Progress on Long-Acting HIV Treatment

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On August 22, the European Commission approved Gilead Sciences' lenacapavir, sold as Sunlenca, as a new option for treatment-experienced people with multidrug-resistant HIV. Lenacapavir, the first HIV capsid inhibitor, has a long half-life in the body and can be administered just once every six months. The Food and Drug Administration (FDA) could approve the new antiretroviral by the end of 2022.

Studies showed that more than 80% of people with highly resistant HIV were able to maintain an undetectable viral load for at least a year after switching from a failing regimen to twice-yearly lenacapavir injections plus an optimized background regimen. Lenacapavir is also being studied as a long-acting option for pre-exposure prophylaxis (PrEP).

"Lenacapavir helps to fill a critical unmet need for people with complex prior treatment histories and offers physicians a long-awaited twice-yearly option for these patients who are at greater risk of progressing to AIDS," says Jean-Michel Molina, MD, of Université Paris Cité.

In other news, Merck announced in September that it plans to start new clinical trials using a lower dose of its long-acting nucleoside reverse transcriptase translocation inhibitor islatravir. Merck and Gilead also agreed to resume a Phase II trial of once-weekly low-dose oral islatravir plus lenacapavir.

Last year, the FDA placed a clinical hold on trials of islatravir after HIV-positive study participants experienced declines in their CD4 T-cell counts and HIV-negative people taking it for PrEP showed decreased total lymphocyte counts. Merck hopes the lower islatravir dose will solve the safety issue for treatment, but studies of once-monthly oral islatravir PrEP have been discontinued.