug Administration (USFDA) for its abbreviated new drug application (ANDA) for risperidone extended-release injectable suspension, a generic version used for the treatment and maintenance of schizophrenia and bipolar disorder in adults. The approval covers single-dose vials in strengths of 25 mg, 37.5 mg, and 50 mg, enabling Lupin to market the product in the US as an alternative to the branded therapy.

## 08<sup>th</sup> October, 2025

The CDSCO has directed all pharmacies in India to stop dispensing cough syrups to children under 2 years, even with a prescription, following reports of child deaths linked to these medicines. Pharmacists must alert prescribers and advise safer alternatives, as most pediatric coughs are self-limiting. The move also requires pharmacies to display a QR code and toll-free number for reporting adverse drug reactions through the PvPI system, reinforcing child safety and pharmacovigilance.

## 18<sup>th</sup> October, 2025



Union Minister Jitendra Singh announced that India has successfully developed its first indigenously discovered antibiotic, a major milestone in the country's pharmaceutical research and development. Nafithromycin is designed to combat resistant respiratory infections, and is expected to be particularly valuable for vulnerable patient groups, including cancer patients, whose immunity is often compromised, and individuals with poorly controlled diabetes, who are more prone to severe infections. This development underscores India's growing capabilities in innovative drug discovery and reduces reliance on imported antibiotics for treating multidrug-resistant infections. Nafithromycin has the potential to improve clinical outcomes in high-risk populations while contributing to global efforts to address antimicrobial resistance (AMR), one of the world's most pressing public health challenges. The announcement also highlights the role of government of India's Department of Biotechnology in collaboration with the well-known private pharma house Wockhardt.

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## 06<sup>th</sup> November, 2025

Bayer has received approval in India for Kerendia (finerenone) to treat heart failure, expanding its use beyond chronic kidney disease associated with type 2 diabetes. This therapy targets heart failure types that previously had limited treatment options, addressing significant cardiovascular and kidney health challenges in India.

## 17<sup>th</sup> November, 2025

Pfizer has launched Rimegepant ODT in India, a novel orally disintegrating tablet for migraine relief. The tablet dissolves on the tongue without water, providing rapid pain relief lasting up to 48 hours, helping patients reduce the impact of debilitating migraine attacks on daily life.

## 18<sup>th</sup> November, 2025

Morning-after pills will remain available over the counter, but will now carry a prominent boxed warning stating that they do not protect against sexually transmitted infections (STIs) and should not be used more than twice a month. Additionally, some contraceptive medications are being reclassified under Schedule K, making them more easily accessible to the public.

## 18<sup>th</sup> November, 2025

Eli Lilly has received CDSCO approval in India for donanemab, a disease-modifying therapy for early-stage Alzheimer's disease. Targeting amyloid plaques, the drug aims to slow cognitive decline, offering patients and their families more time and an improved quality of life. This marks a significant step in expanding treatment options for Alzheimer's in India.

## 23<sup>rd</sup> November, 2025

The Indian government is considering floating global tenders to procure over 65 patented medicines—including drugs for weight-loss, cancer, cardiac, and diabetes for central healthcare institutions like the armed forces and ESIC. The move addresses supply gaps and limited domestic production of certain newer or advanced therapies. Domestic manufacturers will be invited to confirm their ability to supply before the government opens tenders to international suppliers. This initiative aims to improve access to critical medicines for public healthcare beneficiaries while balancing support for local manufacturing.

## 25<sup>th</sup> November, 2025



Glenmark Pharmaceuticals has introduced the world's first nebulised, fixed-dose triple therapy for the treatment of chronic obstructive pulmonary disease (COPD). This therapy combines three medications—typically a long-acting beta-agonist (LABA), a long-acting muscarinic antagonist (LAMA), and an inhaled corticosteroid (ICS)—into a single nebulised formulation, allowing patients to receive comprehensive treatment in one dose. The nebulised format is particularly beneficial for patients who have difficulty using standard inhalers, such as elderly individuals or those with severe COPD, as it ensures more effective drug delivery to the lungs.

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## 28<sup>th</sup> November, 2025

Cipla has inaugurated an integrated lung diagnostics and wellness centre in New Delhi, designed to provide end-to-end respiratory healthcare services. The centre aims to combine advanced diagnostic tools with wellness and preventive care programs, enabling early detection, accurate diagnosis, and effective management of various lung conditions. It will offer services ranging from pulmonary function tests and imaging to personalized treatment plans and lifestyle guidance, targeting patients with chronic respiratory diseases, infections, or other lung-related health concerns. The initiative reflects Cipla's commitment to enhancing access to specialized respiratory care and promoting lung health awareness in India.

## 01<sup>st</sup> December, 2025

Lupin Ltd has received approval from the US Food and Drug Administration (USFDA) for its abbreviated new drug application (ANDA) for risperidone extended-release injectable suspension, a generic version used for the treatment and maintenance of schizophrenia and bipolar disorder in adults. The approval covers single-dose vials in strengths of 25 mg, 37.5 mg, and 50 mg, enabling Lupin to market the product in the US as an alternative to the branded therapy.

## 01<sup>st</sup> December, 2025

Wockhardt Ltd has announced that the United States Food and Drug Administration (USFDA) has formally accepted its New Drug Application (NDA) for Zaynich, a novel antibiotic described by the company as a breakthrough therapy. The acceptance of the NDA marks an important regulatory milestone, allowing the USFDA to begin a detailed review of the drug's safety, efficacy, and manufacturing data submitted by Wockhardt. Zaynich is expected to address critical gaps in the treatment of bacterial infections, particularly those caused by resistant strains, positioning it as a potentially significant addition to the antibiotic arsenal. The acceptance signals that the application is sufficiently complete to warrant formal evaluation and is a key step toward potential approval and commercialization in the US market.

## 03<sup>rd</sup> December, 2025

The Central Drugs Standard Control Organisation (CDSCO) has directed drug licensing authorities across all states and Union Territories to ensure that all retail and wholesale pharmacies prominently display a QR code and a toll-free number for reporting adverse drug reactions. The move aims to make it easier and more efficient for the public and healthcare professionals to submit reports through India's PvPI Adverse Drug Reaction Monitoring System. This directive follows the deliberations of the 16th Working Group Meeting of the Pharmacovigilance Programme of India, held on June 18.



**References:** <https://economictimes.indiatimes.com/www.expresspharma.in>