Gilead Aims to Launch Twice-Yearly PrEP This Summer

The Food and Drug Administration could approve long-acting lenacapavir injections as early as June.

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Twice-yearly lenacapavir pre-exposure prophylaxis (PrEP) could be available this summer pending Food and Drug Administration (FDA) approval, Gilead Sciences officers said last week as part of the drugmaker's annual financial results. Today, the company announced that the expected decision date is June 19.

Lenacapavir is an HIV capsid inhibitor with a long half-life in the body, meaning it can be administered once every six months. Phase III studies showed that it significantly reduced HIV acquisition in populations at high risk. While lenacapavir is an antiretroviral drug that blocks HIV replication—not a vaccine that trains the immune system to fight the virus—all traditional vaccine candidates tested in large trials have failed, so long-acting PrEP is the next best thing.

Results from the PURPOSE 1 trial, first presented at the 2024 International AIDS Conference and published in The New England Journal of Medicine, showed that twice-yearly lenacapavir PrEP was 100% effective for young cisgender women in Africa. The injections significantly reduced HIV incidence compared with the background rate and were superior to daily Truvada pills (tenofovir disoproxil fumarate/emtricitabine). Several studies have found that injectable antiretrovirals can encourage better adherence among women.

Results from the PURPOSE 2 study, presented at the HIV Research for Prevention Conference last October and also published in The New England Journal of Medicine, showed that lenacapavir injections every six months reduced the risk of HIV acquisition by 96% relative to background incidence and by 89% compared to Truvada for gay and bisexual men and gender-diverse people in the United States and six other countries. In both trials, lenacapavir injections were safe and generally well tolerated.

Two smaller Phase II studies are evaluating lenacapavir and Truvada PrEP for cisgender women (PURPOSE 3) and people who inject drugs (PURPOSE 4) in the United States, while PURPOSE 5 is testing lenacapavir and Truvada PrEP in France and the United Kingdom.

Data from the pivotal PURPOSE 1 and PURPOSE 2 trials are adequate for FDA approval, and on December 19, Gilead announced that it had completed New Drug Application (NDA) submissions for twice-yearly lenacapavir PrEP. The company has also submitted an EU-Medicines for All application, whereby the European Medicines Agency collaborates with the World Health Organization to speed up authorization for countries outside Europe. (Lenacapavir, sold as Sunlenca, is currently approved only as part of a treatment regimen for people with multidrug-resistant HIV.)

Lenacapavir PrEP was granted an FDA Breakthrough Therapy designation and Priority Review status, intended to expedite regulatory review and approval of investigational medications for serious or life-threatening conditions that, based on preliminary clinical evidence, have the potential to "demonstrate substantial improvement over available therapy."

Under the Prescription Drug User Fee Act (PDUFA), expedited therapies can be approved as soon as six months after an NDA submission. That puts the PDUFA target action date for lenacapavir PrEP on June 19.

"Today, we are one step closer to introducing the first-ever twice-yearly HIV prevention choice that could, if approved, help transform the landscape for individuals who need or want additional prevention options that better fit into their lives," Gilead chief medical officer Dietmar Berger, MD, PhD, said in a news release. "We're excited about the potential of lenacapavir to make a real difference in HIV prevention in the U.S. and around the world, supporting the broader goal of ending the HIV epidemic for everyone, everywhere."

However, it is possible that the process could take longer. Such strong data usually bode well for prompt review and approval, but it is unclear how FDA reorganization and staff layoffs under the new presidential administration could affect the timeline.

Looking ahead, Gilead chief commercial officer Johanna Mercier said on last week's financial conference call that preparations for the U.S. launch of lenacapavir PrEP are "well underway," BioSpace reported. The company aims to roll out lenacapavir PrEP in the United States this summer and in Europe later this year.

But to have a real impact on the HIV epidemic, advocates and global health officials stress that long-acting PrEP must be widely available and affordable to those who need it most worldwide.

Gilead has agreed to work with pharmaceutical manufacturers to produce and sell generic versions of lenacapavir PrEP in more than 100 resource-limited countries with high HIV incidence. Some fear, however, that this could leave out middle-income countries, such as Brazil, which account for some 40% of new HIV cases.

"We are hopeful that the speed with which these agreements were reached will be maintained and that the rest of the world will soon benefit from similar agreements to make lenacapavir more affordable and offer a further potent option in the HIV prevention toolbox," International AIDS

Society president Beatriz Grinsztejn, MD, PhD, said in an October statement.

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