Pharmaceuticals

Pharma Weekly - ICYMI

This is the twenty-third edition (week ending 30-Aug-26) of our Pharma Weekly – In Case You Missed It. Key developments in the past week:

1) Teva has launched gJynarque (Tolvaptan) in the US, with the launch coinciding with the expiry of the '730 patent. Lupin's 180-day exclusivity in the product (currently the largest in its US portfolio) ended in Nov-25, and gJynarque is expected to become a four-player market with the imminent entry of Apotex and Alkem. In a separate development, Lupin has won a US patent infringement ruling against Vertex Pharma over its proposed generic version of Kalydeco (Ivacaftor) for cystic fibrosis.

2) Aurigene Pharma Services, a wholly-owned subsidiary of Dr Reddy's, has entered into a long-term manufacturing and supply agreement with a leading global pharma company for >20 products across sterile injectables, biologics, and topicals for the US, Europe, Canada, and EMs. The portfolio is expected to reach ~18mnpa units at full commercialization, with phased technology transfers over 2-3 years and revenue expected to commence from CY28.

3) Eli Lilly received USFDA approval to expand Mounjaro's (Tirzepatide) label to include the reduction in the risk of major cardiovascular events in at-risk adults with Type 2 diabetes. Mounjaro showed 8% lower rate of cardiovascular death, heart attack, or stroke versus Lilly's prior-generation GLP-1 diabetes blockbuster Trulicity in phase 3 trials (read-through for Divi's).

4) Celltrion has applied for Korean approval of its biosimilar to MSD's Keytruda (Pembrolizumab) and plans to sequentially file in major markets including the US, EU, and Canada. Notably, Samsung Bioepis had announced its filing for a Korean approval earlier last month – the first regulated market filing for a Keytruda biosimilar (relevant for Zydus, Dr Reddy's, Biocon, and Ipca Labs).

5) Neuren Pharmaceuticals received approval from the European Commission for Daybu (Trofinetide) for neurobehavioral symptoms associated with Rett syndrome, making it the first authorized treatment for the condition in the EU. The approval is expected to support a commercial launch by Acadia in Germany, in 4QCY26 (relevant for Sai Life).

6) The USFDA has accepted United Therapeutics's NDA for Ralinepag for the treatment of pulmonary arterial hypertension (PAH), with a PDUFA action date of 24-Jun-27. If approved, Ralinepag could become the first once-daily oral prostacyclin for PAH (relevant for Sai Life).

7) Rhythm Pharmaceuticals announced that Japan's Ministry of Health, Labour, and Welfare (MHLW) has approved Imcivree (Setmelanotide) for acquired hypothalamic obesity (HO), making it the first approved treatment for the condition in Japan. The company expects to launch the drug by end-CY26 (relevant for Neuland).

8) PTC Therapeutics presented new clinical and real-world data for Sephience (Sepiapterin). New analysis demonstrated that Sephience resulted in a 100% greater reduction in blood phenylalanine among patients switching from Sapropterin (read-through for Laurus Labs).

9) BioCryst Pharma received approval from Japan's MHLW for Orladeyo (Berotralstat), for prophylactic treatment of hereditary angioedema (HAE) in pediatric patients aged between 2 and <12 years. BioCryst plans to launch Orladeyo after the reimbursement pricing process of Japan's National Health Insurance; it has filed for approval in Europe and Canada (relevant for Sai Life).

10) Dr Reddy's has received CDSCO approval to manufacture and market its Abatacept biosimilar in India for moderate-to-severe rheumatoid arthritis and active psoriatic arthritis, subject to a Phase IV study.

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

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News flow – Indian Pharma

1) Biocon Biologics received marketing approval from Japan's Ministry of Health, Labour, and Welfare (MHLW) for its Pegfilgrastim biosimilar to Neulasta—developed and manufactured in-house. Sandoz will exclusively promote and distribute the product in Japan.

2) Sun Pharma initiated a voluntary nationwide recall of ~2,000 bottles of Carbamazepine in the US after black specks were observed on tablets, attributed to burnt excipient used during manufacturing. The affected batch was manufactured at Taro Pharmaceutical's Haifa Bay facility in Israel, with the issue subsequently linked to cGMP deviations. The FDA classified the recall as Class II.

3) Dr Reddy's Laboratories and Emcure Pharmaceuticals have received CDSCO's recommendation for waivers from local Phase 3 and bioequivalence studies for generic Lenacapavir, an injectable HIV therapy. The waiver is subject to conducting a Phase 4 efficacy study in India, with the protocol to be submitted within three months of marketing authorization.

4) Aurigene Pharmaceutical Services, a wholly-owned subsidiary of Dr Reddy's, has entered into a long-term manufacturing and supply agreement with a leading global pharmaceutical company for >20 products across sterile injectables, biologics, and topicals for the US, Europe, Canada, and emerging markets. The portfolio is expected to reach ~18mnpa units at full commercialization, with phased technology transfers over 2-3 years and revenue expected to commence from CY28.

5) Dr Reddy's has received CDSCO approval to manufacture and market its Abatacept biosimilar in India for moderate-to-severe rheumatoid arthritis and active psoriatic arthritis, subject to a Phase IV study. The company has secured approval for both the finished formulation and API (manufacturing at its Bachupally biologics facility and supply partnership with Gland Pharma).

6) AstraZeneca Pharma India has received a stay from the Delhi High Court on the NPPA's demand notice alleging overcharging of Betaloc-50 (Metoprolol 50mg) during Jun–Jul '16. The stay is effective till 10-Feb-27, subject to the company depositing 15% of the demand amount with the Court.

7) Lupin has won a US patent infringement ruling against Vertex Pharmaceuticals over its proposed generic version of Kalydeco (Ivacaftor) for cystic fibrosis. The Court ruled that Lupin's ~74% Ivacaftor formulation does not infringe Vertex's four patents covering 80% of Ivacaftor, with three patents expiring in Feb-30 and one in Aug-33.

8) Jubilant Pharmova received USFDA approval for commercial batch manufacturing on Line 3 at its Spokane, US facility, operated by subsidiary Jubilant HollisterStier. The new isolator-based fill-finish line has an annual manufacturing capacity of ~55mn units, with three compounding suites supporting up to 2,000ltr batches and two new lyophilizers.

News flow – Global innovators, CDMOs, and generic players

1) Neuren Pharmaceuticals received European Commission approval for Daybu (Trofinetide) for neurobehavioural symptoms associated with Rett syndrome, making it the first authorized treatment for the condition in the EU. The approval is expected to support commercial launch by Acadia in Germany, in 4QCY26 (relevant for Sai Life).

2) Roche's Genentech has acquired global rights to Hanmi Pharma's clinical-stage UCN2 analog, for an upfront payment of $190mn, with up to $2.3bn in development, regulatory, and commercial milestones, along with tiered royalties. The non-incretin therapy is being developed as a differentiated obesity treatment aimed at reducing fat mass while preserving or increasing lean muscle mass, with potential applications in type 2 diabetes and cardiovascular disease.

3) Rhythm Pharmaceuticals announced that Japan's MHLW has approved Imcivree (Setmelanotide) for acquired hypothalamic obesity (HO), making it the first approved treatment for the condition in Japan. The company expects to launch the drug by end-CY26, with approval supported by Phase 3 data showing an 18.8% placebo-adjusted reduction in BMI (relevant for Neuland).

4) PTC Therapeutics presented new clinical and real-world data for Sephience (Sepiapterin). New analysis demonstrated that Sephience resulted in a 100% greater reduction in blood phenylalanine among patients switching from Sapropterin (read-through for Laurus Labs).

5) BioCryst Pharmaceuticals received approval from Japan's MHLW for Orladeyo (Berotralstat), for prophylactic treatment of hereditary angioedema (HAE) in pediatric patients aged between 2 and <12 years, expanding its once-daily oral therapy to younger patients. BioCryst plans to launch Orladeyo after the reimbursement pricing process of Japan's National Health Insurance, and has filed for approval in Europe and Canada (relevant for Sai Life).

6) The USFDA has accepted United Therapeutics's NDA for Ralinepag, for the treatment of pulmonary arterial hypertension (PAH), with a PDUFA action date of 24-Jun-27. If approved, Ralinepag could become the first once-daily oral prostacyclin for PAH (relevant for Sai Life).

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10) Eli Lilly's Foundayo crossed 40,000 weekly prescriptions in its 20th week of launch, reaching 40,862 scripts, although still behind Novo Nordisk's Wegovy pill at a similar launch stage. Wegovy's oral formulation recorded ~175k weekly prescriptions in its 33rd week, while total Wegovy prescriptions exceeded 500k. The obesity market share was broadly stable at ~60:40 between Lilly and Novo.

Key regulatory developments

1) The NPPA has proposed making drug manufacturers solely responsible for overpricing of NLEM medicines, potentially removing prosecution liability for retailers, chemists, hospitals, and nursing homes, even where they knowingly sell medicines above revised prices.

2) The Central Bureau of Narcotics (CBN) has signed an MoU with Pharmexcil to strengthen controls and prevent diversion of narcotic and psychotropic substances in pharmaceutical exports. The agreement will introduce a voluntary code of conduct for exporters, improve coordination on export procedures, and include joint workshops and awareness initiatives with agencies such as CDSCO and Customs. The move comes amid increased regulatory focus on controlled substances.

USFDA inspections/inspection outcomes

1) Cipla's Unit 3 facility in Pithampur received seven Form 483 observations following a follow-up USFDA cGMP inspection conducted from 17-Aug-26 to 25-Aug-26. The facility is currently under a Warning Letter, which was issued in Nov-23. Separately, the Jul-26 inspection of Cipla's InvaGen facility in the US was classified VAI.

2) Aurobindo Pharma's subsidiary Apitoria Pharma's Unit-VI API manufacturing facility in Andhra Pradesh underwent a USFDA inspection from 24-Aug-26 to 28-Aug-26, which concluded with 3 procedural observations. Separately, Lannett's Seymour, Indiana facility was inspected by the USFDA from 17-Aug-26 to 21-Aug-26, with the inspection concluding with 4 procedural observations.

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

Final Approval: gDescovy (Natco), Neomycin Sulfate; Polymyxin B Sulfate; Hydrocortisone (Orbicular)

Management changes/Corporate actions

1) Hikal has appointed Sameer Hiremath as Chairman and Managing Director for a five-year term, from 1-Oct-26 to 30-Sep-31.

2) Mankind Pharma's Independent Director Bharat Anand completed his second term and consequently ceased to be an Independent Director effective 30-Aug-26. He has also stepped down from the Audit, Nomination and Remuneration, Risk Management, and CSR Committees.

3) Dishman Carbogen Amcis has announced the cessation of Deepak Ram Chandra Mittal as Vice President (Operations), effective 27-Aug-26.

4) Mankind Pharma has approved the consolidation of Bharat Serums and Vaccines (BSVL) into the company, following the BSVL Board's decision to initiate its voluntary liquidation process. BSVL's business will be transferred to Mankind on a going-concern basis, while Appian Properties will receive cash proportionate to its 4% holding in BSVL.

5) Zydus Lifesciences has incorporated Zydus Global Treasury Centre IFSC (Gift City Company) as a wholly-owned subsidiary on 25-Aug-26, with paid-up capital of Rs50mn. The entity will undertake global/regional corporate treasury activities and treasury services, with Zydus subscribing to 100% of its equity capital in cash.

6) Natco Pharma is investing $14mn in eGenesis through convertible promissory notes, taking its total investment in the company to $22mn, including the $8mn invested in 2024. eGenesis is developing genome-engineered transplantable organs to address organ shortages, with programs focused on kidney, acute liver failure, and heart transplantation.

7) Cipla has rationalized its group structure by transferring the 100% stake in Aspergen USA from Cipla (EU) and Kemwell Biopharma UK to Aspergen India, the existing 60:40 JV between Cipla and Kemwell. Following the restructuring, Aspergen USA has become a wholly-owned subsidiary of Aspergen India.

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ADD	5-15% upside
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