



IAS Calls For Global Access as Gilead Announces Lenacapavir Licensing

The IAS calls on stakeholders to put people first and ensure fast and equitable access to lenacapavir for all those in need.

October 3, 2024 By [International AIDS Society](#)

IAS – [the International AIDS Society](#) – applauds moves by Gilead Sciences to make generic injectable lenacapavir for HIV prevention widely available, but cautions that the current agreements still leave out millions around the world.

Gilead [announced](#) on 2 October 2024 that it had signed royalty-free, non-exclusive licensing agreements with six generic manufacturers to increase access to lenacapavir for HIV prevention in 120 high-incidence, resource-limited countries.

“The licensing agreements enabling generic versions of the HIV prevention drug, lenacapavir, in certain countries is an important step forward, but large parts of the world remain excluded, including countries where trials were conducted,” IAS President Beatriz Grinsztejn said. “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.”

Three of the generic manufacturers have their operations in India, one in Egypt, one in Pakistan and one in the US. Gilead added that the agreements were signed “in advance of any global regulatory submissions to enable these countries to quickly introduce generic versions of lenacapavir for HIV prevention” once they receive regulatory approval.

This will substantially reduce the time to market. However, many countries with high HIV incidence are not included in the licensing arrangements, which will slow access.

Six-monthly injections of lenacapavir showed 100% protection against HIV acquisition among more than 5,000 cisgender women in South Africa and Uganda in the Phase 3 [PURPOSE 1 trial](#), presented at AIDS 2024, [the 25th International AIDS Conference](#).

The results of the [PURPOSE 2 trial](#) released in September 2024, showed that 99.9% of the 2,180 cisgender men and gender-diverse participants in the United States, South Africa, Peru, Brazil, Argentina, Mexico and Thailand who received the injection did not acquire HIV. New data are due to be released at HIVR4P 2024, [the 5th HIV Research for Prevention Conference](#), taking place on

6-10 October 2024.

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