

Recent New Drug Approval

The following approved molecules represent *new chemical or biological drugs* - not just generics or new formulations — with regulatory

approval in late 2025

1. **Zoliflodacin (Nuzolve)**
 - **Type:** NME — First-in-class spiropyrimidinetrione bacterial topoisomerase inhibitor
 - **Indication:** Uncomplicated urogenital gonorrhea
 - **Approving Agency:** FDA
 - **Approved:** 12 Dec 2025
2. **Lerodalcibep (Lerochol)**
 - **Type:** New proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor biological
 - **Indication:** Elevated LDL cholesterol
 - **Approving Agency:** FDA
 - **Approved:** 12 Dec 2025
3. **Amivantamab and hyaluronidase combination (Rybrenta Faspro)**
 - **Type:** Bispecific antibody biologic
 - **Indication:** EGFR-mutated non-small cell lung cancer
 - **Approved:** 17 Dec 2025
4. **Depemokimab-ulaa (Exdensur)**
 - **Type:** IL-5 antagonist biologic
 - **Indication:** Severe eosinophilic asthma
 - **Approved:** 16 Dec 2025
5. **Sibeprenlimab-szsi (Voyxact)**
 - **Type:** APRIL blocker biologic
 - **Indication:** Primary immunoglobulin A nephropathy
 - **Approved:** 25 Nov 2025
6. **Sevabertinib (Hyrnuo)**
 - **Type:** Reversible tyrosine kinase inhibitor (NME)
7. **Plozasiran (Redempro)**
 - **Indication:** HER2-mutant non-small cell lung cancer
 - **Approved:** 19 Nov 2025
8. **Ziftomenib (Komzifti)**
 - **Type:** siRNA therapeutic (NME)
 - **Indication:** Familial chylomicronemia syndrome
 - **Approved:** 18 Nov 2025
9. **Narsoplimab-wuug (Yartemlea)**
 - **Type:** MASP-2 inhibitor monoclonal biologic
 - **Indication:** Relapsed/refractory NPM1-mutated acute myeloid leukemia
 - **Approved:** 13 Nov 2025
10. **Mitapivat (Aqvesme)**
 - **Type:** Pyruvate kinase activator (NME small molecule)
 - **Indication:** Anemia in alpha-/beta-thalassemia
 - **Approved:** 23 Dec 2025
11. **Aficamten (Myqorzo)**
 - **Type:** Cardiac myosin inhibitor (NME)
 - **Indication:** Symptomatic obstructive hypertrophic cardiomyopathy
 - **Approved:** 19 Dec 2025

Reference: *Drugs.com*