

A SHOT AT ENDING AIDS

How new long-acting medicines could revolutionize the HIV response



The opportunity

The AIDS pandemic has claimed more than 42 million lives since it first appeared in the 1980s, the deadliest pandemic in a century.

Although huge progress has been made in the decades-long fight against AIDS, in 2023 alone, 1.3 million people acquired HIV, far higher than the target of 370 000 new infections by 2025. The virus is still winning. However, science has now delivered a unique new opportunity.

Breakthrough innovations have come to light that have proved to be more than 95% effective in preventing HIV infection with injections just twice a year. Once a year might even be possible. They could also be key for 40 million people living with HIV around the world who need better options for treatment.

It's not a cure or a vaccine, but it could be a game-changer if made accessible to all who could benefit.

In the past, the world has taken too long to enable global access and affordability, with deadly consequences. This time, seizing the opportunity requires a moonshot approach...

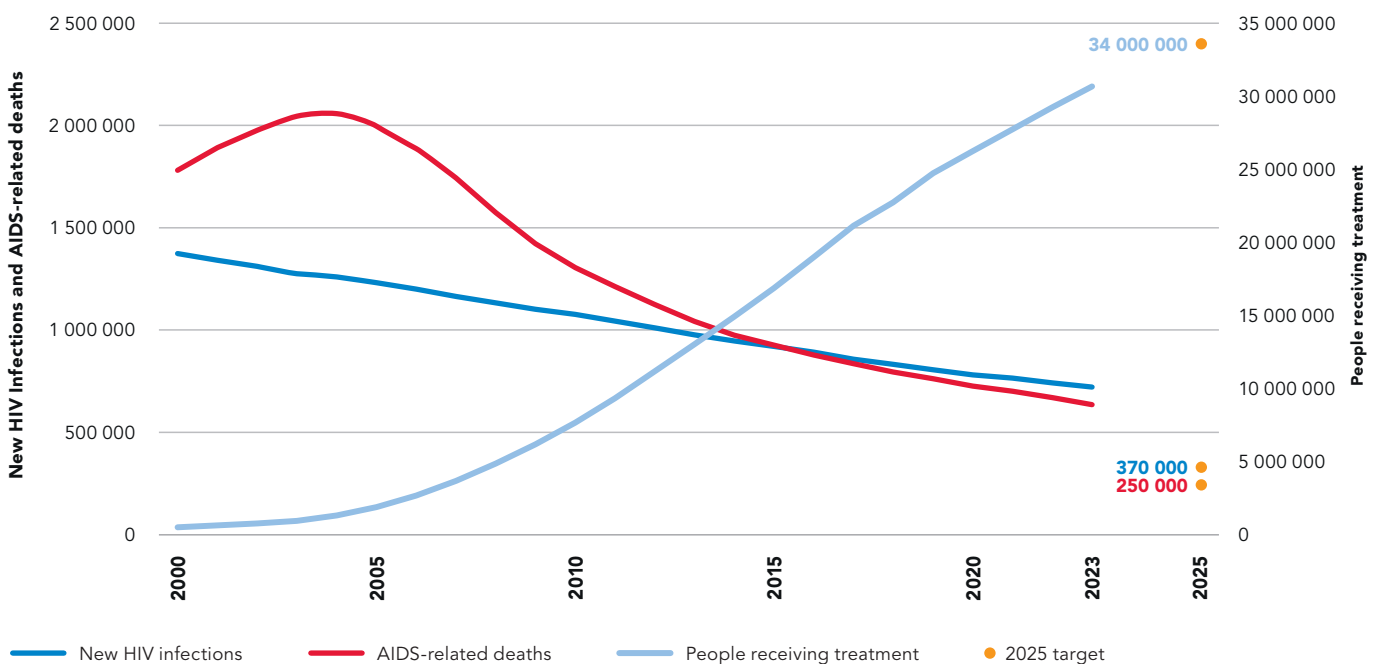
The medicines

Lenacapavir, produced by Gilead, was hailed by *Science* magazine as the '2024 scientific breakthrough of the year'. It can be administered once every six months and is just one of a suite of long-acting HIV medicines coming to market to prevent and treat HIV.

Cabotegravir, another long-acting injectable produced by ViiV and administered once every two months, is already available in some countries. A month-long vaginal ring that can prevent transmission is also now in use in some countries, while longer-acting HIV prevention pills, vaginal rings, and injections could be on the horizon.

This is scientific innovation and the power of collaboration at its best. HIV science hasn't seen this kind of breakthrough since the roll-out of highly effective antiretroviral therapy started some 30 years ago.

Figure 1 New HIV infections, AIDS related deaths and people accessing treatment, Global 2000-2023 and 2025 targets



Source: UNAIDS epidemiological estimates, 2024 (<https://aidsinfo.unaids.org/>).

To seize this unique opportunity, it is necessary to break the cycle of pandemic inequality in which new medicines can take a decade to reach the Global South. This is key to end transmission in high-incidence settings and within key populations at high risk of HIV infection.

If cheaper, high-quality generic medicines are produced to make new innovations universally available and affordable, their roll out fully financed, and structural barriers are removed, this could be our shot at ending AIDS.

The potential

The world has massively expanded access to HIV treatment. Today, three quarters of all people living with HIV are accessing life-saving medicines—30 million of the 40 million people living with HIV.

But still, more than 3500 people acquire HIV every day and the past five years have seen only marginal reductions in new infections. While there is a suite of effective prevention options, after decades of use they have simply not proved to be enough.

Oral pre-exposure-prophylaxis (PrEP), daily pills that prevent HIV transmission are being used in some countries. 3.5 million people used these pills to stay safe in 2023. But UNAIDS roadmap to end AIDS as a public health threat shows that 10 million people need to be on PrEP by the end of this year to make a significant impact on reducing new HIV infections.

New long-acting medicines could be a game changer—giving people at high risk of HIV a tool to stop HIV with injections a few times a year, as billions have done with vaccines this year.

If governments are ambitious, the potential is clear. When the world decided to make COVID-19 vaccination a priority, the world sped from science to regulatory approvals and production within months and vaccinated 4.5 billion people within a year. This kind of ambition is needed now for HIV.

The new medicines could also be key for treatment which would not only save lives, they would also help stop new infections. People living with HIV on effective treatment stops onward transmission of the virus. Supporting people living with HIV to get on and stay on treatment is therefore essential to keep everyone safe.

More innovation is needed to unlock the potential of long-acting medicines for HIV treatment, as well as prevention. For example, there is a need for HIV treatment trials that combine drugs from different companies like long-acting lenacapavir and cabotegravir.

Who could benefit most

The huge and disparate needs and circumstances of people at risk of HIV mean that no single prevention approach will suit all people. Condoms, for example, work well for some, but not for others. Oral PrEP requires establishing a routine that some find difficult to adhere to.

Long-acting HIV prevention technologies could be the solution for many who struggle to protect themselves from HIV. Twice-yearly injections could be a more convenient, discrete, or preferable option than a pill. Long-acting injectable cabotegravir and lenacapavir have also proved to be more effective than oral PrEP.

When injectable contraceptives became available, they proved to be hugely popular. 72 million women around the world accessed them in 2022.

For young women who may not be able to consistently negotiate condom use, LGBTQ+ people in countries where they face criminalization, or sex workers in countries which criminalize sex work, replacing pills with periodic injections could give the autonomy needed to stay safe from HIV and from violence or criminalization.

Without concerted action to make these new medicines widely available to all in need, vulnerable and criminalized communities could be denied access to these new, more effective medicines.

Cost and availability

There are no silver bullets that will end AIDS, but if these new technologies are used at-scale, they could accelerate progress to ending the AIDS pandemic. Whether that happens will depend on cost, availability to the people who could benefit, demand and uptake.

The final price that Gilead will charge for lenacapavir when used for prevention has still not been revealed. In the United States, where lenacapavir is currently used as a treatment for some people living with HIV, it costs around US\$ 40 000 per person per year, a price tag which is out of reach for the vast majority of people at risk of HIV.

It is not possible to end a pandemic with medicines that are so expensive. Innovative, life-saving medicines such as lenacapavir should be global public goods, not luxury items.

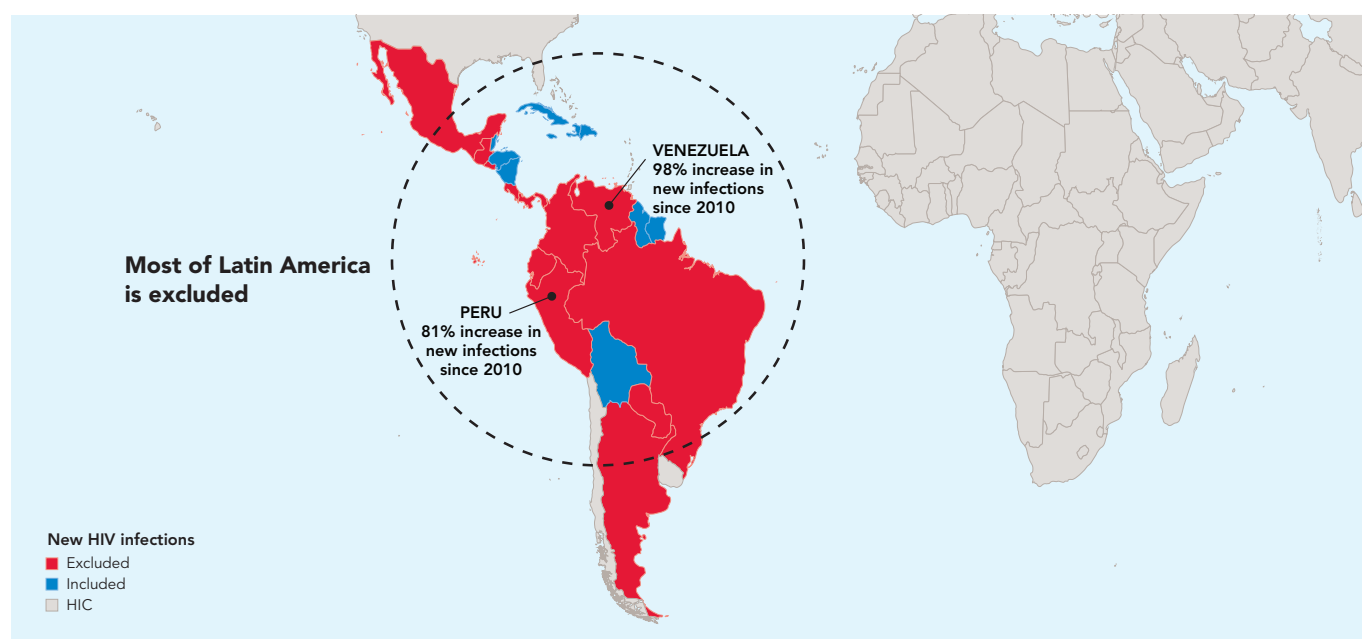
Researchers have calculated that lenacapavir could be produced and sold for as little as US\$ 40 per person per year while still ensuring profit for the pharmaceutical manufacturers if 10 million people were using the medicines¹—a price comparable to oral PrEP.

Both Gilead and ViiV have shown leadership, recognizing that they have a responsibility to ensure countries and people in the Global South can access these game-changing medicines. Gilead had signed voluntary licensing agreements with six pharmaceutical companies to manufacture and supply assured-quality, affordable versions of lenacapavir for HIV prevention for 120 primarily low- and lower-middle-income countries. This is to be applauded.

However, many developing countries—particularly in Latin America, a region of rising new HIV infections—have been left out. Countries, like Brazil, Peru, Mexico, and Argentina, which even participated in clinical trials of lenacapavir, are not included in the license agreement. Some, such as Colombia, Guatemala and Algeria, are poorer than countries in other regions which have been granted access to generic versions of lenacapavir.²

While six companies have been granted a license to produce generic lenacapavir, none are in Southern Africa, where the epidemic is most acute.

Figure 2 Rising new HIV infections in many countries in Latin America which are excluded for Gilead's generic licensing deal



Source: UNAIDS epidemiological estimates, 2024 (<https://aidsinfo.unaids.org/>).

¹ <https://academic.oup.com/jac/article-abstract/79/11/2906/7748089>

² <https://data.worldbank.org/>

The urgency

The United States President's Emergency Plan for AIDS Relief (PEPFAR) and the Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund) have signed a crucial agreement to enable access for 2 million people with lenacapavir over three years, contingent upon regulatory approval from the United States Food and Drug Administration, relevant national pharmaceutical regulators, and recommendation from the World Health Organization. This is a good start.

But action cannot wait. UNAIDS is calling for urgency. There are concerns that the six generics licensees selected by Gilead may not have the capacity to rapidly ramp up production to the levels needed to make the population-level impacts that will significantly reduce new HIV infections and change the trajectory of the AIDS pandemic.

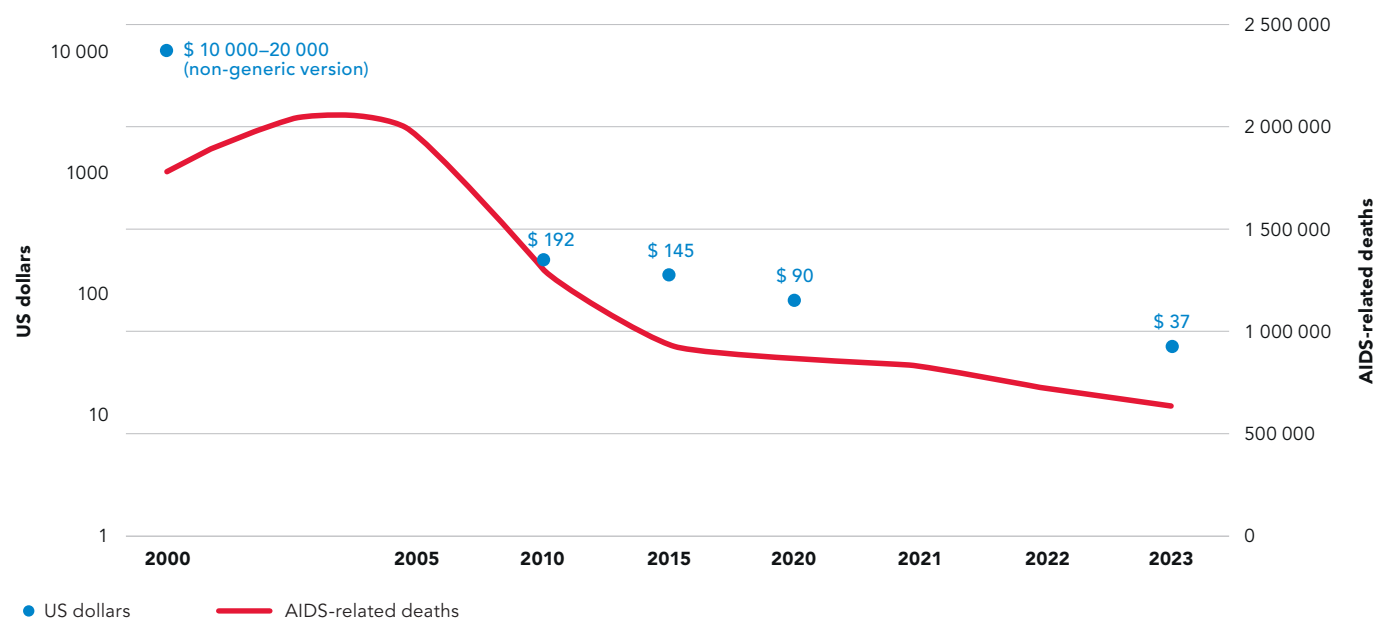
Do not repeat the mistakes of the past

Expanding access to high-quality, low-cost HIV generic medication was an essential step for enabling access to previous generations of HIV medicines. The price for antiretroviral treatment was reduced from its initial cost of around US\$ 20 000 per person per year to less than US\$ 40 per person per year in some countries today.

When scientists first developed antiretroviral treatments, they weren't available or affordable in the Global South. Between 1995 and 2004, more than 12 million people died in Africa, and millions more were infected while people in the Global North already had access.

Part of why there is such a large HIV pandemic today is *because* the world failed then.

Figure 3 Unit prices (median) of antiretroviral treatment in low- and middle-income countries and AIDS-related deaths



Source: UNAIDS estimates from Global AIDS Progress reporting, GAM, WHO Global Price Reporting mechanism, R4D, MSF Access campaign, Perriens et al Antiviral Therapy. 2014;19(3_suppl):39-47. doi:10.3851/IMP2899.

The turning point

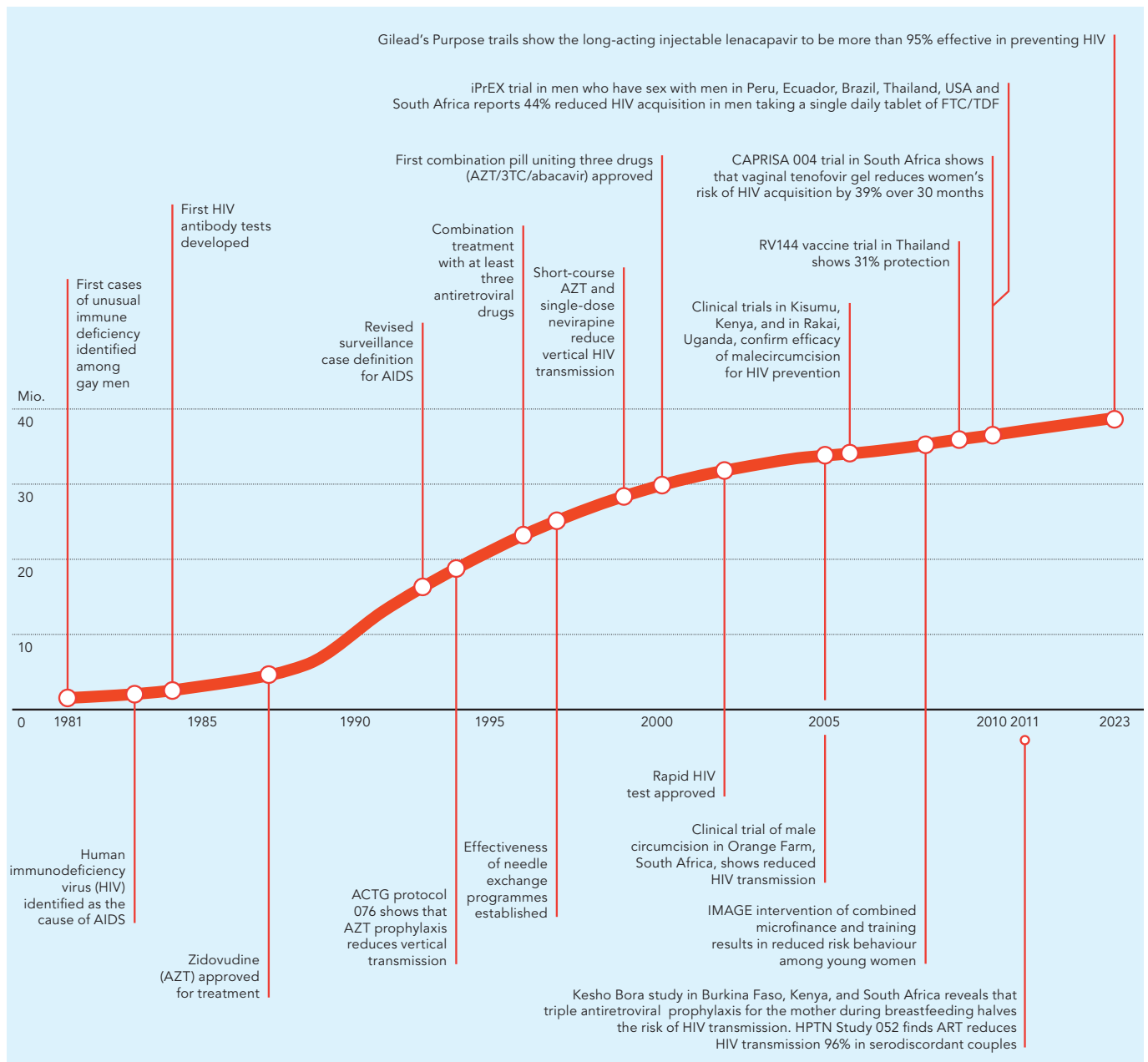
2025 could be the turning point—the moment that ushers in a new era of HIV prevention and treatment with the potential to advance the end of AIDS.

But that can only happen if governments, the private sector, civil society and international organizations work together to ensure these breakthrough innovations are affordable and available for everyone who needs them.

Doing so will take a change of mindset. A moonshot approach that unlocks the potential of long-actings to reach people currently left behind and provide more options for people already on prevention or treatment.

If these new tools can be used to quickly reach millions more people at-risk and improve continuation, it could forever reduce new HIV infections to the point that HIV is no longer a public health threat.

Figure 4 Timeline of the numbers of people living with HIV and scientific breakthroughs, 1981–2023



Source: UNAIDS, 2024.

The call to action

UNAIDS is issuing an urgent call for:

- **Pharmaceutical companies**—To price products fairly and affordably to rapidly scale-up supply and unlock the potential of these game-changing medicines. To increase the number of generic manufacturers and allow all low and middle-income countries to access generic versions of these breakthrough medicines. To collaborate and investigate innovative combinations of long-acting medicines.
- **Developing countries**—To take every measure necessary to secure and sustain access. To move away from reliance on external donors, and towards a localized response. To collaborate, share knowledge and technology, and use flexibilities in intellectual property law when needed. To set ambitious targets and develop campaigns to enable everyone at risk to access new HIV medicines.
- **Governments of high-income countries**—To stand in solidarity with countries in the Global South—the AIDS pandemic cannot be ended in one country alone. To support countries, share resources, and work together to ignite an HIV prevention and treatment revolution. To not discourage the use of flexibilities in intellectual property law. To fully fund the Global Fund and PEPFAR, and work to alleviate fiscal pressures for lower-income countries, such as unaffordable debt payments, to enable their governments to invest in this new era.
- **International organizations like the Global Fund, PEPFAR**—To work with all partners, including UNAIDS, to develop new approaches, learn from community-based and public health approaches, and ensure this new era leaves no one behind.
- **Civil society**—To continue to hold companies and governments to account, advocating for universal affordable access, and working with communities of populations at high risk of HIV infection to disseminate information about PrEP and generate demand.

Widespread generic production, affordable prices, and financial commitment are how access to long-acting medicines can be brought to millions of people. This will not only significantly advance progress but will also help make the HIV response more affordable and sustainable.

By taking this leap forward together, the world will have a shot at ending AIDS.

“Science has delivered a miracle: medicines that prevent HIV infection with injections just twice a year and which could work for treatment too. We must do better this time. Either companies step up, or governments step in. This is our shot to end AIDS—and we cannot afford to miss it.”

Winnie Byanyima, UNAIDS Executive Director



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