ViiV Will Triple Annual Supply of Long-Acting PrEP for Low and Middle-Income Countries

At least 2 million doses of Apretude will be made available to meet growing demand where unmet need is greatest.

October 7, 2024 By Liz Highleyman

ViiV Healthcare announced today that it will triple the supply of Apretude (long-acting cabotegravir), an injectable form of pre-exposure prophylaxis (PrEP) that is administered every other month. The company will offer at least 2 million doses of long-acting cabotegravir for procurement for low- and middle-income countries during 2025–2026. The announcement was made at the HIVR4P 2024 conference taking place this week in Lima.

"We know long-acting PrEP provides a crucial option to suit the needs and circumstances of populations disproportionately affected by HIV, including young women and girls in sub-Saharan Africa," ViiV CEO Deborah Waterhouse said in a statement. "We are committed to working at pace with our partners and the community—globally, regionally, and locally—to continue enabling sustainable access to [long-acting cabotegravir] for PrEP as a key part of our mission to help end the HIV epidemic."

The Food and Drug Administration (FDA) approved Apretude for HIV prevention in 2021. It is currently the only approved long-acting form of PrEP. Two large trials showed that Apretude works even better than daily PrEP pills for cisgender men and transgender women who have sex with men and for cisgender women in Africa. Long-acting cabotegravir has since been approved in more than 50 countries, half of them in sub-Saharan Africa.

ViiV's strategy for long-acting PrEP in lower- and middle-income countries is to "maximize rapid access and uptake for populations with highest unmet needs, in a sustainable way, centered on partnership and integration into existing healthcare services and HIV prevention programs," according to the company.

Long-acting cabotegravir manufactured by ViiV is available at a not-for-profit price for roll-out in low-income and sub-Saharan African countries via partners including the President's Emergency Plan for AIDS Relief (PEPFAR) and the Global Fund. By the end of 2024, ViiV will have supplied the

drug to key partners for roll-out to a total of 13 countries in sub-Saharan Africa and Ukraine. ViiV is also expanding capacity by working with generic manufacturers through a voluntary licensing agreement with the Medicines Patent Pool, implemented in July 2022.

ViiV's announcement comes days after Gilead Sciences announced voluntary licensing agreements with six generic manufacturers to provide its long-acting lenacapavir in low- and lower-middle-income countries. Gilead's agreements do not involve the Medicines Patent Pool.

Lenacapavir, which is administered by injection every six months, was shown to be highly effective as PrEP for cisgender women in Africa and for gay men and gender-diverse people who have sex with men. Lenacapavir (sold as Sunlenca) is currently FDA-approved only as part of a combination HIV treatment regimen for people with multidrug-resistant HIV. Gilead expects to request FDA approval of lenacapavir for HIV prevention by the end of the year, and suggests it could be approved in 2025.

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