

# New HIV drug to be available in March

Dr Robert Mutumba, the head of the Aids Control Programme at the Ministry of Health, told *Daily Monitor* that Ugandans are expected to start accessing the drug free of charge after two months.

BY TONNY ABET

**T**he National Drug Authority (NDA) has approved lenacapavir, a twice-yearly injectable drug for HIV prevention (PrEP). Lenacapavir demonstrated over 99 percent effectiveness in stopping infections in clinical trials conducted in Uganda and South Africa.

NDA, in a statement on Monday, indicated that the approval of lenacapavir for use will revitalise the fight against HIV/Aids as the country races to end the disease by 2030.

"Uganda's National Drug Authority has just approved Lenacapavir, a twice-yearly dose PrEP manufactured by Gilead, a USA-based company! This is a game-changer for HIV prevention, especially for those at high risk. This is a great step towards ending Aids by 2030," the notice reads.

Information from NDA indicates that before approval, a product undergoes rigorous assessment to ensure it meets "national and internationally accepted quality, safety and efficacy standards."

For a product manufactured outside Uganda, the NDA specifies that it should have first received approval from the country of origin. In this case, it is the American Food and Drug Administration (FDA), which approved the drug in June last year.

Dr Robert Mutumba, the head of the Aids Control Programme at the Ministry of Health, told *Daily Monitor* on Monday that Ugandans are expected to start accessing the drug at free cost after two months.

"We got an offer from the Global Fund. Uganda is among 10 countries that will



Health worker conduct test in a laboratory. NDA has approved Lenacapavir, a drug that prevents HIV. PHOTO/FILE

benefit, and we expect 38,000 doses through this initiative. Each person will get two doses. The commodities are expected to be in the country in March," he said.

Dr Mutumba also said they are looking at ways to increase access through engagement of other development partners and importation by the private sector.

"The US government has also shown interest in providing us more doses (unspecified), but discussions with them and other partners are still going on," he said.

"For importation by the private sector, the discussions are also going on, but I think the price might be too high for many Ugandans at the moment. The price will decline over time as demand increases and local manufacturers in Africa also start making generic versions," he added.

Uganda still registers over 37,000 new HIV infections per year. This new drug,

## HIV STATUS IN UGANDA

The number of persons living with HIV in Uganda is 1.5 million. By 2030 Uganda aims to:

- Reduce new HIV infections by 90 percent from 2010 and a continued five percent decline per year after 2030 (less than 10,000 new HIV infections).
- Reduce Aids-related deaths by 90 percent from 2010 (less than 10,000 deaths per year. Currently there are around 20,000 deaths per year).
- Secure the sustainability of the HIV response through 2030.

given the demonstrated effectiveness in preventing infection, is expected to significantly lower the numbers. But a big question remains on availability,

partly because of the cost of the medicine.

The Gates Foundation recently announced a partnership with Indian manufacturer Hetero Labs (Hetero) to make generic versions of lenacapavir at a significantly low cost for poor countries.

This development follows a 2024 move by Gilead Sciences, the developer of lenacapavir, to grant royalty-free licenses for lenacapavir production to six generic manufacturers for 120 low- and middle-income countries.

In a statement on September 14, 2024, the foundation said Hetero Labs will manufacture the drug at "roughly \$40 (about Shs145,000) per patient per year (after a short pre-treatment oral regimen)," following upfront funding and volume guarantees.

Lenacapavir was rolled out at the end of last year, at a cost of \$28,000 (Shs102m) per person annually, but the generic version, which will be avail-

able at \$40 (Shs145,000) per person, is expected to be accessible in 2027 across 120 low and middle-income countries.

## Who will access 38,000 doses?

Dr Nelson Musoba, the Uganda Aids Commission (UAC) director general, said for the initial lenacapavir doses, they will prioritise high-risk groups, including young women, those engaged in transactional sex, and individuals in discordant relationships. This leaves out many Ugandans who may be in need of the drug but may not be able to access it.

Dr Musoba further disclosed that the government is finalising estimates of the number of beneficiaries before submitting an official request for government funding.

He added that they also anticipate the private sector will start purchasing the drug, following approval by the NDA.

Currently, only the group that participated in the clinical trial for lenacapavir is receiving the twice-yearly treatment. But the major rollout for the general population is still awaited as the ministry awaits a larger number of doses this year.

Dr Hudson Balidawa, the officer in charge of monitoring Global Fund HIV investment in Uganda, explained that the doses that will be obtained under the Global Fund, arrangement will be taken to the sites that have been offering PrEP.

The sites have largely been focusing on those at higher risk of HIV infection, like those in discordant relationships, sex workers, and persons who inject drugs.

"We already have the places where PrEP is accessed, and we have different choices of PrEP. We have the oral tablets, vaginal ring, and injectable Cabotegravir, which has been distributed," he said.

"So these sites will be the first sites to offer lenacapavir. If I get a new client on that site, they can also start on Lenacapavir. If the old client wants to switch from oral to Lenacapavir or from Cabotegravir to Lenacapavir, then they can also."

The UAC also advised the population to continue using the available PrEP and adhere to other prevention methods as the country awaits the new drug.

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