Pharmaceuticals

Pharma Weekly – ICYMI

This is the twenty-second edition (week ending 23-Aug-26) of our Pharma Weekly – In Case You Missed It. Key developments in the past week:

1) Sandoz has entered a development, manufacturing, and commercialization agreement with Shanghai Henlius, covering up to 10 biosimilars. The deal is worth up to ~$320mn, and initially covers proposed biosimilars of Erbitux (Cetuximab), Repatha (Evolocumab), and Benlysta (Belimumab).

2) Alvotech highlighted progress across its key biosimilar programs, with Aflibercept already launched in Japan and expected to enter the US market in 4QCY26, subject to approval (relevant for Biocon). Its Keytruda biosimilar, co-developed with Dr Reddy's, is advancing through a PK similarity study, while the Prolia/Xgeva (Denosumab) biosimilar was resubmitted to the FDA in Jun-26 and is under a standard six-month review (relevant for Dr Reddy's).

3) MSN has announced the first generic launch of the Teduglutide (Gattex/Revestive) injection across several key European markets (read through for Cipla; MSN has a US DMF but has not filed a Para IV yet).

4) Formycon's Stelara biosimilar is seeing weaker-than-expected commercial momentum, driven by a highly price-sensitive and challenging market environment. The company said that US market dynamics are improving gradually, while the European autoinjector approval should support its positioning; CY26 revenue guidance for Stelara remains dependent on stronger market penetration (relevant for Biocon).

5) Richter Gedeon's European launch of the Usymro (Ustekinumab/Stelara) biosimilar has stalled due to manufacturing compliance problems at its partner, Bio-Thera Solutions (relevant for Biocon).

6) Novartis announced that the FDA has updated the Leqvio (Inclisiran) label to recognize that lowering low-density lipoprotein cholesterol (LDL-C) reduces the risk of major adverse cardiovascular events (MACE) in adults at increased cardiovascular risk. Novartis continues to advance its clinical trial program, with >60,000 patients enrolled, and expects readout for two trials evaluating secondary outcomes in CY27 (relevant for Anthem).

7) Eli Lilly's once-weekly insulin Onswik (experimental basal insulin) received a positive recommendation for National Health Service (NHS) coverage in the UK, potentially allowing eligible type 2 diabetes patients to reduce their injection frequency by 85% versus daily insulin (relevant for Biocon).

8) Lundbeck highlighted strong progress on Bexicaserin for developmental and epileptic encephalopathies. The Phase 3 trial completed randomization in Jul-26, with headline results expected in 4QCY26, while the Phase 3 trial for Dravet syndrome is on track to complete randomization in 3QCY26. Positive results could support an NDA submission in CY27 (relevant for Neuland).

9) Dicot Pharma has submitted an EU Clinical Trial Application (CTA) for the Phase 2b study of LIB-01, its investigational erectile dysfunction therapy, planned across the US and Europe. The adaptive study will enroll at least 200 patients to assess repeated dosing and support dose selection for Phase 3, with the EU regulatory decision expected in 4QCY26 (read through for Anthem).

10) Novo Nordisk has sued Viatris over the company's proposed generic 9-mg tablet (oral Wegovy), asserting formulation and dosing patents, including a formulation patent that expires in CY39 (vs street expectation of a potential generic launch in CY34). Meanwhile, Novo Nordisk has initiated a Phase 3 trial to evaluate lower maintenance doses of its oral Wegovy to establish greater dosing flexibility.

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

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News flow – Indian Pharma

1) Biocon has received supplemental USFDA approval for Yesintek in 45 mg/0.5 mL and 90 mg/mL single-dose prefilled autoinjector formats. The approval expands delivery options for Yesintek, which was originally approved by the USFDA on 29-Nov-24.

2) Shilpa Medicare initiated a voluntary US recall of ~28k vials of Pemetrexed Injection (Pemetri RTU) across four batches due to atypical discoloration of the drug product. The FDA classified it as a Class II hospital-level recall.

3) The Delhi High Court has restrained Zydus Lifesciences from commercially manufacturing, selling, importing, or exporting Dabrafenib (Tafinlar) products until expiry of Novartis's Indian patent on 04-May-29.

4) Lupin's wholly owned subsidiary VISUfarma has entered into an exclusive licensing agreement with Visus Therapeutics for Yuvezzi, an ophthalmic therapy for presbyopia, across the EU, the UK, Switzerland, Norway, and Iceland. VISUfarma will handle regulatory activities and commercialization with milestone payments and tiered royalties payable to Visus, while Lupin will also make a strategic investment in Visus.

5) Mankind Pharma has entered into an exclusive in-licensing and marketing agreement with China-based Chongqing Chenan Biopharmaceutical for Insulin Degludec and Insulin Degludec + Aspart combination in India.

6) The Delhi High Court has directed the Registrar of Trademarks to cancel Razenta Pharmaceuticals's Daplogin trademark, ruling it deceptively similar to Dr Reddy's Daplo mark for identical diabetes products containing the same API.

7) Orchid Pharma's Europe Phase 2 pediatric cUTI trial of Cefepime-Enmetazobactam has been delayed, with primary completion now expected on 21-May-29, vs the earlier estimate of 30-Sep-25. The trial remains active, with a target enrollment of 40 patients across 8 sites, supporting potential expansion of the drug's indication to pediatric cUTI in the US and Europe.

8) SK Biopharmaceuticals has reached its first patent settlement with MSN Laboratories, over a proposed generic version of Xcopri (Cenobamate). The settlement covers follow-on patents and is expected to extend Xcopri's US market exclusivity beyond the original compound patent expiry in 4QCY32.

News flow – Global innovators, CDMOs, and generic players

1) Sandoz has entered into a development, manufacturing, and commercialization agreement with Shanghai Henlius, covering up to 10 biosimilars, with Sandoz receiving global commercialization rights outside China and Henlius responsible for development and manufacturing. The deal is worth up to $322mn, including up to $100.5mn in near-term payments, and initially covers proposed biosimilars of Erbitux (Cetuximab), Repatha (Evolocumab), and Benlysta (Belimumab), expanding Sandoz's pipeline to 39 assets, with potential to reach 46.

2) AstraZeneca reported positive Phase 3 results for Enhertu in first-line HER2-mutant NSCLC and Orpathys + Tagrisso in EGFR-mutated NSCLC, with both regimens improving progression-free survival versus chemotherapy-based standards. However, Volrustomig failed the Phase 3 trial against Keytruda plus chemotherapy in first-line NSCLC.

3) Dicot Pharma has submitted an EU Clinical Trial Application (CTA) for the Phase 2b study of LIB-01, its investigational erectile dysfunction therapy, planned across the US and Europe. The adaptive study will enroll at least 200 patients to assess repeated dosing and support dose selection for Phase 3, with the EU regulatory decision expected in 4QCY26 (read through for Anthem).

4) Novo Nordisk's oral Wegovy regained momentum, with weekly prescriptions rising to >176,000, the highest level since its January launch, and the pill's share of total Wegovy prescriptions increasing to 35% from 33%. In contrast, Eli Lilly's oral Foundayo weekly prescriptions declined to 36,620 from 38,928, while Novo's overall diabetes/obesity market share rose 0.3% to 37.1%, versus Lilly's 0.1% gain to 56.7%.

5) Amylyx Pharmaceuticals reported positive Phase 3 results for Avexitide in post-bariatric hypoglycemia, with the GLP-1 receptor antagonist reducing hypoglycemic events by 55% through Week 16 versus placebo and meeting all secondary endpoints. The company plans to file for FDA approval by end-CY26, with potential priority review.

6) Ono Pharmaceutical's Taiwan subsidiary received TFDA approval for an additional indication of Opdivo (Nivolumab) as perioperative treatment for resectable NSCLC without EGFR mutations or ALK rearrangements.

7) Merck and Moderna reported positive Phase 3 results for Intismeran Autogene + Keytruda in completely resected stage 2B-4 melanoma, meeting the primary and key secondary endpoints. The trial marks the first positive Phase 3 readout for an individualized neoantigen and mRNA-based cancer therapy, supporting the potential of personalized mRNA treatments in adjuvant melanoma.

8) Jazz Pharmaceuticals has begun recruiting for its Phase 3 trial in Jul-26, evaluating expanded dosing regimens of Xywav that can adapt to different sleep cycles in adults with narcolepsy or idiopathic hypersomnia (relevant for Lupin and Granules).

9) Formycon's Stelara biosimilar is seeing weaker-than-expected commercial momentum, driven by a highly price-sensitive and challenging market environment. The company said that US market dynamics are improving gradually, while the European autoinjector approval should support its positioning; CY26 revenue guidance for Stelara remains dependent on stronger market penetration (relevant for Biocon).

10) Enveda reported positive Phase 1 results for ENV-308, an oral small molecule designed to mimic the exercise-associated hormone Lac-Phe, with favorable tolerability and no serious adverse events in 88 healthy volunteers. The company plans to advance ENV-308 into Phase 2, evaluating its potential to maintain weight loss and metabolic benefits after discontinuation of GLP-1 therapies, while animal studies also suggest muscle preservation and prevention of weight regain.

11) Novartis announced that the FDA has updated the Leqvio (Inclisiran) label to recognize that lowering low-density lipoprotein cholesterol (LDL-C) reduces the risk of major adverse cardiovascular events (MACE) in adults at increased cardiovascular risk. Novartis continues to advance its clinical trial program, with >60,000 patients enrolled, and expects a readout for two trials evaluating secondary outcomes in CY27 (relevant for Anthem).

12) A study of gray-market versions of Eli Lilly's Retatrutide found substantially weaker weight-loss outcomes than those reported in Lilly's clinical trials. Patients taking gray-market versions of the drug achieved a mean weight loss of only 7.2% over 6 to 12 months. In contrast, patients enrolled in official clinical trials experienced a mean weight loss of 15.5% over a similar period.

13) Novo Nordisk has initiated a Phase 3 trial to evaluate lower maintenance doses of its oral Wegovy (Semaglutide) in adults who are overweight or obese. The 450-patient study will assess weight loss over 60 weeks, with Novo aiming to establish greater dosing flexibility beyond the currently approved 25mg maintenance dose.

14) Lilly's once-weekly insulin Onswik received a positive recommendation from National Institute for Health and Care Excellence (NICE) for National Health Service (NHS) coverage in the UK, potentially allowing eligible type 2 diabetes patients to reduce their injection frequency by 85% versus daily insulin. The recommendation was supported by trials showing non-inferior HbA1c reduction versus daily insulin degludec and insulin glargine, with a similar safety profile (relevant for Biocon).

15) Richter Gedeon's European launch of the Usymro (Ustekinumab) biosimilar has stalled due to manufacturing compliance problems at its partner, Bio-Thera Solutions.

16) Lundbeck highlighted strong progress on Bexicaserin for developmental and epileptic encephalopathies. The Phase 3 trial completed randomization in Jul-26, with headline results expected in 4QCY26, while Phase 3 trial in Dravet syndrome is on track to complete randomization in 3QCY26. Positive results could support an NDA submission in CY27 (relevant for Neuland).

17) Alvotech highlighted progress across its key biosimilar programs, with Aflibercept already launched in Japan and expected to enter the US market in 4QCY26, subject to approval (relevant for Biocon). Its Keytruda biosimilar, co-developed with Dr Reddy's, is advancing through a PK similarity study, while the Prolia/Xgeva (Denosumab) biosimilar was resubmitted to the FDA in Jun-26 and is under a standard six-month review (relevant for Dr Reddy's).

18) Novo Nordisk has sued Viatris over the company's proposed generic 9-mg tablet (oral Wegovy), asserting formulation and dosing patents, including a formulation patent that expires in CY39 (vs street expectation of a potential generic launch in CY34).

USFDA inspections/inspection outcomes

1) Aurobindo Pharma's AuroPeptides facility in Sangareddy district, Telangana, underwent a USFDA inspection from 17-Aug-26 to 21-Aug-26, which concluded with one observation related to facility and equipment maintenance. Separately, Aurolife Pharma's Raleigh, North Carolina, facility has received an EIR classifying the Apr-25 USFDA inspection as VAI.

2) Caplin Steriles's Gummidipoondi injectable and ophthalmic facility received a Form 483 with 10 observations following an unannounced USFDA inspection conducted from 13-Aug-26 to 21-Aug-26. The observations were procedural, with no data-integrity concerns and no repeat observations.

3) Jubilant Pharmova announced that the USFDA has approved the commercial batch manufacturing of the first product on its isolator-based fill-and-finish line at its contract manufacturing facility in Spokane, US.

4) Strides Pharma's Bengaluru facility received an EIR from the USFDA classifying it as VAI, closing the May-26 inspection, which had resulted in five Form 483 observations.

5) Natco Pharma's Parawada FDF manufacturing facility in Visakhapatnam received a Form 483 with four observations following a US FDA inspection conducted from 17-Aug-26 to 21-Aug-26.

Management commentary

Umang Vohra, Executive Chairman and Group CEO of Cohance Lifesciences, said the Jun-26 quarter represented the company's bottom, with recovery expected from 2Q and yoy growth returning in 2HFY27. He highlighted improving order visibility, including restocking of a previously destocked commercial molecule and upcoming commercial supplies, while focusing on strengthening quality systems, improving plant utilization, and integrating acquired businesses. Vohra also identified nucleic acids and ADCs as key long-term growth opportunities, supported by increasing global interest in diversifying pharma supply chains beyond China.

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

Final Approval: gAdcirca (Jubilant Generics), gXeljanz CR (Teva), gFlonase (Glenmark), gOfev (Biocon), gXarelto (Epic Pharma), gAscor (Zydus), gLisinopril (Hetero Labs)

Tentative Approval: gRytary (Dr Reddy's)

Management changes/Corporate actions

1) Lupin announced the demise of Dr Sofia Mumtaz, President – Legal and Compliance, Canada, ANZ, and NEA Business and Senior Management Personnel, on 17-Aug-26.

2) Alembic Pharmaceuticals has appointed Chirag Shukla as Company Secretary and Compliance Officer (KMP), effective 20-Aug-26.

3) Venus Remedies appointed Saransh Chaudhary as Executive Director (Whole-Time Director) and Dr Gurminder Singh Bedi as Non-Executive Independent Director, both for a five-year term effective 26-May-26. The company also reappointed Dr Manu Chaudhary as Joint Managing Director for five years effective 1-Oct-26 and Dr Savita Gupta as Non-Executive Independent Director for a second five-year term effective 29-Dec-26.

4) Cipla received approval from the NCLT, Mumbai Bench, for the Scheme of Amalgamation of its wholly owned subsidiary Inzpera Healthsciences with Cipla.

5) Piramal Pharma has increased its stake in Yapan Bio from 33.33% to 74%, thereby making Yapan a subsidiary.

6) Alivus Life Sciences has acquired a 76% stake in IQGenX Pharma for ~Rs91mn. IQGenX Pharma is a custom research organization which operates in formulation development of oral solids, sterile injectables, and ophthalmic solutions for US, EU, Latin America, Middle East, and other highly regulated and semi-regulated markets.

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