

# Biopharmaceutical Innovation in Fighting HIV/AIDS

The human immunodeficiency virus (HIV), the virus that causes acquired immune deficiency syndrome (AIDS), was first identified in the United States more than 40 years ago.<sup>i</sup> Since then, expanded prevention and treatment options have helped patients by bringing down death rates, increasing adherence, improving the quality of life for patients and paving the way for future research focused on preventing the disease.

According to the U.S. Centers for Disease Control and Prevention (CDC), nearly 1.2 million people are living with HIV in the United States today.<sup>ii</sup> While HIV is still fatal if left untreated, thanks to innovative medicines, it is now a chronic manageable disease. This dramatic change followed the introduction of antiretroviral therapy (ART) in the mid-1990s, which transformed treatment, leading to a 91% decline<sup>iii</sup> in death rates due to HIV/AIDS and an estimated 862,000 averted deaths in the United States.<sup>iv</sup> In fact, between 2010 and 2017 alone, the death rate has declined by nearly half and CDC attributes much of this decline to improvements in early diagnosis and helping people get on and stay on lifesaving treatment.<sup>v</sup>

While advances have been made, there was an estimated 36,801 new HIV infections in the U.S. in 2019,<sup>vi</sup> and HIV continues to have a disproportionate impact on certain patient populations, particularly racial and ethnic minorities, as well as gay, bisexual, and other men who have sex with men.<sup>vii</sup> To ensure these and all communities can fight HIV, it is vital to have early and uninterrupted access to effective antiretroviral medications that suppress the virus and keep it at undetectable levels for the rest of their lives.



## Advances in Medical Innovation

The evolution of HIV/AIDS treatments is a testament to biopharmaceutical perseverance in the face of tremendous odds. In the 1980's, HIV/AIDS was considered an acute and fatal disease. Today, HIV/AIDS is no longer an acute fatal illness and patients diagnosed with the virus can expect a normal life expectancy with appropriate treatment.<sup>viii, ix</sup>

### → 1981-1986: The Epidemic Begins

In the early 1980's, predominantly gay men were becoming ill, and doctors were at a loss as to why. What was initially a disease impacting a portion of the population was soon seen in infants and female sexual partners of infected males. The symptoms they faced were later identified as AIDS, caused by HIV.

Researchers raced to understand the disease. Amid rising death rates, concerns about disease transmission developed a culture of fear, promoting discrimination and interfering with medical treatment. Fear and paranoia grew, and sick patients found themselves ostracized by society and without a treatment. In 1984, researchers had their first major breakthrough: HIV was identified as the cause of AIDS. As the number of deaths and infections rose, researchers turned all their efforts toward finding an effective treatment for HIV.<sup>x</sup>

## → 1987-1994: The First Effective Treatment Renews Hope

In 1987, researchers proved that antiviral medicines called nucleoside reverse transcriptase inhibitors (NRTIs) slowed the progression of AIDS in advanced cases.<sup>xi</sup> Through additional testing, researchers realized that the drug also helped manage symptoms for children and people in the early stages of the disease.

Despite these medical victories, the death toll continued to rise. In 1994, AIDS became the leading cause of death for all Americans ages 25 to 44.<sup>xii</sup> By then, 270,000 people had died in America from HIV/AIDS.

## → 1995-Today: Revolutionizing Treatment

The tide turned on HIV/AIDS with the discovery of antiviral medicines called protease inhibitors as a treatment. These inhibitors halted the growth of the disease by preventing infected cells from replicating and spreading the HIV virus. This discovery marked the beginning of highly active antiretroviral therapy (HAART), which would revolutionize the fight against HIV/AIDS. Death rates began declining rapidly and drug treatment became more efficient with combined treatment options.

Biopharmaceutical researchers quickly developed new medicines to compound the success of HAART. Treatments like nucleotide analogs, fusion inhibitors and CCR5 receptor antagonists restricted the replication of HIV and prevented it from entering cells altogether.

In recent years, continued advances in treatment have also brought novel classes of antiretroviral (ART) with new mechanisms of action to HIV patients who cannot manage the disease with available ART medications due to resistance, intolerance or safety considerations.<sup>xiii</sup>



## The Future of Fighting and Preventing HIV/AIDS

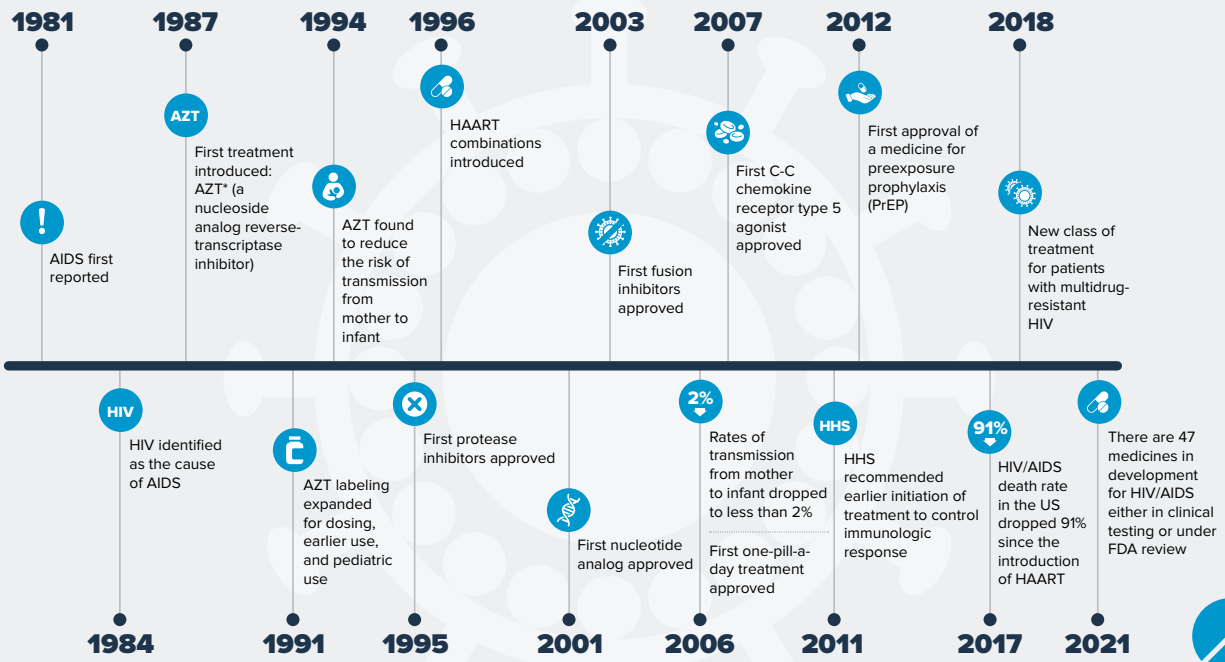
The biopharmaceutical industry has worked to improve medicines for patients with HIV/AIDS by developing ART treatments with fewer side effects, combinations that improve adherence as well as pre-exposure prophylaxis medicines (PrEP) to help prevent transmission of HIV. Additionally, studies have shown PrEP therapies can reduce the risk of getting HIV from sex by about 99% when taken daily.<sup>xiv</sup> Among people who inject drugs, PrEP reduces the risk of getting HIV by at least 74% when taken daily.<sup>xv</sup>

Today, the fight continues with the search for additional treatments, as well as vaccines, which could stop the spread of HIV by teaching the immune systems of healthy people how to fight off HIV before they are exposed. An analysis of medicines in clinical trials or under FDA review shows there are 47 HIV/AIDS medicines in development, including candidates designed to target and prevent HIV.<sup>xvi</sup>



# HIV/AIDS: Treatment Advances Build Over Time

Dramatic declines in death rates did not occur with one single breakthrough but rather through a series of advances providing important treatment options for patients over time.



\*AZT: Zidovudine



## HIV/AIDS Activists Advance Change

While innovative medicines have changed the trajectory of millions of patients' lives, HIV/AIDS is also a great study in the role of patients in drug development. HIV/AIDS activists played a vital role in bringing about continued advancements in medicine. Importantly, near the beginning of the epidemic, these activists brought their concerns about a lack of available treatment options for HIV/AIDS directly to the steps of the U.S. government and worked to raise awareness around key clinical trials at a time when death rates were increasing. AIDS activist group ACT UP! held demonstrations across the United States, including closing down the FDA for a day in 1988, to protest the slow process of drug approval driven in part by a lack of FDA resources. These activities have had far reaching impact on drug development overall, spurring FDA, Congress and Industry to work together to help ensure FDA is resourced appropriately to support the efficient and timely regulatory review process for innovative medicines through the creation of the Prescription Drug User Fee Act (PDUFA).

Before PDUFA, it often took FDA more than two years to review new medicines.<sup>xvii</sup> PDUFA subsequently has taken the median review time of a new medicine to just 10 months.<sup>xviii</sup> Since 1992 when the program was enacted, PDUFA has provided more timely access to more than 1,700 new drugs and biologics including treatments for cancer, rare diseases, cardiovascular, neurological and infectious diseases like HIV/AIDS.

PDUFA continues to play a critical role in strengthening the FDA's ability to review human drug applications. The program also provides biopharmaceutical companies with greater regulatory predictability, which fosters industry investment in research and development. At each five-year reauthorization of PDUFA, FDA and the biopharmaceutical industry have the opportunity to advance initiatives that further support innovation and enhance the regulatory review process. Learn more about reauthorization of the Prescription Drug User Fee Act and more at [PhRMA.org/PDUFA](https://PhRMA.org/PDUFA).

i Kaiser Family Foundation, June 21, 2021 <https://www.kff.org/hiv/aids/fact-sheet/the-hiv-aids-epidemic-in-the-united-states-the-basics/>

ii <https://www.cdc.gov/hiv/basics/statistics.html>

iii Centers for Disease Control and Prevention (CDC), National Center for Health Statistics. Health, United States, 2016: with chartbook on long-term trends in health. Published 2017. Accessed June 2018. <https://www.cdc.gov/nchs/data/abus/abus16.pdf>

iv CDC, NCHS, Deaths: Final Data for 2007. Vol. 58, #19, May 2010. [https://www.cdc.gov/NCHS/data/nvsr/nvsr58/nvsr58\\_19.pdf](https://www.cdc.gov/NCHS/data/nvsr/nvsr58/nvsr58_19.pdf); CDC, NCHS, Fast Stats, AIDS and HIV <https://www.cdc.gov/nchs/fastats/aids-hiv.htm>.

v Bosh KA, Johnson AS, Hernandez AL, et al. Vital Signs: Deaths Among Persons with Diagnosed HIV Infection, United States, 2010–2018. MMWR Morb Mortal Wkly Rep 2020;69:1717–1724.

vi <https://www.hiv.gov/hiv-basics/overview/data-and-trends/statistics>

vii <https://www.hiv.gov/hiv-basics/overview/data-and-trends/statistics>

viii Marcus JL et al. Comparison of Overall and Comorbidity-Free Life Expectancy Between Insured Adults With and Without HIV Infection, 2000-2016. JAMA Network Open, 3: e207954, June 2020.

ix <https://www.acpjournals.org/doi/abs/10.7326/m21-0065>

x <https://www.nytimes.com/1984/04/24/science/new-us-report-names-virus-that-may-cause-aids.html>

xi <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4143801/>

xii <https://www.cdc.gov/mmwr/preview/mmwrhtml/00040227.htm#:~:text=Among%20persons%20aged%2025%2D44%20years%2C%20HIV%20infection%20was%20the,Y-PLL%2D65%20from%20all%20causes.>

xiii <https://www.uspharmacist.com/article/newly-approved-hiv-medications>

xiv Centers for Disease Control and Prevention, Pre-Exposure Prophylaxis (PrEP), <https://www.cdc.gov/hiv/risk/prep/index.html>

xv CDC. [www.cdc.gov/hiv/basics/prep.html#](https://www.cdc.gov/hiv/basics/prep.html#)

xvi Number of medicines obtained through public government and industry sources, and the Springer "AdisInsight" database; current as of October 29, 2021.

xvii See FDA, "FY 1995 PDUFA Performance Report," <https://wayback.archive-it.org/7993/20170406002629/https://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/UserFeeReports/PerformanceReports/ucm117257.htm#DISCUSSIONOFFY95PERFORMANCE>

xviii Median approval time for a new medicine is 10 months for standard applications and 8 months for priority applications. See FDA, "FY 2019 Performance Report to Congress for the Prescription Drug User Fee Act" at 22, <https://www.fda.gov/media/138325/download>