

This is the twenty-eighth edition (week ending 4-Oct-26) of our Pharma Weekly – In Case You Missed It. Key developments in the past week:

1) Biocon has begun recruiting patients for its Phase 1 trial comparing Bmab1800, its proposed Keytruda (Pembrolizumab) biosimilar. The randomized, double-blind study plans to enroll 138 patients, with primary completion expected by 15-Dec-27. Meanwhile, STADA has partnered with China's SBP Group for biosimilars, under which SBP will develop, manufacture, and supply a proposed Keytruda (Pembrolizumab) biosimilar, with STADA holding exclusive commercial rights in the EU, Switzerland, the UK, and CIS, plus options for the US and GCC (read-through for Biocon, Dr Reddy's, Ipca, and Zydus).

2) Eli Lilly's Olumiant (Baricitinib) received USFDA approval for severe alopecia areata in patients aged 12 and above, with 42% of patients on the 4mg dose achieving at least 80% scalp hair coverage in the Phase 3 trial (relevant for Sun Pharma's Leqselvi, which is approved only for adults and is undergoing an investigator-led trial in this age group).

3) The Centers for Medicare & Medicaid Services (CMS) has finalized the GLOBE Model, requiring manufacturers to pay rebates on certain high-spend Medicare Part B drugs whose US prices exceed international benchmarks across 19 reference countries, starting 1-Jan-27. The final rule has sharply narrowed its scope by exempting manufacturers in the voluntary GENEROUS Model (consequently, companies like Sun Pharma will be exempt).

4) Wave Life Sciences aligned with the USFDA on a single two-year registrational trial for WVE-006, its RNA-editing therapy for alpha-1 antitrypsin deficiency (AATD), with a one-year interim analysis to support potential accelerated approval based on AATD biomarkers. Data from the 600mg monthly dose cohort of the ongoing Phase 1b/2a trial are expected in 4QCY26 (read-through for Cohance).

5) Eli Lilly presented full Phase 3 data showing its oral GLP-1 Foundayo (Orforglipron) was non-inferior to insulin glargine on cardiovascular safety in adults with type 2 diabetes, obesity, and high cardiovascular risk. Compared with insulin glargine, Foundayo lowered cardiovascular death by 53% and all-cause mortality by 57%. It also cut A1C by 1.6% against 1.0% and reduced weight by 8.8% against a 1.7% gain at 52 weeks (read-through for Divi's).

6) Novo Nordisk has escalated its oral semaglutide patent battle in India, objecting to Torrent's court undertaking on the SNAC concentration in its product and seeking to verify Sun Pharma's claims about its oral version. On a related note, Eli Lilly's Orforglipron and Novo Nordisk's oral Wegovy (Semaglutide) are expected to launch in India in 1HCY27, with both already filed with Indian regulators and Orforglipron likely to launch first, around Jan-Feb-27.

7) Kodiak Sciences's Tarcocimab (Zenkuda) and Tabirafusp both matched Eylea (Aflibercept) on vision gains in the Phase 3 trial in wet AMD. More than half of patients on Tarcocimab were maintained on 24-week dosing in year one, vs every eight weeks for Aflibercept. Kodiak plans to file Tarcocimab with the USFDA in 4QCY26 (read-through for Eylea biosimilars).

8) Lilly presented full Phase 3 data for Retatrutide in adults with obesity and type 2 diabetes, with the 12mg dose delivering 20.8% mean weight loss at Week 80 vs 4% for placebo, and 34.9% of patients losing at least 25% of their body weight. Lilly plans to file for USFDA approval in 1QCY27. Lilly's eloraT2P, a combination of its amylin agonist Eloralintide with Tirzepatide, delivered 23.3% average weight loss at 48 weeks in a Phase 2 trial, topping Retatrutide. However, up to 27% of patients discontinued treatment, mainly due to GI side effects. Lilly plans to start Phase 3 trials for this combination in 4QCY26.

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

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News flow – Indian Pharma

1) Lupin received USFDA tentative approval for its 505(b)(2) NDA for Apixaban Oral Suspension 1.25mg/mL, a liquid version of BMS's Eliquis for adult patients who have difficulty swallowing tablets. Upon final approval, the product will be manufactured at Lupin's Somerset, New Jersey facility.

2) Morepen Laboratories submitted its first US ANDA, for Sitagliptin Tablets USP in 25mg, 50mg, and 100mg strengths, on 28-Sep-26. The company plans to leverage this capability for CDMO partnerships and possible 505(b)(2) programs.

3) Sun Pharma's two-year data for Leqselvi in adults with severe alopecia areata showed a safety profile in line with earlier trials, with no deaths, blood clots, or major cardiac events at the approved 8mg twice-daily dose. Hair regrowth was durable, with 93.9% of patients who had responded at the start of the extension study and were still responding at Week 52 maintaining that response through Week 108.

4) Sun Pharma in-licensed exclusive rights to commercialize and manufacture Lerodalcibep, LIB Therapeutics's once-monthly PCSK9 inhibitor for lowering LDL cholesterol, worldwide excluding the US and China. The drug was approved in the EU as Lyrokaul on 21-Sep-26. LIB will receive an upfront payment, milestones, and royalties on sales.

5) Sanofi India's promoter group entity Sanofi Healthcare India bought a 15.19% stake in Sanofi India at Rs3,052 per share, worth ~Rs10.7bn, through an open market block deal, while promoter Hoechst GmbH sold the same number of shares at the same price, cutting its holding to 45.17% from 60.37%.

6) HRV Pharma, a Hyderabad-based asset-light API company that outsources production to 54 partner sites, is preparing an IPO to raise over Rs8bn and plans to file its DRHP in 1HCY27. It expects FY27 revenue of Rs6bn and net profit of Rs800mn and is investing Rs1.5bn in peptide and high-potency oncology API capacity.

7) Novo Nordisk has escalated its oral semaglutide patent battle in India, objecting to Torrent's court undertaking on the SNAC concentration in its product and seeking to verify Sun Pharma's claims about its oral version.

8) Sun Pharma is planning to raise ~Rs100bn through a rupee-denominated debt sale with 2-4-year maturities, to partly refinance the ~\$12bn, 18-month bridge loan taken for its Organon acquisition.

9) Piramal Pharma Solutions' Aurora, Canada drug substance site received a \$1.75mn grant from the Ontario government under its Life Sciences Scale-Up Fund. The grant supports Piramal's \$5.3mn investment to upgrade site infrastructure and expand R&D, clinical, and commercial API production.

10) Symbiotec Pharmed granted a global pharma company exclusive US rights to commercialize two dual chamber vial (DCV) injectables, which together address a ~\$288mn US market. Symbiotec will handle development, filings, manufacturing, and supply, and will receive milestone payments plus a share of profits after launch.

11) Aurobindo Pharma launched Adquey (Difamilast 1% ointment), licensed from Otsuka, for mild-to-moderate atopic dermatitis in patients aged 2 and above. The company has established a dedicated dermatology business unit with specialized commercial capabilities across marketing, sales, and field-based engagement.

12) Piramal Pharma Solutions and its partner NP2 plan to complete development of the generic cancer injectable Cyclophosphamide in Oct-26, with manufacturing to follow at Piramal's Lexington, US site. The site is undergoing an \$85mn capacity expansion, and the product aims to ease US supply risk, where two overseas manufacturers account for 92% of sales.

13) Piramal Pharma's sales and distribution support agreement with Bayer Pharma in India, under which it earned commission income, will expire on 31-Dec-26 and will not be renewed. The arrangement contributes less than 5% of consolidated revenue, and the company does not expect any material impact on profitability.

14) Natco Pharma has challenged the validity of the Indian patent covering GSK's ovarian cancer drug Zejula (Niraparib) and is seeking to have it revoked.

- 15) Eli Lilly's Orforglipron and Novo Nordisk's oral Wegovy (Semaglutide) are expected to be launched in India in 1H CY27, with both already filed with Indian regulators and Orforglipron likely to launch first, around Jan-Feb-27.
- 16) Linux Laboratories raised \$70mn in equity from ChrysCapital and Tata Capital Healthcare Fund III, with ChrysCapital taking a significant minority stake and Tata Capital Healthcare Fund II fully exiting. Linux will use the proceeds for brand acquisitions, entry into adjacent therapy areas, and investments in manufacturing and R&D.
- 17) Novartis India changed its name to Evonile Pharma following ChrysCapital's acquisition of a controlling 70.68% stake in Jul-26.
- 18) Dr Reddy's filed an ANDA with a Paragraph IV certification for a generic version of Tonix Pharmaceuticals' Tonmya (Cyclobenzaprine sublingual tablets 2.8mg), a fibromyalgia treatment, challenging all four of its Orange Book-listed patents.
- 19) Biocon has begun recruiting patients for its Phase 1 trial comparing Bmab1800, its proposed Keytruda (Pembrolizumab) biosimilar. The randomized, double-blind study plans to enroll 138 patients with primary completion expected by 15-Dec-27.
- 20) The Maharashtra FDA cancelled the drug sale and distribution licenses of Cipla's carrying and forwarding warehouse at Wadki, Pune, on 1-Oct-26, citing misbranding of Reactin Plus tablets and storage deficiencies, after completing fresh proceedings as directed by the Bombay High Court.
- 21) Pfizer sued Sun Pharma in the US District Court for Delaware, alleging that Sun's proposed gLorbrena (Lorlatinib 25mg and 100mg tablets) infringes four Orange Book-listed patents. The patents cover the compound, which expires in Mar-33, and its crystalline forms, which expire between Jul-36 and Oct-38.
- 22) Sun Pharma settled the US Paragraph IV patent litigation over Imvexxy (Estradiol vaginal insert) with Mayne Pharma and TherapeuticsMD, with no financial payment involved. The settlement allows Sun Pharma to launch its generic version on 21-Oct-32, ahead of the last listed patent expiry in Feb-34.

News flow – Global innovators, CDMOs, and generic players

- 1) Eli Lilly's Olumiant (Baricitinib) received USFDA approval for severe alopecia areata in patients aged 12 and above, with 42% of patients on the 4mg dose achieving at least 80% scalp hair coverage in the Phase 3 trial (relevant for Sun Pharma's Leqselvi, which is currently only approved for adults and is undergoing an investigator-led trial in this age group).
- 2) STADA has partnered with China's SBP Group (via subsidiary CTTQ) for biosimilars, where CTTQ will develop, manufacture, and supply TQB3570, a proposed Keytruda (Pembrolizumab) biosimilar, and up to three more molecules, with STADA holding exclusive commercial rights in the EU, Switzerland, the UK, and CIS, plus options for the US and GCC. The deal includes milestones and profit sharing (read-through for Biocon, Dr Reddy's, Ipca, and Zydus).
- 3) Sandoz opened a high-volume biosimilar drug substance manufacturing center in Lendava, Slovenia, with over 300 employees. The site expands Sandoz's in-house European biosimilar capacity and is a first step toward its Bio100 goal of having more than 100 biosimilars in its portfolio by CY40.
- 4) Novo Nordisk in-licensed global rights (excluding Greater China) to Hengrui Pharma's HRS-1596, a Phase 1-ready GLP-1/GIP dual agonist with potential for once-weekly oral dosing, for up to \$2.6bn, including \$300mn upfront, plus royalties.
- 5) Teva received USFDA approval for Degevma (Denosumab), a biosimilar to Amgen's Xgeva. Together with Ponlinsi, its Prolia biosimilar approved in Mar-26, this gives Teva coverage across both denosumab brands, and it plans to launch both in the US in the coming months (read-through for Biocon and Dr Reddy's).
- 6) Kodiak Sciences's Tarcocimab (Zenkuda) and Tabirafusp both matched Eylea (Aflibercept) on vision gains in the Phase 3 trial in wet AMD. More than half of patients on Tarcocimab were maintained on 24-week dosing in year one, vs every eight weeks for Aflibercept. Kodiak plans to file tarcocimab with the USFDA in 4Q CY26 (read-through for Biocon's Yesafili).
- 7) Roche discontinued Emugrobarb, an anti-myostatin antibody intended to preserve muscle during GLP-1 weight loss, after an interim analysis of the Phase 2 obesity trial showed success

was unlikely and returned rights to subsidiary Chugai. Chugai plans to resume development in spinal muscular atrophy, with a possible Phase 3 study, while also exploring out-licensing.

8) Meitheal Pharmaceuticals received USFDA approval for a high-concentration formulation of Yusimry (Adalimumab), interchangeable with Humira across all nine indications. Emerge Bioscience holds the BLA and Meitheal holds exclusive US commercialization rights (read-through for Biocon).

9) Fresenius Kabi partnered with Waltz Health to supply its biosimilars Idacio (Adalimumab), Tyenne (Tocilizumab), and Otufli (Ustekinumab) directly to US employers through the Waltz Connect platform, bypassing wholesaler and PBM rebate arrangements. Products will still be dispensed through specialty pharmacies, and Waltz already runs similar direct-to-employer programs for Lilly's and Novo's GLP-1s (read-through for Biocon).

10) Ascleptis Pharma's oral IL-17A inhibitor ASC50 showed a 48.9% placebo-adjusted reduction in PASI score after 28 days of 200mg once-daily dosing in a US proof-of-concept trial in mild-to-moderate plaque psoriasis, rising to 65.9% 15 days after the last dose. Its 6.5-day half-life supports potential once-weekly oral dosing, and no liver safety signals were seen.

11) Eli Lilly's oral GLP-1 Foundayo (Orforglipron) weekly prescriptions rose ~21% week-on-week to 64,268, lifting its share of the US oral obesity market to 26% from <23% in two weeks, while Novo's Wegovy pill held flat at ~182k weekly scripts. Zepbound remained the overall market leader with 805.7k weekly scripts, up 2.3% week-on-week, while total Wegovy scripts across pill and injection fell 0.6% to 519.6k (read-through for Divi's).

12) Novo Nordisk in-licensed global rights to Nanexa's PharmaShell long-acting injectable platform for up to five peptide programs in obesity, type 2 diabetes, and cardiometabolic diseases, in a deal worth up to \$1.33bn. Of this, \$700mn covers the upfront payment and development and regulatory milestones, and \$626mn is tied to sales milestones.

13) AbbVie's long-acting amylin analogue ABBV-295 delivered placebo-adjusted weight loss of up to ~9.5% over 12-13 weeks in a Phase 1 study, with mean weight reductions of 7.8% to 9.8% across weekly, every-other-week, and monthly regimens vs 0.3% for placebo. GI side effects were mostly mild with no serious adverse events, and AbbVie plans to move it into Phase 2.

14) Eli Lilly's eloraTZP, a combination of its amylin agonist Eloralintide with Zepbound (Tirzepatide), delivered 23.3% average weight loss at 48 weeks in a Phase 2 trial in patients with obesity or overweight and type 2 diabetes, topping its own triple-G drug candidate Retatrutide. However, up to 27% of patients discontinued treatment, mainly due to GI side effects. Lilly plans to start Phase 3 trials in 4QCY26.

15) Eli Lilly presented full Phase 3 data for Retatrutide in adults with obesity and type 2 diabetes, with the 12mg dose delivering 20.8% mean weight loss at Week 80 vs 4% for placebo, and 34.9% of patients lost at least 25% of their body weight. Lilly plans to file for USFDA approval in 1QCY27.

16) Novo Nordisk's real-world OCTANE study found that adults who switched from injectable Tirzepatide or Semaglutide to the Wegovy pill (oral Semaglutide) lost an additional 4.1% of body weight on average over three months. The share of patients with obesity (BMI ≥ 30) fell from 87.1% to 65.5% in three months.

17) Regeneron's anti-myostatin antibody Trevogrumab, given with Semaglutide, halved muscle loss vs Semaglutide alone in a Phase 2 obesity trial of ~1,000 patients. Patients on Semaglutide alone lost 6.7% of lean mass over 26 weeks, against 3.3% with the 75mg Trevogrumab add-on. Muscle mass returned to baseline when patients stopped Semaglutide but stayed on Trevogrumab.

18) Samsung Bioepis and Teva expanded their partnership to cover up to six biosimilars, starting with SB41 (referencing AstraZeneca's Fasenra/Benralizumab) and SB44 (referencing Novartis' Ilaris/Canakinumab), with an option on four more. Samsung Bioepis will handle development, regulatory filings, and manufacturing, and Teva will commercialize in the US, Europe, and Canada.

19) Eli Lilly presented full Phase 3 data showing its oral GLP-1 Foundayo (Orforglipron) was non-inferior to insulin glargine on cardiovascular safety in adults with type 2 diabetes, obesity,

and high cardiovascular risk. Compared with insulin glargine, Foundayo lowered cardiovascular death by 53% and all-cause mortality by 57%. It also cut A1C by 1.6% against 1.0% and reduced weight by 8.8% against a 1.7% gain at 52 weeks (read-through for Divi's).

20) Boehringer Ingelheim's Survodutide (glucagon/GLP-1 dual agonist), partnered with Zealand Pharma, met its co-primary endpoints in the Phase 3 Synchronize-2 trial in obesity and type 2 diabetes, with 13.1% mean weight loss on the high dose at Week 76 vs 3.1% for placebo. Tolerability remained a concern, with 39% of patients vomiting and 26% discontinuing due to adverse events.

21) Ascleitis Pharma presented preclinical data at for ASC36_35FDC, a fixed-dose combination of its amylin agonist ASC36 and GLP-1/GIP agonist ASC35. In obese rats, it delivered 24.8% weight loss by Day 14, against 12.5% for an Eloralintide/Tirzepatide combination. Half-lives of about 30-33 days in primates support potential once-monthly to once-quarterly dosing, and an oral once-weekly tablet version is also in development.

22) Wave Life Sciences aligned with the USFDA on a single two-year registrational trial for WVE-006, its RNA-editing therapy for alpha-1 antitrypsin deficiency (AATD), with a one-year interim analysis to support potential accelerated approval based on AATD biomarkers. Data from the 600mg monthly dose cohort of the ongoing Phase 1b/2a trial are expected in 4QCY26 (read-through for Cohance).

23) Fresenius acquired the remaining 45% stake in biosimilar developer mAbxience from Insud Pharma for up to €750mn, including a €50mn payment contingent on site approvals, making it a wholly owned part of Fresenius Kabi's biopharma business. mAbxience has four marketed products, eight in development and three drug substance plants in Spain and Latin America.

24) Fresenius Kabi received a USFDA warning letter for its sterile injectables facility in Melrose Park, Illinois, following a Jan-Feb-26 inspection. The FDA cited failures to investigate batch problems and prevent microbial contamination, as well as weak quality control.

Key regulatory developments

1) The proposed final text of the revised EU pharma directive makes all antimicrobials, including common OTC antifungals and antivirals such as Canesten and Zovirax, prescription-only by default, but leaves individual member states free to waive this requirement for topical products, rather than granting an EU-wide exemption. The Commission aims to publish the directive in Nov-26, with entry into force in Dec-26, followed by a 24-month implementation window for member states.

2) The Indian Supreme Court suggested that the MRP of cancer drugs and other medicines should be capped at 16% above the price charged to retailers. The court also raised concerns about corporate hospitals making patients buy costly medicines from their own pharmacies. The government said it would find a balanced solution, and the next hearing is on 12-Oct-26.

3) The CDSCO shelved its plan for a digital platform to publicly disclose test reports of drug batches tested under routine quality surveillance, after the proposal failed to reach consensus.

4) The Centers for Medicare & Medicaid Services (CMS) finalized the GLOBE Model, requiring manufacturers to pay rebates on certain high-spend Medicare Part B drugs whose US prices exceed international benchmarks across 19 reference countries, starting 1-Jan-27. The final rule sharply narrowed its scope by exempting manufacturers in the voluntary GENEROUS Model and excluding orphan-only drugs, cell and gene therapies, and plasma-derived products. As a result, only about four manufacturers are now expected to be affected, and projected savings fell to ~\$440mn over seven years from \$11.9bn under the proposed rule.

USFDA inspections/inspection outcomes

The USFDA completed a cGMP inspection of Zydus Lifesciences's SEZ II manufacturing plant in Ahmedabad from 21-Sep-26 to 28-Sep-26, which closed with one observation.

Management Commentary

1) Zydus Lifesciences's Chairman Pankaj Patel said India should become a full member of ICH to benchmark the quality of its products and clinical data and earn the trust of global companies, and the industry needs a predictable regulatory system with firm timelines and fast-track pathways for breakthrough therapies. He also said the government should restore

the 200% weighted deduction on R&D spending, since Indian pharma currently spends only 4-5% of revenue on R&D and needs to double this to catch up with global peers. The government should also be willing to be the first customer for local innovations, by extending Ayushman Bharat coverage to newer modalities such as biosimilars.

2) Eli Lilly's Chairman and CEO David Ricks said generic Semaglutide has not hurt Mounjaro in India, instead, lower prices are bringing in new patients, as seen in India, Brazil, and Canada, and Mounjaro continues to grow month by month. He said Lilly setting up its own manufacturing in India remains a possibility and India's biotech ecosystem holds tremendous promise for acquisitions given its science and talent base, but it lags China due to weak venture funding and an underdeveloped clinical trial and laboratory ecosystem.

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

Final Approval: gPred Forte (Upsher Smith Labs), gBactroban (Zydus), Loperamide HCl (Taro), gCartinor (Gland), gKonakion (Lupin)

Tentative Approval: gFarxiga (Bionpharma, Sciegen Pharma)

Management changes/Corporate actions

1) Tarsons Products re-appointed Sanjive Sehgal as Chairman and Managing Director at its AGM on 24-Sep-26, after he retired by rotation.

2) Sai Parenterals announced the resignation of Shivali Aggarwal as Company Secretary and Compliance Officer, effective 30-Sep-26, and appointed Ashwani Singh Bisht in her place. The board also appointed Arvind Gannimitta as Chief Operating Officer, effective 30-Sep-26.

3) Aarti Drugs's Prakash M Patil has stepped down as Chairman, MD, and CEO on taking early retirement, effective 30-Sep-26. Adhish P Patil, CFO, has been promoted to Managing Director from 1-Oct-26 and has given up the CFO role.

4) Piramal Pharma appointed Viral Gandhi as Chief Technology Officer and Senior Management Personnel, effective 1-Oct-26.

5) Gland Pharma's Wenjie Zhang resigned as Non-Executive Non-Independent Director with immediate effect. The board appointed Xingli Wang as an Additional Director (Non-Executive Non-Independent) from 1-Oct-26.

6) Hikal's Executive Chairman Jai Hiremath's term ended on 1-Oct-26, and the board named him Chairman Emeritus, an honorary non-board role, for five years. Sugandha Hiremath resigned as Non-Executive Director effective 30-Sep-26 due to personal commitments, and Anish Swadi was appointed CEO of Animal Health and Specialty Ingredients from 1-Oct-26.

7) Natco Pharma raised its investment in eGenesis, a biotech firm that uses gene editing to create pig organs for human xenotransplantation, to \$16.7mn from the earlier disclosed \$14.0mn.

8) Indoco Remedies incorporated a wholly owned subsidiary, Warren Lifesciences on 26-Sep-26 with the object to manufacture, develop, and sell pharmaceutical products.

9) Bharat Parenterals approved a preferential issue of up to 9,12,759 equity shares at Rs1,522.85 per share to non-promoter investors, raising ~Rs1.39bn. The board also approved investments in or loans to its subsidiaries to fund existing and new projects.

10) Lupin's step-down subsidiary, Multicare Pharmaceuticals Philippines, completed the buyback of its remaining 30,559 shares, making it a wholly owned subsidiary of Nanomi BV and a step-down wholly owned subsidiary of Lupin, effective 1-Oct-26.

11) Granules India incorporated a wholly owned foreign subsidiary, Triton Farmaceutica do Brasil, in Brazil, to manufacture, promote, sell, and distribute pharmaceuticals and other related products.

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

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