

Novel Drug Approval

July 2025

- **Ekterly (sebetralstat)** – Augment HAE on-demand therapy; FDA approval on July 3 and highlighted in both “New Drug Approvals” and “Novel Drug Approvals” sections
- **Kirsty (insulin aspart-xjhz)** – Interchangeable insulin biosimilar, approved July 15
- **Zegfrovy (sunvozertinib)** – EGFR exon 20 inhibitor for NSCLC, approved July 2
- **Lynozyl (linvoseltamab-gcpt)** – Bispecific antibody targeting multiple myeloma; FDA accelerated approval July 2; prior EU conditional authorization in April.

June 2025

- **Andembry (garadacimab-gxii)** – Prophylaxis for hereditary angioedema; approved June 16
- **Ibtrozi (taletrectinib)** – ROS1+ NSCLC therapy; June 11
- Additional approvals: **Arynta** (lisdexamfetamine dimesylate), **Harliku** (nitisinone), and **Yeztugo** (lenacapavir) all on June 16–18
- **Vimseltinib (Romvimza)** – For tenosynovial giant cell tumor; FDA approval mid-February.

May 2025

- **Avutometinib/defactinib (Avmapki Fakzynja Co-Pack)** – KRAS-mutant ovarian cancer, approved. May 8 https://en.wikipedia.org/wiki/Avutometinib/defactinib?utm_source=chatgpt.com.
- Continued biosimilar pathway advancement with products like **Starjemza** (ustekinumab-hmny) approved May 22.

April 2025

- **Vanrafia (atrasentan)** – First selective endothelin A receptor antagonist for primary IgA nephropathy (proteinuria reduction); accelerated approval April 2–3, 2025.
- **Valtoco (diazepam nasal spray)** – Extended-label approval for ages 2–5 years to treat seizure clusters; approved April 16, 2025.

- **Rinvoq (upadacitinib)** – Once-daily oral treatment approved for giant cell arteritis (GCA); FDA approval April 29, 2025.

March 2025

- **Blujepa (Gepotidacin)** – Novel oral antibiotic for uncomplicated urinary tract infections (UTIs) in females ≥ 12 years; approved March 25, 2025.
- **Encelto (Revakinagene taroretcel)** – Intravitreal cell-based gene therapy for macular telangiectasia type 2; granted March 21, 2025.
- **Osenvelt (denosumab-bmwo)** – Biosimilar to Xgeva (denosumab) for bone-related conditions; approved March 3, 2025.
- **Imfinzi (durvalumab)** – Approved as neoadjuvant and adjuvant treatment with gemcitabine/cisplatin for muscle-invasive bladder cancer (MIBC) on March 28, 2025.
- **Cabozantinib (Cabometyx)** – Approved for previously treated advanced neuroendocrine tumors; March 31, 2025.
- **Pembrolizumab (Keytruda)** combined therapy – First-line treatment for HER2-positive gastric/GEJ adenocarcinoma with PD-L1 CPS ≥ 1 ; approved March 19, 2025.
- **Omlyclo (omalizumab-igec)** – First interchangeable biosimilar to Xolair, for asthma, nasal polyps, urticaria, and IgE-mediated food allergy; approved March 9, 2025.

February 2025

- **Vimseltinib (Romvimza)** – First-in-class kinase inhibitor indicated for symptomatic tenosynovial giant cell tumor (TGCT); FDA approval on February 14, 2025.
- **Mirdametinib (Gomekli)** – Oral kinase inhibitor for neurofibromatosis type 1 (plexiform neurofibromas); approved February 11, 2025.

Reference: Drugs.com