Pharmaceuticals

Pharma Weekly – ICYMI

This is the twenty-sixth edition (week ending 20-Sep-26) of our Pharma Weekly – In Case You Missed It. Key developments in the past week:

1) BMS and Ono Pharma have sued Amgen, alleging that its proposed Opdivo (Nivolumab) biosimilar infringes seven patents. Amgen has submitted the first Opdivo biosimilar application to the FDA, with a decision expected by year-end, while BMS estimates the earliest US entry of Opdivo biosimilars in CY28 (relevant for Biocon).

2) Amneal received FDA approval and has announced the immediate launch of Lanreotide injection (120mg/0.5mL), with Competitive Generic Therapy (CGT) designation. The company has stated that it has large-scale in-house manufacturing capabilities for the product (relevant for Cipla).

3) Sandoz has received Health Canada's marketing authorization for generic Semaglutide (read through for Dr Reddy's).

4) The USFDA has accepted for review Organon's sNDA for Miudella, seeking to extend its duration of use from 3 to up to 6 years for the prevention of pregnancy, with PDUFA action expected in 2QCY27. Organon completed the exclusive global licensing of Miudella in Jun-26, with commercial availability anticipated in late-CY26.

5) Knight Therapeutics's New Drug Submission for Gemtesa (Vibegron) has been accepted for review by Health Canada for treating overactive bladder in adults. Knight has an exclusive supply and distribution agreement with Sumitomo Pharma for Gemtesa in Canada (relevant for Piramal Pharma).

6) AstraZeneca and Daiichi Sankyo's Enhertu has received a positive CHMP opinion in the EU for adjuvant treatment of resected HER2-positive breast cancer with residual invasive disease. Separately, the National Institute for Health and Care Excellence has recommended Enhertu for routine National Health Service use in England in HER2-low advanced or metastatic breast cancer (relevant for Cohance).

7) Gilead's Trodelvy + Keytruda failed both dual primary endpoints in the Phase 3 trial in first-line, PD-L1-high NSCLC, with progression-free survival improving but not reaching statistical significance, while median overall survival was lower vs Keytruda alone (relevant for Cohance).

8) Lundbeck announced that the last patient has been randomized in the global Phase 3 trial evaluating Bexicaserin in children and adults with Dravet syndrome. The trial enrolled over 100 participants aged 2-65 years (relevant for Neuland).

9) Eli Lilly said Foundayo has captured over 30% of new US patients starting oral obesity treatments, narrowing Novo's early lead with the Wegovy pill (relevant for Divi's). Lilly also said 60-70% of participants in the US Medicare obesity drug pilot are new to weight-loss treatments, while noting that generic GLP-1 launches in India and Canada have expanded the overall market and absolute volumes for Mounjaro continue to grow.

10) Hikma launched Semaglutide in Saudi Arabia as the first generic version of Ozempic available in the country. The product was developed by OneSource, which received approval earlier this year, with Hikma as its exclusive commercialization partner across MENA.

11) EU lawmakers have backed allowing biosimilar manufacturers to build inventory during the Supplementary Protection Certificate (SPC) period for launch immediately after the expiry of SPC vs earlier allowing manufacture and stockpiling only during the final six months of an originator's SPC term.

Further coverage of Global innovators, CDMOs, and generic players on the next page

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News flow – Indian Pharma

1) Neuland Laboratories has commenced operations at Module 1 of its commercial peptide manufacturing facility, adding 7kl reactor capacity, including 750l SPPS and 6,250l LPPS capacity. The company plans to accelerate development of Module 2, which could add up to 18kl capacity, as customer requirements are finalized.

2) Aurobindo Pharma received USFDA final approval for Beclomethasone Dipropionate HFA Inhalation Aerosol (40mcg and 80mcg), the generic equivalent of QVAR, marking its first metered-dose inhaler (MDI) product. The product will be manufactured at its Raleigh, North Carolina facility.

3) Takeda and Dr Reddy's have entered an exclusive agreement for Dr Reddy's to promote and distribute QDENGA, India's first CDSCO-approved dengue vaccine, across the private pediatric and adult vaccination market. Following its approval for individuals aged 4-60 years in Jul-26, QDENGA is expected to become available in India in 1HCY27.

4) Ajanta Pharma has initiated a voluntary recall of ~403k Fluphenazine HCl tablets in the US after an individual organic impurity exceeded specifications during long-term stability testing. The impurity level was 1.1% vs the 1% limit, with the Class III recall initiated on 25-Aug-26.

5) Dr Reddy's Labs and Emcure Pharmaceuticals have obtained royalty-free, non-exclusive voluntary licenses from Gilead to manufacture investigational once-yearly Lenacapavir for HIV prevention across 120 high-incidence low- and lower-middle-income countries. The agreements include technology transfer and future supply planning, with the once-yearly formulation currently being evaluated in a Phase 3 trial.

6) Dr Reddy's Laboratories has launched Nivorz, a biosimilar of BMS's Nivolumab in India. Nivorz will be available in 40mg, 100mg, and 240mg single-dose vials, manufactured at Dr Reddy's Bachupally biologics facility, following a multi-country clinical trial demonstrating comparable efficacy, safety, and immunogenicity to the reference product.

News flow – Global innovators, CDMOs, and generic players

1) BMS and Ono Pharma have sued Amgen, alleging that its proposed Opdivo (Nivolumab) biosimilar infringes seven patents. Amgen has submitted the first Opdivo biosimilar application to the FDA, with a decision expected by year-end, while BMS estimates the earliest US entry of Opdivo biosimilars in CY28 (relevant for Biocon).

2) Novo Nordisk has partnered with Anthropic to use Claude's AI models to accelerate drug discovery and development, initially applying them to R&D workflows and scientific research. Novo will also use Anthropic's frontier models for AI-driven software development, building on its existing use of Claude to automate clinical trial report generation and reduce patient documentation timelines.

3) Hypera Pharma launched Semavy, its generic Semaglutide, alongside companion supplement line Semavy Nutri in Brazil. Under its partnership with Sun Pharma, the Semaglutide drug is manufactured in India, while Hypera markets it under the Mantecorp brand through its distribution network in Brazil.

4) Viatris's Wakix (Pitolisant) has received Japan's Ministry of Health, Labour and Welfare (MHLW) approval for excessive daytime sleepiness associated with obstructive sleep apnea syndrome in patients receiving airway-obstruction treatment, as well as narcolepsy (Type 1 and Type 2). Wakix is the first histamine H3 receptor antagonist/inverse agonist approved in Japan for these indications (relevant for Lupin and Suven Life).

5) Novo has terminated its $285mn collaboration with Ascendis Pharma to develop a once-monthly GLP-1 using Ascendis's TransCon platform, less than two years after signing the deal. Following the termination, Ascendis will regain rights and plans to develop TransCon Semaglutide, a once-monthly Semaglutide prodrug, while Novo said developing less-frequently dosed injections remains an R&D focus.

6) Corbus Pharmaceuticals's Phase 1b study of CRB-913, a CB1 inverse agonist for obesity, showed placebo-adjusted weight loss of up to 5% at Week 12, with no apparent plateau. Neuropsychiatric adverse events such as depression, anxiety, irritability, and insomnia were reported at lower rates than previously observed with Novo's Monlunabant, while gastrointestinal tolerability was broadly comparable with oral GLP-1 therapies.

7) Lundbeck announced that the last patient has been randomized in the global Phase 3 trial evaluating Bexicaserin in children and adults with Dravet syndrome. The trial enrolled over 100 participants aged 2-65 years (relevant for Neuland).

8) Eli Lilly said Foundayo has captured over 30% of new US patients starting oral obesity treatments, narrowing Novo's early lead with the Wegovy pill (relevant for Divi's). Lilly also said 60-70% of participants in the US Medicare obesity drug pilot are new to weight-loss treatments, while noting that generic GLP-1 launches in India and Canada have expanded the overall market and absolute volumes for Mounjaro continue to grow.

9) Eli Lilly has terminated the Phase 1 trial of LY4064912, an early-stage injectable/infusion obesity candidate, after the drug did not meet its bar for continued development. The trial enrolled 77 participants, including healthy volunteers and people with obesity/who were overweight.

10) Akeso and Summit Therapeutics's Ivonescimab reduced the risk of death by 27% versus Pembrolizumab (Keytruda) in treatment-naïve, PD-L1-positive advanced NSCLC in the Phase 3 trial. Median overall survival was 30.8 months vs 22.6 months, with the benefit particularly pronounced in patients with a tumor proportion score of at least 50%.

11) Gilead's Trodelvy + Keytruda failed both dual primary endpoints in the Phase 3 trial in first-line, PD-L1-high NSCLC, with progression-free survival improving but not reaching statistical significance, while median overall survival was lower vs Keytruda alone (relevant for Cohance).

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17) Sandoz has entered into a licensing, development, manufacturing, and commercialization agreement with mAbxience for a proposed Emicizumab biosimilar, with Sandoz holding exclusive global commercialization rights except for Argentina, Uruguay, and Paraguay. The collaboration adds Emicizumab, a $5.7bn reference market, as the first haemophilia biosimilar to Sandoz's pipeline, expanding its biosimilar pipeline to 40 assets.

18) Amneal received FDA approval and has announced the immediate launch of Lanreotide injection (120mg/0.5mL), with Competitive Generic Therapy (CGT) designation. The company has stated that it has large-scale in-house manufacturing capabilities for the product (relevant for Cipla).

19) Novo has acquired three non-incretin obesity programs from Kallyope, including K-554, a potential first-in-class once-weekly peptide that is IND-ready and targets food intake through a mechanism distinct from GLP-1s. The other two programs comprise a follow-on small molecule for a novel target and a small molecule receptor agonist.

20) Wegovy pill prescriptions fell ~12% week-over-week to ~161k in the latest week following the US Labor Day holiday, while Foundayo prescriptions declined just 1% to >47k. Lilly's total Zepbound prescriptions fell 8.5% week-over-week, but its market share increased 0.4% versus Novo's Wegovy franchise, whose prescriptions declined 10%.

21) Anthropic launched its Life Sciences Verification Program (LSVP), giving verified life sciences organizations access to Claude Mythos, Opus, and Sonnet with reduced prompt-level restrictions for legitimate drug discovery and related research. The program offers Standard and High-risk access, with organizations required to declare research scopes and undergo ongoing monitoring, while high-risk Mythos access remains limited to specially vetted users.

Key regulatory developments

1) FDA has launched an Expedited IND Pilot Program to accelerate the start of US Phase 1 trials by pairing drug sponsors with qualified research institutions and enabling faster, rolling IND submissions and reviews. The pilot will select 8-10 sponsor-institution pairs, with applications open until 30-Oct-26, prioritizing novel therapies for diseases with severe unmet medical needs and sufficient preclinical data.

2) EU lawmakers have backed allowing biosimilar manufacturers to build inventory during the Supplementary Protection Certificate (SPC) period for launch immediately after the expiry of SPC vs earlier allowing manufacture and stockpiling only during the final six months of an originator's SPC term.

3) An internal Centers for Medicare & Medicaid Services (CMS) email obtained via a Freedom of Information Act (FOIA) request has officially confirmed that pharmaceutical companies participating in the GENEROUS drug pricing demonstration program (offering supplemental Medicaid rebates so net prices align with economically comparable nations) are exempted from parallel mandatory models, GLOBE (targeting Medicare Part B drugs) and GUARD (targeting Medicare Part D).

4) India is considering simplifying bioavailability and bioequivalence (BA/BE) requirements for domestic drug approvals, allowing eligible applicants to start studies after intimating the regulator rather than obtaining prior permission. The proposal would exclude high-risk categories such as sex hormones, cytotoxic drugs, beta-lactam antibiotics, vaccines, cell and gene therapies, live-microorganism biologics, and narcotics/psychotropics.

5) China's 15th Five-Year pharmaceutical plan (CY26-30) targets making the country a global biopharma leader by CY30, with first-in-class new drugs accounting for >25% of the global total and revenues of major pharmaceutical industrial enterprises exceeding CNY3.5trn ($522bn). The plan targets >20% annual growth in innovative drugs, R&D intensity of >10% for listed pharma companies, and greater globalization through international clinical trials, overseas registrations, sales network, R&D centers, and manufacturing bases abroad.

6) The Centers for Medicare & Medicaid Services (CMS) plans to expand its ACCESS Model (voluntary 10-year Medicare program that uses digital tools, remote monitoring, and outcome-based payments to improve care for beneficiaries with chronic conditions) from Apr-27 to include four additional chronic conditions – heart failure, COPD, substance use disorder, and tobacco cessation, along with expanded support for chronic musculoskeletal conditions.

7) India's CDSCO has constituted an expert committee to develop regulatory pathways for evaluating, approving, and regulating AI in healthcare products.

8) The Trump administration announced that Medicaid plans in all 50 states, Washington DC, and Puerto Rico will have access to the most-favored-nation pricing on hundreds of brand-name drugs. The White House estimates the program could generate ~$65bn in Medicaid drug savings over the next decade, with rebates covering medicines across major categories including oncology, diabetes, and asthma.

USFDA inspections/inspection outcomes

1) Alembic Pharmaceuticals said the USFDA has issued an Establishment Inspection Report (EIR) and closed the inspection of its Bioequivalence Facility in Vadodara, Gujarat, conducted from 03-Mar-25 to 07-Mar-25.

2) Aurobindo Pharma's Apitoria Pharma Unit-II API facility in Telangana underwent a USFDA inspection from 07-Sep-26 to 15-Sep-26, which concluded with one procedural observation.

3) Piramal Pharma's Morpeth, UK, facility underwent a USFDA GMP inspection from 03-Sep-26 to 11-Sep-26, which concluded with a Form 483 containing seven observations.

4) Shilpa Medicare's Unit VII Analytical Services Division in Hyderabad underwent a USFDA surveillance inspection during 16-Sep-26 to 18-Sep-26, which concluded with one procedural observation.

5) Concord Biotech's Unit II formulation facility in Ahmedabad, Gujarat, underwent a USFDA inspection that was completed on 18-Sep-26, which concluded with one minor procedural observation.

Key USFDA Approvals (Final + Tentative): Indian Pharma/global generic players competing with Indian players in the specific product

Final Approval: gFemara (Zydus), gAdrenalin (Zydus), gHaldol (Ajanta), gQVAR (Aurobindo), gAdrenalin (Difgen Pharma), gAvita (Zydus), gSavella (Macleods), gSavella (Strides), gNeoral (Aurobindo), Calcium Gluconate (Cipla)

Management changes/Corporate actions

1) Pfizer India's Senior Director – Policy and Public Affairs, Sharad Goswami, resigned from the company effective 25-Sep-26 to pursue opportunities outside Pfizer. He will also cease to be a Senior Management Personnel from the same date.

2) Alkem Laboratories has appointed Dr Shubhadeep Sinha to a senior management position, effective 15-Sep-26.

3) AstraZeneca Pharma India's Director – Medical Affairs, Biopharmaceutical Business Unit and Rare Disease Business Unit, Dr Sandeep Arora, will leave the company to pursue opportunities outside the organization. He was relieved on 15-Sep-26.

4) Granules India's promoter group has paid the balance 75% subscription amount of Rs10.93bn toward the preferential issue, making 24.9mn warrants fully paid and eligible for conversion into equity shares. Subsequently, the company allotted 24.9mn equity shares upon warrant conversion, increasing its paid-up capital, with 17,094 warrants issued to non-promoter investors remaining outstanding.

5) RPG Life Sciences has completed the acquisition of the API and intermediates business of Raghava Life Sciences through its wholly owned subsidiary RPG Active Pharma, with the transfer of the business effective 16-Sep-26.

6) Alivus Life Sciences has incorporated Alivus Life Sciences Do Brasil, a wholly owned subsidiary in Brazil, on 15-Sep-26. The new pharmaceutical entity has an authorized capital of R$500,000, with Alivus subscribing to 100% of the share capital.

7) Indoco Remedies has approved the incorporation of Warren Lifesciences as a wholly owned subsidiary, with name approval received from the Registrar of Companies, Mumbai.

8) Gujarat Themis Biosyn has completed the acquisition of MicroBiopharm Japan (MBJ) through its wholly owned subsidiary Themis Biosyn Japan, following an investment of Rs4.75bn as capital contribution and Rs7.45bn as a loan to the subsidiary. The company has also entered into a loan agreement with Themis Biosyn Japan for up to Rs8bn.

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ADD	5-15% upside
REDUCE	5% upside to 15% downside
SELL	>15% downside

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