

# Top 10 Novel Drugs Approved by the FDA in 2023 and Other Pharma Breakthroughs to Look Out for

2023 saw an uptick in the number of FDA drug approvals with Oncology, Immunology and Infectious diseases in spotlight

AHMEDABAD, GUJARAT, INDIA, February 27, 2024 /EINPresswire.com/ -- The U.S. Food and Drug



Oncology continues to be the dominant sector for new drug approvals in 2023, with 16 drugs greenlit, followed by immunology, infectious diseases, rare diseases as other areas in spotlight"

*Dr. Purav Gandhi*

Administration recorded a stellar increase in the drug approvals compared to 2022 - with as much as 50% more drugs receiving approval in 2023 than in 2022, which saw only 37 drugs being approved. This year, the agency approved a notable 55 drugs, recording the second-highest total in the last 30 years. While reasons for the increase are being speculated, it is largely being attributed to COVID-related inspection delays in 2022 that led to significant backlog accumulated from yesteryears.

As [Healthark Insights'](#) report on '[Top 10 Novel Drugs of](#)

[2023'](#) highlights, Oncology continues to be the dominant sector for new drug approvals in 2023, with 16 drugs greenlit, including four promising bispecifics. Other sectors in spotlight include infectious diseases, rare diseases, and immunology. A significant highlight was the emergence of long-awaited RSV vaccines. GSK led the way in May with Arexvy for adults over 60, followed by Pfizer securing two approvals for Abrysvo. Notably, July saw Sanofi and AstraZeneca gain approval for their protective antibody, Beyfortus, specifically targeting infants.

Another key area seeing significant activity in drug development is Alzheimer's disease, where Leqembi from Biogen is being considered as a new ray of hope after the failure of Aduhelm. Eli Lilly is also eyeing an approval for its drug in the same space, the drug is expected to be a close competitor with higher efficacy.

The 55 drugs approved this year are divided between 17 biologics, 9 TIDES (five peptides and four oligonucleotides) and 29 so-called small molecules. In total, 38 new chemical entity (NCE) drugs (TIDES and small molecules) received FDA approval. As many as 36 of the 55 novel drug approvals of 2023 (65%) used one or more expedited programs. Out of those, 20 (36%) of the

novel approvals were first-in-class, 9 (16%) received accelerated approval, 9 (16%) were breakthrough therapies, 25 (45%) were fast track, 28 (51%) were orphan drugs, and 31 (56%) got priority review designation.

FDA demonstrated efficiency in bringing out therapies to the market. It approved 46 of the 55 novel drugs of 2023 (84%) on the 'first cycle' of review. This high percentage is in part reflective of the extent to which FDA staff provided the clarity to drug developers. Throughout 2023, FDA met or exceeded the PDUFA goal date for taking action on 89% (49 of 55) of the novel drugs approved. Thirty-five of the 55 novel drugs approved in 2023 (64%) were approved in the U.S. before any other country.

In 2023, Pfizer secured the highest number of FDA approvals among all pharmaceutical companies, with a remarkable seven nods. This achievement surpasses not only the nearest competitor by more than double, but also doubles the average approvals each company received in the past three years. The last time a company came close to Pfizer's performance was in 2019, with Novartis securing six approvals from FDA.

2023 also saw multiple drugs which were the first ever treatment for the disease including Skyclarys for Friedrich's ataxia, Daybue for Rett Syndrome, and Sohonos for fibrodysplasia ossificans progressive. The industry's drug development and approvals are back at their peak levels, which indicates that the workflow disruptions, staffing and bandwidth issues and, most importantly, communications with developers, have hopefully been improving. It is anticipated that similar level of FDA approvals would be seen in 2024 and the years to come.

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