APPROVED FDA DRUGS IN 2023

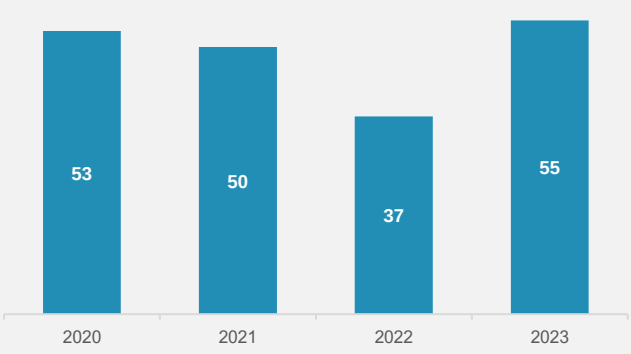
A DEEP DIVE INTO KEY ELEMENTS

In 2023, the **FDA's Center for Drug Evaluation and Research (CDER) approved 55 new drugs, a nearly 50% surge from 2022**, owing to the variability caused by the absence of COVID-related inspection delays. Outperforming all other companies, Pfizer received seven approvals, achieving twice the accomplishments of the past three years. **Oncology and neurology topped the charts for number of approvals, receiving 13 and 9 approvals each.**

Current Landscape: Approved Drugs in 2023

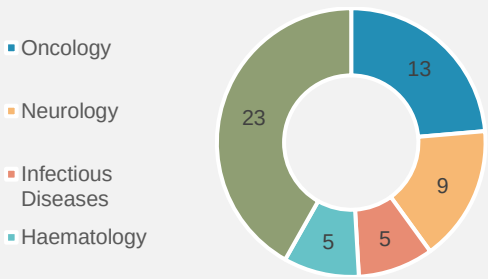
A total of **55 drugs and 16 gene therapies** were approved by the FDA in 2023. By brand criteria, **Pfizer** accomplished the maximum number of approvals, and by therapy area, oncology was the leading segment in number of approvals attained.

Number of FDA Approvals in 2023
2020–present



- In 2023, the FDA's CDER approved 55 new drugs, marking a nearly 50% increase compared to the 2022 approvals.
- The 10-year average for CDER approvals is now at 46 per year, the highest in over two decades.
- The variation in approvals between 2022 and 2023 may be attributed to COVID-related inspection delays affecting some approvals.
- Pfizer secured seven FDA approvals in 2023, surpassing any other company and doubling the achievements of drugmakers over the past three years.
- The FDA maintained a consistent pace, granting approvals for an expanding array of cell and gene therapies, vaccines, and blood products.

Number of FDA Approvals by Therapy Area



- In terms of therapeutic area, oncology remains the leading category for approvals, with CDER granting approval for 13 (24%) new cancer therapies in 2023.
- Following closely, neurology secured the second position with nine (16%) approvals, in line with recent patterns.
- Infectious diseases and hematology shared the third spot, each receiving approval for 5 (9%) therapies.

Oncology Segment: Highlights

Company	Highlight
AstraZeneca	• Astra Zeneca's first-in-class AKT inhibitor received approval in combination with fulvestrant for metastatic breast cancer. Analysts forecast peak sales of around USD 690 Mn for the drug.
SpringWorks Therapeutics	• SpringWorks announced its first γ-secretase inhibitor received FDA approval for rare desmoid tumors from. The annual peak sales of around USD 650 Mn are forecast for the drug.
Johnson & Johnson	• The initial approval for multiple myeloma of the first GPRC5D × CD3-targeted T-cell engager, a bispecific antibody that mobilizes T-cells for cancer cell elimination, has been granted to J&J. • The drug is anticipated to achieve approximately USD 260 Mn in annual peak sales.
GSK	• Approval has been granted for a JAK1/JAK2/ACVR1 inhibitor targeting myelofibrosis patients experiencing anemia. • Analysts project peak sales to reach USD 930 Mn for the drug.

Gene Therapies Approved in 2023: Key Highlights

Bluebird bio's SCD gene therapy, **Lyfgenia**, Beremagene's **geperpavec**, and **Casgevy**, the CRISPR–Cas9 gene editor for sickle cell disease were amongst the notable gene therapies that received FDA approval

- CBER approved the first **CRISPR–Cas9-based gene editor, Casgevy (exagamglogene autotemcel)**, for sickle cell disease (SCD). It's an ex vivo gene-edited cell therapy using BCL11a transcription factor modification.
- Bluebird bio's SCD gene therapy, Lyfgenia (lovotibeglogene autotemcel), gained approval. It uses a lentiviral vector system to insert a transgene and is priced at USD 3.1 Mn.
- Krystal Biotech's beremagene geperpavec received approval for dystrophic epidermolysis bullosa (DEB), the first gene therapy for topical use in a re-dosable format.
- CellTrans's donislecel (Lantidra) became the first FDA-approved cell therapy for type 1 diabetes patients unable to approach target HbA1c levels.
- Seres Therapeutics' and Nestlé's Vowst got FDA approval for preventing Clostridioides difficile recurrence, the first pharmaceutical-grade orally administered faecal microbiota product.

New Entrants for Approval: Expected Timelines for 2024

Sponsor	Indication	Expected Approval
Astellas	Gastric cancer	January
Iovance	Melanoma	February
Madrigal/Synta	NASH	March
Merck & Co./Acceleron	PAH	March
Moderna	RSV prevention	April
Eli Lilly	Alzheimer disease	Q1
Abeona	RDEB	May
Merck & Co.	NSCLC	June
Geron	Transfusion-dependent anaemia	June

- Astellas's zolbetuximab offers a modestly effective option for metastatic gastric cancer, addressing a claudin-18.2-targeted pipeline.
- Madrigal's resmetirom, a thyroid hormone receptor β agonist, aims to be the first therapy for non-alcoholic steatohepatitis following Intercept's setbacks.

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