

## PLAIN LANGUAGE SUMMARY

# Emerging concepts in HIV pre-exposure prophylaxis: focus on twice-yearly lenacapavir

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HIV continues to affect millions of people worldwide, and many individuals who could benefit from HIV prevention medicines (called pre-exposure prophylaxis, or PrEP) are not using them consistently. Daily pills work very well when taken regularly but many people face challenges with daily medication — such as forgetting doses, stigma or difficulty accessing healthcare services. These challenges have driven the development of long-acting PrEP options that require fewer doses and may be easier for people to use.

Lenacapavir is a new type of HIV prevention medicine that is given as an injection under the skin twice a year. It works differently from other HIV medications by targeting the virus's protective outer shell (the capsid). Because of its design, lenacapavir stays in the body at protective levels for many months after each injection.

Early-stage studies found that lenacapavir is long-lasting and well tolerated. Larger phase III trials — called PURPOSE 1 and PURPOSE 2 — showed that twice-yearly lenacapavir was extremely effective at preventing HIV in a wide range of people, including adolescent girls and young women, men who have sex with men, transgender women and men, and nonbinary individuals. In the PURPOSE 1 trial, no participants who received lenacapavir contracted HIV over the first year. Side effects were mostly mild and

related to the injection site such as temporary pain, redness or nodules.

Because it is only needed every 6 months, lenacapavir may help overcome common barriers to PrEP use, like remembering daily pills or accessing frequent clinic visits. Global health organizations, including the World Health Organization and US CDC, now recommend lenacapavir as a PrEP option for people at risk for sexually acquired HIV. It is approved for adults and adolescents (weighing at least 35 kg) who test negative for HIV before starting treatment.

Lenacapavir is expected to expand access to HIV prevention, especially for people who struggle with daily pill-taking or have limited access to regular healthcare. However, important considerations remain, such as ensuring the medication is widely available, affordable and delivered safely. Ongoing monitoring is also needed to track drug resistance and real-world effectiveness.

Overall, twice-yearly lenacapavir represents a major step forward in HIV prevention. Its long-acting, highly effective protection has the potential to reduce new HIV infections and make PrEP more accessible to people who need it most.