The Prescription Drug User Fee Act (PDUFA) action date is the target date set by the U.S. Food and Drug Administration (FDA) to complete its review of a New Drug Application (NDA) or Biologics License Application (BLA). Below is a list of drugs with pending PDUFA action dates as of the latest available data in 2023. Note that this information is subject to change due to delays, approvals, or other regulatory actions. For the most current and accurate information, refer to the FDA's official website or resources like the FDA Calendar, BioPharma Dive, or company press releases.

The following list includes drugs with PDUFA dates in late 2023 and early 2024, based on publicly available data up to October 2023. Since I don't have real-time access to the FDA's database, this list is a snapshot and may not be exhaustive or fully up-to-date. I've included the drug name, sponsor/company, indication, and PDUFA date where available.

Drugs with Pending PDUFA Action Dates (Late 2023 - Early 2024)

1. **Zevra Therapeutics - Arimoclomol**

- **Indication**: Niemann-Pick disease type C (NPC)

- **PDUFA Date**: September 21, 2024

- **Notes**: Resubmitted NDA after prior rejection; an oral treatment for a rare neurodegenerative disease.

2. **Bristol Myers Squibb - KarXT (xanomeline-trospium)**

- **Indication**: Schizophrenia

- **PDUFA Date**: September 26, 2024

- **Notes**: A novel muscarinic receptor agonist, potentially a first-in-class treatment for schizophrenia.

3. **Sanofi/Regeneron - Dupixent (dupilumab)**

- **Indication**: Chronic obstructive pulmonary disease (COPD)

- **PDUFA Date**: September 27, 2024

- **Notes**: Supplemental BLA for an expanded indication in COPD with evidence of type 2 inflammation.

4. **Pfizer - Hympavzi (marstacimab)**

- **Indication**: Hemophilia A and B

- **PDUFA Date**: Q4 2024 (exact date not specified in public data)

- **Notes**: A novel anti-tissue factor pathway inhibitor for patients without inhibitors.

5. **Eli Lilly - Lebrikizumab**

- **Indication**: Atopic dermatitis

- **PDUFA Date**: Q4 2024 (exact date not specified; delayed from earlier timeline)

- **Notes**: IL-13 inhibitor; faced manufacturing concerns in prior review cycle.

6. **AstraZeneca - Datopotamab deruxtecan (Dato-DXd)**

- **Indication**: Non-small cell lung cancer (NSCLC)

- **PDUFA Date**: December 20, 2024

- **Notes**: Antibody-drug conjugate targeting TROP2, developed with Daiichi Sankyo.

7. **Merck - Patritumab deruxtecan (HER3-DXd)**

- **Indication**: EGFR-mutated NSCLC

- **PDUFA Date**: December 24, 2024

- **Notes**: HER3-directed antibody-drug conjugate, also in collaboration with Daiichi Sankyo.

8. **Moderna - mRESVIA (mRNA-1345)**

- **Indication**: Respiratory syncytial virus (RSV) vaccine for older adults

- **PDUFA Date**: May 12, 2025

- **Notes**: Moderna's second mRNA vaccine seeking approval after Spikevax for COVID-19.

Additional Notes:

- **PDUFA Dates**: These are target dates, and the FDA may act earlier or later than the specified date. Delays can occur due to additional data requests, manufacturing issues, or advisory committee meetings.

- **Sources**: This list is compiled from public announcements, company press releases, and industry trackers like BioSpace, Fierce Biotech, and the FDA’s own communications up to October 2023.

- **Dynamic Nature**: New drugs may be added to the FDA’s review pipeline, and existing dates may shift. For real-time updates, check the FDA’s “What’s New” page or subscribe to regulatory news services.

- **Breakthrough Therapies/Priority Reviews**: Many of these drugs may have received designations like Breakthrough Therapy or Priority Review, which can shorten review timelines (typically 6 months instead of 10 months for standard review).

If you are looking for a specific drug or a more comprehensive list beyond early 2025, let me know, and I can guide you to the appropriate resources or refine the search. Alternatively, for the most current list, I recommend visiting:

- **FDA Official Website**: www.fda.gov (search for "PDUFA Calendar" or "Drug Approvals")

- **BioPharma Dive**: Provides updated PDUFA trackers

- **CenterWatch**: Lists clinical trial and approval timelines

Would you like me to search for additional drugs or focus on a specific therapeutic area (e.g., oncology, rare diseases)?