Biobusiness briefs

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FDA new drug approvals in Q1 2025

While the fourth quarter of 2024 continued the trend seen throughout the year of increasing momentum in FDA new drug approvals, with 16 such approvals handed out, the first quarter of 2025 has definitely seen that trend bucked. Only seven new drug approvals were awarded by the FDA in Q1 (Table 1), notably lower than in any individual quarter in 2024. By contrast, the commercial expectations for the latest quarter's approval cohort are much more positive, driven in large part by two potential blockbuster products.

The first and potentially most commercially important approval in the quarter was Daiichi Sankyo and AstraZeneca's Datroway (datopotamab deruxtecan). This TROP2-targeted antibody–drug conjugate (ADC) is now approved to treat unresectable or metastatic, hormone receptor-positive, HER2-negative breast cancer in patients who have received prior endocrine-based therapy and chemotherapy for unresectable or metastatic disease. While this approval for breast cancer is the first for a TROP2-directed ADC, it is less commercially relevant than other potential uses for the product. Datroway will probably face substantial competition in breast cancer, including from Daiichi Sankyo and AstraZeneca's initial collaboration success, the HER2-targeted ADC Enhertu (trastuzumab deruxtecan). The potentially bigger prize is non-small-cell lung cancer (NSCLC), the indication for which datopotamab deruxtecan was initially filed with the FDA. This regulatory application was subsequently withdrawn and refiled earlier this year in a more targeted patient setting, reducing the likely market. Evaluate Pharma forecasts for the ADC were revised down as a result, with 2030 forecasts of US$4.3 billion at the time of writing. There is potential for volatility in the forecasts in the coming months as the launch in breast cancer and application in NSCLC progress.

The second potential blockbuster approval was the much-anticipated Journavx (suzetrigine) from Vertex Pharmaceuticals, an $Na_V1.8$ sodium channel blocker approved to treat moderate to severe acute pain. The product is the first novel pain medication approved for decades, and notable also as a non-opioid analgesic. Evaluate Pharma forecasts sales of $2.9 billion for the drug in 2030, including further uses in chronic pain settings that Vertex is pursuing for the product. However, mixed results from a phase II trial in one chronic pain setting, lumbosacral radiculopathy, that were announced late last year, plus premium pricing as it enters the US market, are acting as potential headwinds on sentiment for the product, despite the breakthrough.

A third approval attracting substantial forecasts is SpringWorks Therapeutics' MEK1/2 inhibitor Gomekli (mirdametinib), approved to treat patients with neurofibromatosis type 1 who have symptomatic plexiform neurofibromas not amenable to complete resection. The product is the first approved for both adults and children with the condition, and has a 2030 sales forecast of $824 million.

The other approvals in the quarter were GSK's first-in-class antibiotic Blujepa (gepotidacin) to treat uncomplicated urinary tract infections, Sanofi's siRNA therapeutic Qfitlia (fitusiran) to prevent or reduce the frequency of bleeding episodes in haemophilia A or B, Ono Pharmaceutical's kinase inhibitor Romvimza (vimseltinib) to treat symptomatic tenosynovial giant cell tumours, and Medexus Pharmaceuticals' alkylating agent Grafapex (treosulfan) for use in combination with fludarabine as a preparative regimen for allogeneic haematopoietic stem cell transplantation in specific haemo-oncology settings.

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Competing interests
The author declares no competing interests.

Table 1 | Select FDA new drug approvals in Q1 2025

Date	Drug (brand name; company)	Mechanism	Indication	2030 global sales forecast (US$)
17 Jan	Datopotamab deruxtecan (Datroway; Daiichi Sankyo, AstraZeneca)	TROP2-targeted ADC	HR-positive, HER2-negative breast cancer	$4,289 million
21 Jan	Treosulfan (Grafapex; Medexus Pharmaceuticals)	Bifunctional alkylating agent	Part of a preparative regimen for allogeneic HSCT	$110 million
30 Jan	Suzetrigine (Journavx; Vertex Pharmaceuticals)	$Na_V1.8$ inhibitor	Moderate to severe acute pain	$2,902 million
11 Feb	Mirdametinib (Gomekli; SpringWorks Therapeutics)	MEK1/2 inhibitor	Neurofibromatosis type 1	$824 million
14 Feb	Vimseltinib (Romvimza; Ono Pharmaceutical	CSF1R inhibitor	Tenosynovial giant cell tumours	$169 million
25 Mar	Gepotidacin (Blujepa; GSK)	Topoisomerase II inhibitor	Uncomplicated urinary tract infections	$386 million
28 Mar	Fitusiran (Qfitlia; Sanofi)	Antithrombin-targeted siRNA	Haemophilia A or B	$352 million

ADC, antibody–drug conjugate; CSF1R, colony stimulating factor 1 receptor; HER2, human epidermal growth factor receptor 2; HR, hormone receptor; HSCT, haematopoietic stem cell transplantation; mAb, monoclonal antibody; siRNA, small interfering RNA. Source: EvaluatePharma April 2025, Evaluate.