Pharmaceuticals

Pharma Weekly - ICYMI

This is the twenty-fifth edition (week ending 13-Sep-26) of our Pharma Weekly – In Case You Missed It. Key developments in the past week:

1) Roivant's Mosliciguat delivered positive Phase 2 results in patients with pulmonary hypertension associated with interstitial lung disease (PH-ILD), supporting advancement into Phase 3 (relevant for Sai Life).

2) FDA has finalized the voluntary withdrawal of BMS's Krazati's (Adagrasib) indication in mutated colorectal cancer (CRC), following failure of the Phase 3 trial to meet its co-primary endpoints. The withdrawal affects the CRC indication only; Krazati's accelerated approval in second-line mutated NSCLC remains unaffected (relevant for Syngene).

3) Celltrion has received regulatory clearance for amended Phase 3 trial plans for its Keytruda biosimilar in the US. The trial will enroll a significantly fewer number of patients vs earlier (relevant for Zydus, Ipca, Dr Reddy's, Biocon and Cipla).

4) Evommune's EVO756 failed to meet primary and secondary endpoints in a Phase 2b trial in adults with moderate-to-severe atopic dermatitis, and the company will not advance the drug in AD. EVO756 was generally well tolerated and will continue to be evaluated for migraine prophylaxis (relevant for Piramal Pharma).

5) Lupin's Global CFO Ramesh Swaminathan said the company would continue investing in both Somerset and Coral Springs manufacturing units in the US to manufacture products that are only economically feasible. He also said the company is scaling up its biosimilars business, targeting ~$500mn revenue over the next five years, and the company has invested ~Rs5bn in biosimilar manufacturing capacity.

6) AbbVie's Qulipta (Atogepant) met the primary endpoint in a Phase 3 trial, showing a greater reduction in menstrual migraine days versus placebo over three menstrual cycles, while also delivering statistically significant improvements across all eight secondary endpoints; AbbVie plans to submit the data to global regulators (relevant for Sai Life).

7) Neuland Laboratories approved Rs1.26bn capex for the purchase of ~134 acres of land at Auro Industrial City, Kakinada (Andhra Pradesh), for future expansion. The company also has a right of first refusal for an additional ~66 acres, potentially taking the total land parcel to ~200 acres; the acquisition will be funded through internal accruals.

8) The FTC has urged the US Court of Appeals for the Fourth Circuit to recognize that acquiring pending patent applications can constitute exclusionary conduct under antitrust law. The case involving Amgen's Enbrel could create a new avenue for biosimilar developers to challenge patent transactions and thickets used to delay competing products and maintain market exclusivity.

9) Novo Nordisk's Wegovy (Semaglutide) has been approved in China for the treatment of metabolic dysfunction-associated steatohepatitis (MASH), making it the first GLP-1 receptor agonist approved in the country for the condition. On a separate note, Novo Nordisk said 40.4% of children aged 6 to under 12 with obesity treated with Semaglutide were no longer classified as having obesity after 68 weeks in the Phase 3 trial, assuming full treatment adherence.

10) IOL Chemicals & Pharma is investing Rs3.5bn to expand its backward-integrated Ibuprofen capacity by 6,000 MTPA, taking the total capacity to 18,000 MTPA. It is also investing Rs1.1bn in a 1.5bn tablet/year formulation CDMO facility and Rs350mn in a dedicated specialty chemicals facility, with both facilities targeted for commercialization in 3QFY27.

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

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News flow – Indian Pharma

1) IOL Chemicals & Pharmaceuticals is investing Rs3.5bn to expand its backward-integrated Ibuprofen capacity by 6,000 MTPA, taking the total capacity to 18,000 MTPA. It is also investing Rs1.1bn in a 1.5bn tablets/year formulation CDMO facility and Rs350mn in a dedicated specialty chemicals facility under a long-term tolling arrangement, with both facilities targeted for commercialization in 3QFY27.

2) Biocon has entered a partnership with Bahiafarma and Bionovis for Pertuzumab in Brazil, securing 100% allocation under Brazil's 10-year Productive Development Partnership (PDP) program. The deal provides exclusive access to Brazil's public healthcare market, representing ~70% of Pertuzumab demand, with Biocon to receive milestone payments and a share of revenue, while production is expected to be progressively localized in Brazil.

3) Neuland Laboratories approved Rs1.26bn capex for the purchase of ~134 acres of land at Auro Industrial City, Kakinada, Andhra Pradesh, for future expansion. The company also has a right of first refusal for an additional ~66 acres, potentially increasing the total land parcel to ~200 acres; the acquisition will be funded through internal accruals.

4) Novartis India has agreed to acquire Pfizer's Minipress (Prazosin Hydrochloride) trademark for Rs12.5bn through an asset purchase agreement and trademark assignment. Minipress generated Rs2.3bn revenue in MAT Jul-26, growing at a 6.3% CAGR over the past four years versus 9% for the category.

5) Novartis India has entered the ophthalmology segment through an exclusive promotion and distribution agreement with Novartis Healthcare for its retina portfolio, comprising Accentrix (Ranibizumab) and Pagenax (Brolucizumab). The company will pay Rs100mn upfront for exclusive commercial rights in India.

6) Morepen Laboratories has completed the first phase of its API and CDMO manufacturing capacity expansion ahead of schedule, increasing installed reactor capacity from 535 KL to 614 KL. The expansion is aimed at supporting the scale-up of commercial CDMO supplies, the existing API business, and future customer programmes.

7) HRV Pharma plans to invest Rs1.5bn, to build capabilities in peptide manufacturing and high-potency oncology APIs. The company will invest up to Rs500mn in cGMP peptide capacity through a strategic capacity-underwriting arrangement, expected to be ready in 6–8 months, and Rs1bn in a JV to develop 20–30 oncology and high-potency APIs in phases.

8) Activ Pine LLP, backed by True North, sold 16.5mn shares (1.02% stake) in Biocon at Rs385/share on 9-Sep-26, worth ~Rs6.38bn. The shares were acquired by 12 domestic and global institutional investors.

9) Lupin has secured approval to manufacture and market its pegfilgrastim biosimilar in India, with production planned at its Nagpur facility. The product, with brand name 'Armlupeg', is already approved in the US, where commercial rights have been out-licensed to Valorum Biologics.

10) Sun Pharma's subsidiaries Sun Pharmaceutical Industries, Taro Pharmaceutical Industries, and Taro USA have settled claims with a plaintiff in the Generic Pharmaceuticals Pricing Antitrust Litigation in the US for a confidential amount. The settlement provides a full release of claims against the subsidiaries and their current/former affiliates, directors, officers, and employees, with other terms remaining confidential.

News flow – Global innovators, CDMOs, and generic players

1) Gan & Lee Pharmaceuticals has signed an exclusive license agreement with Menarini for Bofanglutide, a once-every-two-weeks GLP-1 RA being developed for obesity/overweight. Gan & Lee will receive €62mn upfront and up to €664mn in milestones, plus double-digit royalties. Menarini will handle registration and commercialization across 39 European and nearby markets, while Gan & Lee plans a global Phase 3 program.

2) Novo Nordisk's Wegovy pill reached ~183k prescriptions, up from 181k the prior week, while Eli Lilly's Foundayo rose nearly 8% to 47.5k prescriptions, both recording their highest weekly levels so far. The total GLP-1 prescriptions increased 5.4% over the latest four weeks, with Lilly's Tirzepatide share rising to ~57% from 49.5% last year, while Novo's Semaglutide remained broadly stable at ~37%.

3) Novo Nordisk said 40.4% of children aged 6 to under 12 with obesity treated with Semaglutide were no longer classified as having obesity after 68 weeks in the Phase 3 trial, assuming full treatment adherence. The trial met its primary endpoint, showing superior BMI reduction versus placebo, with safety and tolerability consistent with previous Semaglutide studies.

4) Roivant's Mosliciguat delivered positive Phase 2 results in 135 patients with pulmonary hypertension associated with interstitial lung disease (PH-ILD), achieving a 56.3% placebo-adjusted reduction in pulmonary vascular resistance at Week 16. The data supports advancement into Phase 3; Mosliciguat is being developed as a potential once-daily inhaled treatment (relevant for Sai Life).

5) Moonwalk Biosciences has raised $70mn in Series B funding, co-led by Alpha Wave Global and YK Bioventures, to advance its RNAi-based obesity pipeline. Its lead candidate MW101, targeting body fat metabolism and lipolysis rather than appetite suppression, is planned to enter human trials by end-CY27, with the company aiming to potentially avoid GLP-1-associated gastrointestinal side effects and muscle loss.

6) Formosa Pharmaceuticals has submitted a CTA in Europe for a clinical trial of TSY-110, its biosimilar to Roche's Kadcyla (Trastuzumab Emtansine) for HER2-positive breast cancer. The trial will assess safety, tolerability, pharmacokinetics, and immunogenicity versus Kadcyla, with TSY-110 positioned as a potential biosimilar for major regulated markets.

7) FDA has finalized the voluntary withdrawal of Bristol Myers Squibb's Krazati's (Adagrasib) indication in KRAS G12C-mutated colorectal cancer, following failure of the Phase 3 trial to meet its co-primary PFS and OS endpoints. The withdrawal affects the CRC indication only; Krazati's accelerated approval in second-line KRAS G12C-mutated NSCLC remains unaffected (relevant for Syngene).

8) Celltrion has received regulatory clearance for amended Phase 3 trial plans for its Keytruda biosimilar CT-P51 in the US and Darzalex biosimilar CT-P44 in South Korea. CT-P51's trial will enroll meaningfully lower number of patients with previously untreated metastatic non-squamous NSCLC vs earlier plans, while CT-P44's trial will enroll 394 patients with relapsed/refractory multiple myeloma (relevant for Zydus, Ipca, Dr Reddy's, Biocon and Cipla).

9) Evommune's oral MRGPRX2 antagonist EVO756 failed to meet primary and secondary endpoints in a Phase 2b trial in 121 adults with moderate-to-severe atopic dermatitis, and the company will not advance the drug in AD. EVO756 was generally well tolerated and will continue to be evaluated for migraine prophylaxis (relevant for Piramal Pharma).

10) Sandoz has unveiled its Bio100 strategy, targeting a portfolio of >100 biosimilars by CY40, up from 13 currently, while aiming to increase its share of biosimilar loss-of-exclusivity opportunities from ~50% to ~80% from 2035. The company targets mid-to-high single-digit CAGR in net sales during CY25–30 and plans a $300mn investment in a new Ljubljana, Slovenia drug-substance facility, adding 8kl of biologics capacity by CY29.

11) AbbVie's Qulipta (Atogepant) met the primary endpoint in the Phase 3 trial, showing a greater reduction in menstrual migraine days versus placebo over three menstrual cycles. Qulipta reduced migraine days by 1.2 days vs 0.4 days with placebo, a 0.8-day advantage, while also delivering statistically significant improvements across all eight secondary endpoints; AbbVie plans to submit the data to global regulators (relevant for Sai Life).

12) Novo Nordisk's Wegovy (Semaglutide) has been approved in China for the treatment of metabolic dysfunction-associated steatohepatitis (MASH), making it the first GLP-1 receptor agonist approved in the country for the condition. The approval expands Wegovy's established indications in weight management and cardiovascular health into liver health.

13) Samsung Biologics has signed a $262mn manufacturing agreement with a European pharmaceutical company, with production at its Songdo, South Korea facility and commitments running through CY33. The deal takes Samsung Biologics's cumulative contract value above $21.9bn.

Key regulatory developments

1) FDA finalized guidance allowing 505(b)(2) drug sponsors to request therapeutic equivalence (TE) ratings even when their products differ in inactive ingredients from the

reference drug. The guidance requires FDA to issue a TE decision at approval or within 180 days, potentially enabling faster market entry and substitution for eligible follow-on products.

2) FDA said it is open to flexible trial designs for psychedelic therapies targeting severe mental illnesses such as major depressive disorder and PTSD. The agency may accept active or lower-dose comparators, consider initial approvals based on ~12 weeks of efficacy with longer-term safety follow-up, and allow intermittent dosing, while relying on post-marketing studies and REMS to manage safety risks.

3) The FTC has urged the US Court of Appeals for the Fourth Circuit to recognize that acquiring pending patent applications can constitute exclusionary conduct under antitrust law. The case involving Amgen's Enbrel could create a new avenue for biosimilar developers to challenge patent transactions and thickets used to delay competing products and maintain market exclusivity.

USFDA inspections/inspection outcomes

1) The USFDA completed a Section 704(a)(4) records assessment at Dr Reddy's Laboratories's API manufacturing facility in Mexico between 17-Jul-26 and 8-Sep-26. The agency issued a Form FDA 2953 with two observations.

2) Strides Pharma Science said the USFDA conducted a routine cGMP inspection at its Alathur, Chennai formulations facility from 2-Sep-26 to 11-Sep-26. The inspection concluded with three Form 483 observations.

3) Senores Pharmaceuticals said the USFDA completed an inspection at its subsidiary Apnar Pharma's Vadodara manufacturing facility from 7-Sep-26 to 11-Sep-26. The inspection concluded with one minor procedural observation and no GMP-related observations.

4) Jubilant Pharmova said the USFDA has classified its subsidiary Jubilant HollisterStier's Spokane, Washington CMO facility as VAI (Voluntary Action Indicated) following the inspection conducted from 8-Jun-26 to 17-Jun-26.

5) Alembic Pharmaceuticals said the USFDA successfully completed an unannounced onsite bioequivalence inspection at its Vadodara facility from 31-Aug-26 to 10-Sep-26. The inspection concluded with no Form 483 observations.

6) Indoco Remedies said the UK MHRA completed a cGMP inspection at its Plant I solid oral dosage facility in Goa from 7-Sep-26 to 9-Sep-26. The inspection concluded with no critical or major observations.

7) Aurobindo Pharma said the USFDA completed an inspection at Apitoria Pharma's Unit-IV API manufacturing facility in Andhra Pradesh from 7-Sep-26 to 11-Sep-26. The inspection concluded with zero observations.

Management commentary

Lupin's Executive Director, Global CFO and Head of API Plus SBU Ramesh Swaminathan said the proposed 100–200% US tariffs on generic drugs could increase medicine prices or cause shortages, as intense competition may limit manufacturers' ability to pass on higher costs. He told US manufacturing would require firm volume and pricing commitments and potentially government support. Lupin would continue to invest in both Somerset and coral springs manufacturing units to manufacture products that are feasible from an economic point of view. Lupin remains focused on generic Semaglutide through its Zydus partnership and sees significant long-term potential in the GLP-1 segment. He also said the company is scaling up its biosimilars business, targeting ~$500mn revenue over the next five years, with Pegfilgrastim and Ranibizumab among key launches and plans to expand into Nivolumab, Denosumab, and Pertuzumab in India. Lupin has invested ~Rs5bn in biosimilar manufacturing capacity and plans to take this to Rs7bn, while its current capacity of 11kl of mammalian and 100l of microbial capacity is also being expanded.

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

Final Approval: gBriviact (Zhejiang Jutai Pharma), gImbruvica (Hetero Labs), gAldactazide (Rubicon), Isotretinoin (Aurobindo)

Tentative Approval: gFotivda (Glenmark)

Management changes/Corporate actions

1) Eris Lifesciences's Executive Director and COO Krishnakumar Vaidyanathan has resigned from his duties effective 30-Sep-26.

2) Abbott India's Company Secretary and Compliance Officer (KMP) Sangeeta Shetty has resigned, and will be relieved from duties effective 28-Oct-26.

3) Gland Pharma approved the acquisition of 100% of Gland Pharma USA from its wholly-owned subsidiary Gland Pharma International. Following completion, Gland US will become a direct wholly-owned subsidiary of Gland Pharma.

4) Alembic Pharmaceuticals incorporated Alembic Pharmaceuticals Global FZCO, a wholly-owned subsidiary in Dubai, UAE, on 24-Aug-26. The company received intimation of the incorporation on 7-Sep-26.

5) Viyash Scientific has received the requisite Italian FDI/Golden Power approval for Alivira Animal Health's proposed acquisition of 100% of BioForLife Italia. The transaction timeline has been revised and is now expected to close within two months, with all other material terms unchanged.

6) Natco Pharma approved a rights issue of up to Rs13bn to eligible shareholders, with the record date and issue terms to be announced subsequently.

7) Granules India promoter Dr Krishna Prasad Chigurupati sold 17.2mn shares through a block deal/open market transaction on 11-Sep-26, with participation from institutional investors. The sale was undertaken to fund the second tranche of the ongoing preferential issue and support growth initiatives.

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

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