Pharmaceuticals

Pharma Weekly - ICYMI

This is the seventeenth edition (week ending 19-Jul-26) of our Pharma Weekly – In Case You Missed It. Key developments in the past week:

1) Q32 Bio reported positive 36-week Phase 2a results for Bempikibart in severe alopecia areata, demonstrating 35.3% mean improvement in hair regrowth (SALT ≤ 20 score) with a favorable safety profile, supporting advancement into a Phase 3 trial in 1HCY27 (relevant for Sun's Leqselvi).

2) Merck received USFDA approval for Lipfendra (Enlicitide), the first oral PCSK9 inhibitor for hypercholesterolemia, offering a once-daily alternative to injectable therapies which reduced LDL cholesterol by nearly 60% in Phase 3 trials with sales potential of ~$2.7bn by 2031 (read through for Divis).

3) J&J's immunology franchise continues to shift beyond Stelara (~69% yoy decline in 2QCY26 due to biosimilar competition), as Tremfya delivered ~84% yoy growth on strong Inflammatory Bowel Disease (IBD) uptake and share gains in the US. Newly launched Icotyde (oral IL-23) has been prescribed to ~11,000 patients with a data readout for psoriatic arthritis expected in 2HCY26 (relevant for Sun's Ilumya).

4) Health Canada approved Novartis's Vanrafia (Atrasentan) to reduce proteinuria in adults with primary IgA nephropathy at risk of rapid disease progression, based on interim Phase 3 trial results (relevant for Anthem).

5) Zoetis has launched Lenivia (Izenivetmab) in Canada and the EU, a long-acting anti-nerve growth factor that provides up to three months of osteoarthritis pain relief in dogs with a single injection (read through for Syngene).

6) The European Commission approved Boehringer Ingelheim's Jascayd (Nerandomilast) for idiopathic pulmonary fibrosis (IPF) and progressive pulmonary fibrosis (PPF), making it the first new IPF treatment in the EU in over a decade (relevant for Cohance).

7) Takeda reported additional Phase 3 data showing its oral TYK2 inhibitor Zasocitinib achieved clear or almost clear scalp psoriasis in ~75% of patients at Week 16 (following positive Phase 3 results in plaque psoriasis in Dec-25), outperforming Amgen's Otezla, with the company planning a USFDA submission by 1QCY27 (read through for Sun's Ilumya).

8) Avere Therapeutics licensed Hansoh Pharma's oral IL-23 (AVR-001) with a Phase 2b psoriasis study expected next year and a readout expected in 1HCY28 (relevant for Sun's Ilumya).

9) Accord BioPharma (Intas Pharmaceuticals's US division) received USFDA approval for Ennumo (Pegfilgrastim), Accord's second Pegfilgrastim biosimilar in the US (relevant for Biocon and Lupin).

10) The European Commission approved Novo Nordisk's oral Wegovy (Semaglutide) as the first GLP-1 obesity tablet in Europe, alongside the 7.2 mg high-dose formulation, giving Novo a potential first-mover advantage ahead of Eli Lilly's Foundayo in the region.

11) US drug shortages increased for the third consecutive quarter to 227 active shortages, with nearly half new shortages involving single-manufacturer products. 16% of active shortages are controlled substances, and 10% of all new shortages in 2026 are contrast media agents.

12) Celltrion reduced the planned enrollment for its Phase 3 Pembrolizumab (Keytruda) biosimilar trial from ~600 to ~220 patients following discussions with the USFDA, but the original two-year trial duration remains (reflects easing biosimilar regulations).

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

Shashank Krishnakumar
shashank.krishnakumar@emkayglobal.com
+91-22-66242466

Mohd Suheb Alam
suheb.alam@emkayglobal.com
+91-22-66242413

News flow – Indian Pharma

1) Mylan exited Biocon by selling its entire 5.64% stake for Rs36.8bn through a block deal, with the shares largely absorbed by domestic mutual funds and insurance companies.

2) Pfizer voluntarily dismissed its US patent infringement lawsuit against Alkem Labs over proposed generic versions of Inlyta (Axitinib), clearing the litigation related to the product.

3) RPG Life Sciences partnered with Archerchem Healthcare to exclusively market and distribute Naprosyn ES (Naproxen + Esomeprazole), a differentiated NSAID combination with gastroprotection, marking the first launch of the combination in India.

4) Biocon received EMA approval for a new drug product fill-finish line for Semglee (Insulin Glargine) at its Malaysia insulin facility, with commercial supplies to Europe expected to commence from 2QFY27.

5) OneSource Specialty Pharma entered into a strategic manufacturing partnership with Formycon AG to provide integrated drug substance and drug product manufacturing for its global biosimilar pipeline from OneSource's Bengaluru biologics facility.

6) Sun Pharma has received approval from South Africa's SAHPRA to manufacture and market generic Semaglutide for type 2 diabetes, marking South Africa as the second market after India to approve the company's generic GLP-1 product. The company plans to launch pre-filled, multi-dose injectable pen in two strengths (2 mg/1.5 mL and 4 mg/3 mL).

7) Bristol Myers Squibb filed a US patent infringement lawsuit against Aurobindo Pharma to block the launch of proposed generic Camzyos (Mavacamten).

8) Pfizer has temporarily discontinued Premarin vaginal cream in India due to supply constraints, reducing treatment options for genitourinary syndrome of menopause (GSM).

9) Glenmark Pharmaceuticals has agreed to pay $29.6mn to settle US multi-state litigation alleging generic drug price-fixing, while implementing an antitrust compliance program and continuing to cooperate with authorities in the ongoing investigation.

10) Cipla's Yurpeak (Tirzepatide) became the second-largest GLP-1 brand in India within six months of launch, achieving Rs274mn monthly sales and 15.7% market share in June, driven by strong penetration beyond metro cities through Cipla's extensive distribution network.

11) Maharashtra FDA directed Cadila Pharmaceuticals to recall and halt the sale of Aciloc brands and seized Rs24.5mn of inventory, citing the risk of medication errors due to branding similarities with Ranitidine-based Aciloc products despite containing a different active ingredient (Famotidine).

12) Novo Nordisk received CDSCO approval for Wegovy (Semaglutide) to treat metabolic dysfunction-associated steatohepatitis (MASH) in India, expanding its label beyond obesity and providing access to a differentiated indication currently insulated from generic competition.

13) Reliance Life Sciences voluntarily recalled Pemetrexed, Bortezomib, and Azacitidine injections from the US market due to lack of sterility assurance, with the USFDA classifying the action as a Class II recall (classification used for products that might cause temporary or medically reversible adverse health consequences).

14) Accord BioPharma (Intas Pharmaceuticals's US division) received USFDA approval for Ennumo (Pegfilgrastim), Accord's second Pegfilgrastim biosimilar in the US (relevant for Biocon and Lupin).

News flow – Global innovators, CDMOs, and generic players

1) Teva entered into a global licensing agreement with Polpharma Biologics to exclusively commercialize the IV and subcutaneous biosimilar of Ocrevus (ocrelizumab) across the US, Europe, and other key markets, while Polpharma will retain development and manufacturing responsibilities.

2) Celltrion reduced the planned enrollment for its Phase 3 Pembrolizumab (Keytruda) biosimilar trial from ~600 to ~220 patients following discussions with the USFDA, but the original two-year trial duration remains (reflects easing biosimilar regulations).

3) A US federal appeals court reinstated >500 lawsuits alleging a link between Tylenol (Acetaminophen) use during pregnancy and autism/ADHD, ruling that plaintiffs' expert testimony was improperly excluded.

4) Health Canada approved Novartis's Vanrafia (Atrasentan) to reduce proteinuria in adults with primary IgA nephropathy at risk of rapid disease progression, based on interim Phase 3 trial results (relevant for Anthem).

5) The US FTC reached a settlement with CVS Health's Caremark requiring changes to its PBM practices to improve pricing transparency, lower patients' out-of-pocket drug costs, support community pharmacies, and resolve allegations of anticompetitive insulin rebate practices, with projected consumer savings of up to $13bn over the next decade.

6) Q32 Bio reported positive 36-week Phase 2a results for Bempikibart in severe alopecia areata, demonstrating 35.3% mean improvement in hair regrowth (SALT ≤ 20 score) with a favorable safety profile, supporting advancement into a registration-directed program in 1HCY27 (relevant for Sun's Leqselvi).

7) Merck received USFDA approval for Lipfendra (Enlicitide), the first oral PCSK9 inhibitor for hypercholesterolemia, offering a once-daily alternative to injectable therapies which reduced LDL cholesterol by nearly 60% in Phase 3 trials with sales potential of ~$2.7bn by 2031 (read through for Divis).

8) US drug shortages increased for the third consecutive quarter to 227 active shortages, with nearly half new shortages involving single-manufacturer products. 16% of active shortages are controlled substances, and 10% of all new shortages in 2026 are contrast media agents used for potentially life-saving procedures, such as CT scans and MRIs.

9) Merck's Keytruda became the first PD-1 inhibitor to demonstrate a progression-free survival benefit as a monotherapy in first-line mismatch repair-deficient (dMMR) advanced or recurrent endometrial cancer, supporting a potential chemotherapy-free treatment option.

10) The European Commission approved Novo Nordisk's oral Wegovy (Semaglutide) as the first GLP-1 obesity tablet in Europe, alongside the 7.2 mg high-dose formulation, giving Novo a potential first-mover advantage ahead of Eli Lilly's Foundayo in the region.

11) US 340B drug purchases exceeded $100bn in 2025 (up 23% YoY), driven by increased use of oncology, immunology, and obesity/diabetes medicines, with Merck's Keytruda and Gilead's Biktarvy among the largest products by spend.

12) InnoCare Pharma's TYK2 inhibitor Soficitinib (ICP-332) met the primary endpoint in the Phase 2 portion of a Phase 2/3 trial in nonsegmental vitiligo. InnoCare is running mid- to late-phase trials in atopic dermatitis, chronic spontaneous urticaria, plaque psoriasis, and prurigo nodularis.

13) Zoetis has launched Lenivia (Izenivetmab) in Canada and the EU, a long-acting anti-nerve growth factor that provides up to three months of osteoarthritis pain relief in dogs with a single injection (read through for Syngene).

14) The European Commission approved Boehringer Ingelheim's Jascayd (Nerandomilast) for idiopathic pulmonary fibrosis (IPF) and progressive pulmonary fibrosis (PPF), making it the first new IPF treatment in the EU in over a decade (relevant for Cohance).

15) Takeda reported additional Phase 3 data showing its oral TYK2 inhibitor Zasocitinib achieved clear or almost clear scalp psoriasis in ~75% of patients at Week 16, outperforming Amgen's Otezla, with the company planning a USFDA submission by 1QCY27 (read through for Sun's Ilumya).

16) Eli Lilly's oral Foundayo showed an uptick in US prescriptions to 24.3K weekly scripts, while Zepbound and Novo Nordisk's Wegovy prescriptions declined amid a 5.1% sequential decline in the overall GLP-1 market.

17) UK generic medicine prices saw broad increases in June, led by Bisoprolol (up 314%) and recently launched Ezetimibe, which rose more than 10-fold.

18) Avere Therapeutics licensed Hansoh Pharma's oral IL-23 (AVR-001) with a Phase 2b psoriasis study expected next year and a readout expected in 1HCY28 (relevant for Sun's Ilumya).

19) J&J's immunology franchise continues to shift beyond Stelara (~69% yoy decline in 2QCY26 due to biosimilar competition), as Tremfya delivered ~84% growth on strong Inflammatory Bowel Disease (IBD) uptake and share gains in the US. The newly launched Icotyde (oral IL-23) has been prescribed to ~11,000 patients, with a data readout for psoriatic arthritis expected in 2HCY26 (relevant for Sun's Ilumya).

Key regulatory developments

1) The Organisation of Pharmaceutical Producers of India (OPPI) renewed its call for Regulatory Data Protection (RDP) in India, arguing that protecting innovators's clinical and regulatory data would encourage R&D investment and drug discovery, while industry and public health groups continued to oppose the proposal over concerns of delayed generic competition.

2) Several Southeast Asian countries are evaluating the EU's Joint Clinical Assessment (JCA) framework for health technology assessment (HTA) to centralize clinical assessment of new medicines and medical devices.

3) The India–UK Comprehensive Economic and Trade Agreement (CETA) came into force, granting zero-duty access for Indian pharmaceutical exports to the UK while preserving TRIPS, despite concerns from patient groups of favoring voluntary licensing over compulsory licensing.

4) Centers for Medicare & Medicaid Services (CMS) proposed making Medicare Part D 340B claims reporting mandatory, replacing voluntary submissions to improve 340B program transparency, reduce duplicate discounts, and strengthen oversight of manufacturer rebate obligations.

5) The Union Ministry of Science and Technology has launched Phase 3 of the Biomedical Research Career Programme (BRCP) with a Rs15bn outlay, including Rs10bn from the Department of Biotechnology and Rs5bn from the Wellcome Trust.

6) The USFDA finalized its guidance for clinical trials of psychedelic therapies, outlining recommendations on trial design, participant safety, abuse potential, and data collection. The FDA outlined a risk-based approach to assessing abuse liability, allowing sponsors to use computational models instead of strictly requiring new animal studies in every scenario.

USFDA inspections/inspection outcomes

1) Cipla's US subsidiary InvaGen Pharmaceuticals received one Form 483 observation following a routine USFDA inspection of its Central Islip, New York manufacturing facility from 13-Jul-26 to 17-Jul-26.

2) The USFDA issued a Warning Letter to a clinical investigator in Alembic Pharma involved in a bioequivalence study at its Vadodara Bioequivalence Facility, citing deficiencies related to informed consent procedures following an inspection conducted from 3-Mar-25 to 7-Mar-25.

Management commentary

1) Kiran Mazumdar-Shaw (Chairperson, Biocon) said Syngene had drifted away from its core strengths in CDMO and biomanufacturing under the previous management by expanding into undifferentiated commodity services. She said the company has now realigned its strategy under new leadership to focus on differentiated CDMO offerings, where it has strong capabilities. She expects FY27 to show the first signs of recovery, with a strong turnaround in FY28.

2) Himanshu Baid (Managing Director, Poly Medicure) said the company aims to double its international business by FY30, supported by two new manufacturing facilities, a pipeline of >50 new products, and deeper penetration in overseas markets. He expects the Global South—particularly the Middle East, Southeast Asia, Africa and Latin America—to be the biggest export opportunity, while targeting 20–25% annual growth in India and 15–20% export growth. Baid added that renal care, critical care, and cardiology will be the key growth drivers, and the company will continue evaluating technology- and regulatory-led acquisitions.

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

Final Approval: gBriviact (Shandong), gXanax (Unichem), gPromacta (Teva), gDiprivan (Anthea Pharma), gGilotrif (Hetero Labs), gGilotrif (Apotex), gLodine (Aurobindo)

Tentative Approval: gLynparza (Alembic/Natco)

Management changes/Corporate actions

1) Sun Pharma Advanced Research Company appointed Anil Raghavan, currently CEO, as Managing Director and CEO, effective 11-Aug-26, while Dr Rajamannar Thennati will retire from the Board of Directors upon completion of his term on 10-Aug-26.

2) Syngene International announced that Surender Sharma, General Counsel, and a member of the Executive Committee, stepped down from the company, effective 15-Jul-26.

3) Shilpa Medicare announced that Dr Sridevi Khambhampaty resigned as CEO of Shilpa Biologicals, its material subsidiary, effective 15-Jul-26.

4) Torrent Pharma voluntarily dissolved Curatio Inc Philippines, its Philippines wholly-owned subsidiary, effective 10-Jul-26.

5) Emcure Pharma will acquire the remaining 12.05% stake in Gennova Biopharmaceuticals for Rs2.3bn, making it a wholly-owned subsidiary. Gennova will be led by Samit Mehta and will focus on its biologics franchise.

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Emkay Global Financial Services Ltd.
CIN - L67120MH1995PLC084899
7th Floor, The Ruby, Senapati Bapat Marg, Dadar - West, Mumbai - 400028. India
Tel: +91 22 66121212 Fax: +91 22 66121299 Web: www.emkayglobal.com

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Seshadri Kumar Sen

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