

This is the fourteenth edition (week ending 17-May-26) of our Pharma Weekly – In case you missed it. Key developments in the past week:

1) Sandoz received European Commission approvals for biosimilars Bysumlog (Insulin Lispro) and Dazparda (Insulin Aspart), developed by Gan and Lee Pharma (read-through for Biocon).

2) Daiichi Sankyo has outlined plans to become a top 5 global oncology player by 2035, targeting total sales of USD19bn and oncology sales of USD14.5bn by 2030, driven by its ADC portfolio (including Enhertu and Datroway).

3) The USFDA has completed an inspection of Alvotech's Reykjavik manufacturing facility; the company expects to quickly address the FDA's observations and resubmit the relevant BLAs in 2QCY26 (note that Dr Reddy's' partnered filing for Denosumab had received a CRL following an earlier inspection of this facility).

4) BeOne Medicines received the USFDA's accelerated approval for Beqalzi (Sonrotoclox) in relapsed/refractory mantle cell lymphoma, positioning the drug as a potential challenger to AbbVie/Roche's Venclexta, which is used off-label for this type of blood cancer (relevant for Anthem).

5) Alkermes reported positive Phase 3 results for Lumryz in idiopathic hypersomnia and plans to file for FDA approval by end-2026, potentially intensifying competition for Jazz Pharma's Xywav, currently the only approved therapy in the indication (read-through for Xywav generic filers).

6) ViiV Healthcare lost a legal challenge against Colombia's compulsory license for its HIV drug Tivicay (read-through for Laurus Labs).

7) Almirall reported 1QCY26 Ilumetri sales of EUR62mn, up 12% YoY, with the management reiterating confidence in achieving peak sales of over EUR300mn (relevant for Sun Pharma).

8) Bayer witnessed a 40% YoY decline in Xarelto sales in 1QCY26 amid loss of exclusivity, while Eylea sales declined 21% due to biosimilar-driven pricing pressures, although Eylea HD accounted for 46% of the franchise sales (read-through for Eylea biosimilars). Bayer also highlighted encouraging early uptake for its newly launched Lynkuet (relevant for Cohance and Aarti Pharmed Labs).

9) Eisai reported 20% YoY growth in global Dayvigo sales in 4QFY26, with the drug maintaining its leadership in Japan; the company highlighted steady expansion in Canada, China, and Thailand, alongside plans for a US relaunch through telehealth initiatives and regulatory filings in the UK+EU (relevant for Aarti Pharmed Labs).

10) Daiichi Sankyo reported an increase in its EU specialty business revenue, driven by strong growth in Nilemdo/Nustendi (Bempedoic Acid), with brand sales rising ~65% YoY to EUR107mn in 4QFY26 and FY26 sales meeting the company's guidance at EUR361mn; the company has guided for EUR480mn sales in FY27 (read through for Neuland, Blue Jet, and Piramal).

11) HLS Therapeutics's Nilemdo has witnessed a strong early launch in Canada, with over CAD250,000 in sales within the first month, growing wholesaler reorders and coverage from major private insurers; the company expects Nexlizet to be launched in 1HCY27 and sees peak annual revenue for the Bempedoic Acid franchise at CAD50-100mn (read through for Neuland, Blue Jet, and Piramal).

12) Unicycive Therapeutics reiterated that the FDA review of Oxylanthanum Carbonate remains on track with a target action date of 29-Jun-26, while commercial launch readiness activities continue ahead of the potential approval (read-through for Shilpa Medicare).

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

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### News flow – Indian Pharma

- 1) Eli Lilly paused its obesity awareness campaign in India after the CDSCO raised concerns that the initiative could indirectly promote prescription drug Mounjaro and violate restrictions on consumer advertising of prescription medicines.
- 2) Zydus Lifesciences acquired Assertio Holdings for USD166.4mn in cash to strengthen its specialty and oncology presence in the US, with the deal adding oncology supportive-care product Rolvedon to its portfolio.
- 3) Impetis Biosciences (a Tata group company) out-licensed two preclinical selective JAK inhibitor drug candidates to Vyome Holdings for inflammatory and autoimmune diseases, including rheumatoid arthritis, alopecia areata, and ulcerative colitis.
- 4) OneSource Specialty Pharma has received in-principle approval from the Karnataka government for the expansion of its flagship Unit II manufacturing facility in Bengaluru Rural.
- 5) Lupin launched its Atharv Ability neuro-rehabilitation center in Delhi, expanding its specialized rehabilitation network for neurological disorders following earlier centers in Mumbai and Hyderabad.
- 6) All India Organisation of Chemists and Druggists (AIOCD) has announced a nationwide one-day shutdown on 20-May-26 protesting against alleged regulatory inaction on e-pharmacies, deep discounting practices, and continued COVID-era relaxations for online medicine sales.
- 7) Piramal Pharma inaugurated a new payload-linker development and manufacturing suite at its Michigan facility as part of a broader USD90mn US expansion plan aimed at strengthening ADC and sterile injectable manufacturing capabilities.
- 8) Sun Pharma recalled one batch of Doxorubicin Hydrochloride liposome injection in the US after detecting glass particles in some vials during production.

### News flow – Global innovators, CDMOs and generic players

- 1) Fractyl Health received regulatory approval in the Netherlands to initiate a first-in-human, Phase 1/2 study of RJVA-001, a GLP-1 gene therapy for obesity and type 2 diabetes, with the first patient dosing and preliminary data expected in 2H CY26.
- 2) Daiichi Sankyo outlined plans to become a top 5 global oncology player by 2035, targeting total revenue of USD19bn and oncology revenue of USD14.5bn by 2030, driven by its ADC portfolio consisting of Enhertu and Datroway, while also launching a USD1.3bn cost optimization program focused on AI and procurement efficiencies.
- 3) BMS partnered with Hengrui Pharma in a deal worth up to USD15.2bn, paying USD600mn upfront for ex-China rights to four oncology and hematology assets and collaboration on five additional drug programs, while Hengrui will receive China rights to four BMS immunology assets.
- 4) Bayer reported 4% YoY sales growth to EUR13.4bn, with continued momentum in Nubeqa and Kerendia, partly offset by declines in Xarelto and Eylea. Xarelto sales fell 40% YoY amid loss of exclusivity, while Eylea declined 21% due to biosimilar-driven pricing pressures, although Eylea HD contributed 46% to the franchise sales. Bayer also highlighted encouraging early uptake for its newly launched Lynkuet.
- 5) Eli Lilly reported late-stage trial data, showing that obesity patients maintained long-term weight loss with oral Foundayo or lower-dose Zepbound after switching from higher-dose injectable incretin therapies, while Novo Nordisk presented new data highlighting strong efficacy of higher-dose Wegovy 7.2mg, with early responders achieving up to 27.7% weight loss.
- 6) BeOne Medicines received the USFDA's accelerated approval for Beqalzi (Sonrotoclax) in relapsed/refractory mantle cell lymphoma, positioning the drug as a potential challenger to AbbVie/Roche's Venclexta, which is used off-label for this type of blood cancer.
- 7) AstraZeneca reported positive Phase 3 results for Imfinzi plus Padcev in cisplatin-ineligible muscle-invasive bladder cancer, strengthening its position against Merck's competing Keytruda-Padcev combination in the bladder cancer market.
- 8) Japan will cut the price of Mounjaro by 25% as part of broader reforms to its innovative drug pricing system aimed at improving patient access while controlling healthcare costs.
- 9) Eli Lilly's oral obesity drug Foundayo recorded ~10,000 prescriptions in the fifth week post-launch, while Novo Nordisk's Wegovy maintained a 40.5% share of the obesity GLP-1 market despite a decline in prescriptions for its oral formulation.

- 10) Apotex and Dr. Reddy's launched generic semaglutide injections in Canada following Health Canada approvals, making Canada the first G7 country to approve generic versions of Novo Nordisk's Ozempic.
- 11) Sandoz received European Commission approvals for its biosimilars Bysumlog (insulin lispro) and Dazparda (insulin aspart), developed by Gan and Lee Pharma.
- 12) The USFDA has completed an inspection of Alvotech's Reykjavik manufacturing facility; the company expects to quickly address the FDA's observations and resubmit the relevant BLAs in 2QCY26 (note that Dr Reddy's' partnered filing for Denosumab had received a CRL following an earlier inspection of this facility).
- 13) Alkermes reported positive Phase 3 results for Lumryz in idiopathic hypersomnia and plans to file for FDA approval by end-2026, potentially intensifying competition for Jazz Pharmaceuticals's Xywav, currently the only approved therapy in the indication.
- 14) ViiV Healthcare lost a legal challenge against Colombia's compulsory license for its HIV drug Tivicay, allowing generic drug entry.
- 15) Almirall reported 1QCY26 Ilumetri sales of EUR62mn, up 12% YoY, with the management reiterating confidence in achieving peak sales of over EUR300mn.
- 16) Eisai reported FY25 revenue growth of 4.6% YoY, driven by strong performance of key brands including Dayvigo, Lenvima, and Leqembi. Dayvigo sales rose 20% YoY, with the drug maintaining its leadership position in Japan. Dayvigo continues to see steady expansion in Canada, China, and Thailand, while the company plans a US relaunch through telehealth-based initiatives across more than 30 states and intends to file for approval in the UK and EU.
- 17) Daiichi Sankyo reported an increase in its EU specialty business revenue, driven by strong growth in Nilemdo/Nustendi (Bempedoic Acid) with brand sales rising ~65% YoY to EUR107mn in 4QFY26 and FY26 sales meeting the company's guidance at EUR361mn; the company has guided for EUR480mn sales in FY27.
- 18) Unicycive Therapeutics reiterated that the FDA review of Oxylanthanum Carbonate remains on track with a target action date of 29-Jun-26, while commercial launch readiness activities continue ahead of the potential approval.

### Key regulatory developments

- 1) Germany is considering linking drug rebate exemptions to local R&D and clinical trial activity under proposed healthcare reforms, aimed at boosting domestic pharmaceutical innovation and investment.
- 2) Optum Rx introduced a new transparent, fee-based pharmacy benefit model that eliminates spread pricing linked to drug prices or prescription volumes, with full transition of group purchasing to flat service fees targeted by end-2027.
- 2) The EU Council and European Parliament reached a provisional agreement on the Critical Medicines Act to strengthen local drug manufacturing to prevent shortages of critical medicines, reduce dependence on external supply chains, and give member states greater powers to mandate medicine supply obligations from Dec-27 to prevent shortages across Europe.
- 3) The US Department of Commerce stated that drugmakers seeking exemption from proposed 100% pharma import tariffs must submit detailed US manufacturing onshoring plans, investment and production plans, periodic progress reports for onshoring milestones, and API sourcing disclosures by 12-Jun-26 to qualify for a reduced 20% tariff rate.
- 4) India's drug regulator CDSCO is working on new guidelines governing the use of high-risk solvents such as Propylene Glycol and its toxic impurities Diethylene Glycol (DEG) and Ethylene Glycol (EG) in oral liquid medicines following multiple child deaths linked to contaminated cough syrups.
- 5) The CDSCO has allowed parallel submission of clinical trial applications to the regulator and ethics committees to streamline reviews and reduce approval timelines for clinical trials and new drug applications in India.
- 6) The Centers for Medicare & Medicaid Services in the US will launch a temporary Medicare GLP-1 Bridge program from Jul-26, allowing eligible obesity patients to access GLP-1 drugs at a subsidized cost of USD50 per month outside Medicare Part D coverage.
- 7) India's CDSCO tightened post-marketing safety reporting norms for new drugs, mandating Periodic Safety Update Report submissions to begin from the actual commercial launch date instead of approval date to improve pharmacovigilance and adverse event monitoring.

8) The USFDA launched a pilot programme in Apr-26 for one-day inspectional assessments to improve inspection efficiency through shorter, targeted facility reviews, while continuing full-scale inspections for higher-risk and complex sites, with around 46 assessments under this pilot completed so far.

#### **USFDA inspections/inspection outcomes**

1) The USFDA completed a cGMP inspection at Emcure Pharma's formulations facility in Sanand, Ahmedabad, from 06-May-26 to 15-May-26, with the inspection concluding with 7 form 483 observations.

2) Indoco Remedies received an EU GMP certification from the Malta Medicines Authority for its Baddi-based oral solid dosage manufacturing facility following an inspection conducted from 29-Jan-26 to 03-Feb-26.

3) Alembic Pharmaceuticals received an Establishment Inspection Report (EIR) from the USFDA for its injectable facility (F-III) at Karakhadi for inspection conducted from 09-Feb-26 to 18-Feb-26, while also successfully completing an ANVISA GMP inspection at its API-III facility for multiple APIs from 11-May-26 to 15-May-26 with no observations.

#### **Management Commentary**

1) Novartis India's country president and MD Amithabh Dube said the company is repositioning India as a key innovative medicines market and early-stage research hub following the divestment of its listed arm, with one planned launch in CY26 and two launches in CY27.

2) Pfizer India country president Meenakshi Nevatia said India remains a must-win market for the company, with focus areas spanning oncology, obesity, vaccines, and specialty drugs, alongside efforts to accelerate launches of innovative therapies at India-relevant pricing. She also highlighted plans to expand access through local partnerships and push for regulatory data protection.

3) Dr Reddy's CEO Erez Israeli said biosimilars could surpass traditional generics in the US by the early 2030s, aided by rising demand for biologics, increasing patent expiries, and the growing shift toward complex specialty therapies. He highlighted Semaglutide as a large opportunity, with launches planned in multiple geographies over the next 2-3 years.

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

**Final Approval:** gAfinitor (Apotex), gPepcid (Lupin), gSuprax (FDC), gLac-hydrin (Zydus), Phytonadinone (Dr Reddy's), gVenclexta (Dr Reddy's)

**Tentative Approval:** gBridion (Tamarang), gNubeqa (Alembic), gNexlizet (Sandoz), gKerendia (Macleods), gFotvida (Sandoz), gUbrelyv (Zydus)

#### **Management Changes/Corporate Actions**

1) Alembic Pharma's Rohit Garg resigned from his role as Senior VP – Strategy and Business Excellence and was relieved from the company effective 14-May-26.

2) Indoco Remedies informed about the demise of its Non-Executive Director Dr Anand Nadkarni on 15-May-26.

3) Senores Pharma's Vinay Kumar Mishra resigned as Company Secretary and Compliance Officer, and will cease to be a Key Managerial Personnel effective close of business hours on 10-Jun-26.

4) Gland Pharma reappointed Naina Lal Kidwai as Independent Director for a second five-year term from 17-May-26 to 16-May-31.

5) Brooks Laboratories said the board of its associate Brooks Steriscience decided not to pursue the proposed merger and composite scheme involving OneSource Specialty Pharma in its current form.

6) Cipla appointed Sushrut Kulkarni as President & Global Chief – Integrated Product Development (IPD), and as a member of the Management Council and Senior Management Personnel effective 18-May-26.

7) OneSource Specialty Pharma's Prateek Gupta, SVP & Head – Technical Development and Senior Management Personnel, resigned from the company effective 13-May-26.

8) Zydus Lifesciences's Apurva S Diwanji ceased to be an Independent Director effective 12-May-26 upon completion of his tenure.

9) Dr. Reddy's reappointed Dr K P Krishnan as an Independent Director for a second five-year term from 07-Jan-27, appointed Srikanth Velamakanni as an Independent Director for a five-

year term from 01-Jul-26, and elevated Sandeep Khandelwal as Senior Management Personnel and member of the Management Council.

10) Neuland Labs appointed Dr Mauricio Futran as an Additional Director categorized as Non-Executive Non-Independent Director effective 12-May-26.

11) Sun Pharma appointed Dr Andreas Busch as an Independent Director for a five-year term effective 12-May-26, subject to shareholder approval, and appointed Satyavati Berera to the Audit Committee and Risk Management Committee following the retirement of Rama Bijapurkar on completion of her tenure. The company has received a request to reclassify Sudhir Valia, Raksha Valia, and Krishna Valia from 'Promoter Group' to 'Public' category.

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<b>SELL</b>	>15% downside

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