Pharmaceuticals

Pharma Weekly - ICYMI

This is the eleventh edition (week ending 19-Apr-26) of our Pharma Weekly – In case you missed it. Key developments in the past week:

1) Dr Reddy's' Semaglutide (Embeltah) registration request was rejected by Brazil's ANVISA due to deficiencies in technical requirements. Meanwhile, Hetero Labs aims to sell ~1.5mn Semaglutide pens in the first year across markets and launch in >75 countries (including Canada in the next 18 months).

2) Amneal has launched gProAir (Albuterol) and gQVAR in the US, the company's first two metered-dose inhalation (MDI) launches (read-through for Lupin and Cipla).

3) Eli Lilly plans a Type 2 Diabetes submission for Foundayo (Orforglipron) by the end of 2QCY26, even as the USFDA has requested additional liver safety data and post-marketing studies (relevant for Divi's).

4) J&J has launched its psoriasis pill, Icotyde (Icotrokinra - oral IL-23 receptor antagonist), post Mar-26 approval with strong early uptake, positioning it alongside Tremfya as a key growth driver amid a sharp decline in Stelara sales (-60% YoY in 1QCY26) and supporting the company's CY26 revenue outlook of ~USD100bn (we do not perceive Icotyde as a meaningful threat to Sun's Ilumya; link to our note).

5) Sun Pharma's UNLOXCYT has received the USFDA's regulatory review period determination, paving the way for a potential patent term extension (~200 days).

6) J&J reported Rybrevant + Lazcluze sales of USD257mn (+80% YoY) in 1QCY26, with sequential growth of ~19% being driven by a strong uptake across markets and share gains in both first- and second-line treatment (read-through for Cohance).

7) Evommune will advance EVO756 into Phase 2b for migraine, with top-line data for chronic urticaria expected in 2QCY26 and an atopic dermatitis readout expected in 2HCY26 (relevant for Piramal Pharma).

8) ADC updates: Piramal Pharma has partnered with Ajinomoto Bio-Pharma Services to support ADC development and manufacturing; BioNTech reported positive Phase 2 results for Trastuzumab Pamirtecan (a potential competitor to Enhertu) in HER2-expressing and advanced endometrial cancer, and has plans for a CY26 BLA filing; GSK is progressing its B7-H4-targeted ADC in platinum-resistant ovarian cancer and advanced endometrial cancer into Phase 3, while Eli Lilly will acquire ADC-focused CrossBridge Bio in a deal worth up to ~USD300mn, adding preclinical dual-payload oncology assets to its pipeline.

9) The DCGI has proposed easing biosimilar approval norms with reduced emphasis on bioequivalence studies and more focus on characterization, to demonstrate equivalence, bringing its norms at par with the standards in regulated markets.

News flow – Indian Pharma

1) Dr Reddy's' Semaglutide (Embeltah) registration request was rejected by Brazil's ANVISA due to failure to meet technical requirements on efficacy, safety, and quality. Cipla's Liraglutide applications were rejected on similar grounds.

2) Dr Reddy's (Aurigene) and Alveus Therapeutics have advanced their metabolic disease collaboration with the nomination of ALV-200, an AMYR3 peptide candidate, for development.

3) Sun Pharma and Germany's Grünenthal are evaluating binding bids for Organon, with Sun pharma having secured commitments from a group of overseas banks.

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

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Additional News flow – Indian Pharma

1) Dr Reddy's received CDSCO approval to manufacture and sell generic Semaglutide tablets in India, following clinical studies demonstrating non-inferiority to Novo Nordisk's Rybelsus.

2) The Bombay High Court restrained Meghmani Lifesciences from using the 'Esiraft' trademark in a dispute with Sun Pharma over alleged infringement of its 'Raciraft' brand.

3) Aurobindo Pharma's subsidiary TheraNym Biologics has expanded its CMO agreement with Merck, to add a new product schedule, including plans to invest USD150-175mn for setting up a greenfield 60KL mammalian drug substance facility.

4) Unichem Labs initiated a voluntary recall of Buspirone Hydrochloride Tablets (5mg) in the US due to out-of-specification assay results at the 12-month stability stage, with no adverse events reported.

5) India's pharma exports declined 23% in Mar-26 due to West Asia conflict-led logistics disruptions. Overall pharma exports grew 2% in FY26.

6) Hetero Labs aims to sell ~1.5mn Semaglutide pens in the first year across markets, with plans to launch in >75 countries in Africa, Asia, and the Middle East. The company targets launching in India in Apr-26 and in Canada within the next 18 months.

7) Piramal Pharma has partnered with Ajinomoto Bio-Pharma Services to support ADC development and manufacturing using Ajinomoto's AJICAP technology, including for a technology transfer to enable Piramal's commercial-scale production.

8) Lupin agreed to pay USD30mn to settle its US antitrust litigation with Humana, while denying all allegations and any admission of liability or unlawful conduct (amount of settlement already provided for in the company's prior financial results).

9) Rubicon Research's subsidiary Advagen Holdings has acquired all assets of InvaTech Pharma Solutions for ~USD3mn via a court-approved sale.

10) Sun Pharma's UNLOXCYT has received the USFDA's regulatory review period determination, paving the way for a potential patent term extension (~200 days).

11) Torrent Pharma plans to divest its Calcigard (Nifedipine) brand, to address the Competition Commission of India's concerns and secure approval for its acquisition of JB Chemicals, which would otherwise result in >90% market share in the segment.

12) Rubicon Research has acquired an 85% equity stake in Arinna Lifesciences for ~Rs1.76bn (EV ~Rs2bn), entering the domestic CNS segment, with deal closure expected within 30 days.

13) MSN Laboratories launched generic semaglutide (Semabest) in India in a pre-filled pen following CDSCO approval, priced at ~Rs3,990-5,490 (~50% lower than the innovator's).

News flow – Global innovators, CDMOs, and generic players

1) Amneal has launched gProAir (Albuterol) and gQVAR (Beclomethasone Dipropionate) in the US, marking its entry into the metered-dose inhalation segment.

2) The USFDA has requested additional liver safety data and post-marketing studies for Eli Lilly's Foundayo (Orforglipron), as the company plans to submit the drug for a Type 2 Diabetes approval by the end of 2QCY26 following Phase 3 data showing superiority to insulin glargine and ~16% lower cardiovascular risk.

3) Johnson & Johnson launched its psoriasis pill Icotyde (Icotrokinra - oral IL-23 receptor antagonist peptide) post Mar-26 approval with strong early uptake (~1,500 prescriptions), positioning it alongside Tremfya (>USD10bn peak sales potential) as a key growth driver amid a decline in Stelara sales (-60% YoY in 1QCY26) and supporting the company's CY26 revenue outlook of ~USD100bn.

4) Global Semaglutide API prices have declined sharply to ~USD90-160 per gram for synthetic variants and to ~USD50 per gram for recombinant variants, from ~USD900 per gram three years ago, driven by capacity expansion and patent expiries, with a further 20-30% correction expected in the near term.

5) Novo Nordisk has partnered with OpenAI to deploy AI across R&D, manufacturing, and commercial operations, for accelerating drug discovery and improving efficiencies. OpenAI has also launched GPT-Rosalind, a life sciences-focused AI model to support research in biology, drug discovery, and translational medicine.

6) Eli Lilly's Tirzepatide showed greater weight loss but higher lean mass loss (~1.1% at 3 months; ~2% at 12 months) vs Novo Nordisk' Semaglutide, in a ~8,000-patient study.

7) China's biopharma sector recorded ~USD57bn in licensing deals in 1QCY26, driven by major cross-border partnerships, reinforcing China's growing role in global drug innovation and outsourcing.

8) Obesity drugmaker Kailera Therapeutics raised ~USD625mn in an upsized US IPO, with the stock surging ~63% on debut and the company being valued at ~USD3bn.

9) Eli Lilly will acquire ADC-focused CrossBridge Bio in a deal worth up to ~USD300mn, adding preclinical dual-payload oncology assets to its pipeline. CrossBridge's lead asset, dubbed CBB-120, is expected to enter the clinic this year for patients with solid tumors.

10) J&J reported Rybrevant + Lazcluze sales of USD257mn (+80% YoY) in 1QCY26, with sequential growth of ~19% being driven by a strong uptake across markets and share gains in both first- and second-line treatment.

11) Samsung Bioepis secured a US appellate court win to continue its supply of Ustekinumab (Stelara) biosimilar via Sandoz to Cigna's Quallent after the court denied Johnson & Johnson's injunction bid.

12) A US court allowed key antitrust claims against Teva over alleged exclusive PBM deals blocking generic Copaxone, while dismissing certain claims in cases brought by wholesalers and Viatris.

13) Daiichi Sankyo agreed to divest its consumer health unit to Suntory Holdings for ~USD1.55bn, starting with the handover of 30% of its consumer health subsidiary's share in Jun-26, shifting its focus toward oncology and other innovative medicines.

14) Biotech early-stage funding slowed in 1QCY26, with investments of ~USD2.3bn across 50 deals, putting CY26 on track for the weakest year since before the pandemic as investors shift focus to later-stage assets.

15) Evommune is advancing its MRGPRX2 inhibitor EVO756 as a novel migraine prevention therapy, with plans to initiate a Phase 2b trial in mid-CY26. The phase 2b data for chronic urticaria is expected in 2QCY26 and for Atopic Dermatitis in 2HCY26.

16) BioNTech reported positive Phase 2 data for Trastuzumab Pamirtecan (BNT323) in HER2-expressing endometrial cancer (Objective Response Rate: ~48–49%). The company plans to file a BLA in CY26, positioning BNT323 as a potential competitor to Daiichi Sankyo's Enhertu.

17) GSK reported strong Phase 1 data for its B7-H4-targeted ADC Mocertatug Rezetecan (Objective Response Rate: ~62–67%) in ovarian and endometrial cancers, advancing into five Phase 3 trials in CY26.

18) Pfizer has filed US patent infringement suits against Biocon, Changzhou Pharma, and Micro Labs over their proposed generic versions of Cibinqo (Abrocitinib).

Key regulatory developments

1) The DCGI has proposed easing biosimilar approval norms with reduced emphasis on bioequivalence studies and more focus on characterization to demonstrate equivalence, bringing its norms at par with the standards in regulated markets. The timeline for approvals of clinical trials has reduced to 120-135 days, and the time taken for granting market authorization to under 150 days in CY25.

2) The USFDA removed 12 peptide drug substances from Category 2 (bulk drug substances deemed by the FDA to have significant safety risks), ahead of a Jul-26 advisory meeting to review their potential inclusion in the 503A compounding bulks list (list of active ingredients that state-licensed pharmacies are permitted to use), signaling a possible shift from prior restrictions on compounding.

3) US lawmakers have introduced the 'Every Dollar Counts' Act that requires insurers to count direct-to-consumer drug purchases toward deductibles and out-of-pocket limits, aiming to reduce patient costs.

4) The Centers for Medicare & Medicaid Services proposed new prior authorization rules setting 24-hour (urgent) and 72-hour (standard) decision timelines for drug approvals, alongside enhanced transparency requiring insurers to publicly report metrics around prior authorization, including approval and denial rates, appeal outcomes, and decision timeframes.

5) A US appeals court ruled in favor of AbbVie, Novartis, AstraZeneca, and PhRMA (Pharmaceutical Research and Manufacturers of America) by vacating a lower court decision and reopening challenges to Maryland's 340B drug discount law.

USFDA inspections/inspection outcomes

1) Zydus received a USFDA EIR for its SEZ1 Ahmedabad oncology injectable facility following a Pre-Approval Inspection conducted during 4–13 Nov-25, related to its new isolator injectable line.

2) Lupin's Somerset, New Jersey facility underwent a USFDA inspection from 13-Apr-26 to 17-Apr-26 which concluded with the issuance of three Form 483 observations.

3) Cipla's Verna (Goa) facility underwent a USFDA inspection from 6–Apr-26 to 17-Apr-26 which concluded with the issuance of two Form 483 observations.

4) Indoco Remedies's Aurangabad testing facility cleared a USFDA Pre-Approval Inspection conducted from 8–Apr-26 to 10-Apr-26 with zero Form 483 observations.

5) OneSource Specialty Pharma has received the renewal of EU-GMP certification for its Unit II biologics manufacturing facility in Bengaluru.

6) Morepen Laboratories's API facility at Masulkhana, Himachal Pradesh cleared a USFDA inspection with zero observations on 17-Apr-26, marking its fourth consecutive zero-observation outcome.

Management Commentary

Mankind Pharma's COO Arjun Juneja has warned that medicine prices in India could rise within 15–30 days due to petrochemical input cost inflation triggered by the Iran conflict, adding that LPG and petroleum-linked shortages are beginning to impact API and formulation manufacturing, with supply disruptions likely to persist for 6–12 months.

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

Final Approvals: gEndometrin (Glenmark), gInfuvite (Apotex-Gland), gInvokana (Apotex), gRavicti (MSN, Aurobindo, Teva), Atropine Sulfate (Edenbridge Pharma), gDelsym (Aurobindo), gAlphagan P (Mankind), gUptravi (RK Pharma)

Tentative Approvals: gImbruvica (Hetero Labs), gBridion (Qilu Pharma)

Management Changes/Corporate Actions

1) Alkem Laboratories incorporated wholly-owned subsidiary Alkem Pharma Trading FZCO in Dubai, with share capital of AED4mn for supporting exports across Africa, Southeast Asia, and other international markets.

2) Mankind Pharma approved the closure of Sri Lankan subsidiary Mankind Pharma Lanka due to changes in regulatory requirements and lack of business operations.

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REDUCE	5% upside to 15% downside
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