Long-Acting Injectable HIV Regimen Approved in Europe

The European Medicines Agency gave the green light to injectable cabotegravir and rilpivirine for HIV treatment.

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On December 21, the European Medicines Agency (EMA) granted authorization for the first long-acting injectable regimen for HIV treatment, according to ViiV Healthcare. It is the first complete regimen that does not require daily pills, and recipients only need to take the treatment six or 12 times a year.

The two-drug regimen consists of the long-acting integrase inhibitor cabotegravir and an injectable version of the non-nucleoside reverse transcriptase inhibitor (NNRTI) rilpivirine. ViiV's injectable cabotegravir, as well as a tablet version, will be marketed under the brand name Vocabria in Europe. Injectable rilpivirine, from Janssen, will be sold as Rekambys; this is a long-acting version of the daily oral NNRTI Edurant.

Injectable cabotegravir and rilpivirine are indicated as maintenance therapy for adults living with HIV who have achieved viral suppression (viral load less than 50) on daily oral treatment and who have no present evidence or past history of resistance to NNRTIs or integrase inhibitors.

The injectables are administered by a health care provider as two separate shots in the buttocks once a month or every other month. To ensure tolerability, cabotegravir and rilpivirine pills are taken for a month-long lead-in period before switching to the injections.

The monthly injectable regimen (but not the every-other-month schedule) was first approved in Canada, where the combination will be sold as Cabenuva. Last year, the U.S. Food and Drug Administration (FDA) held up approval of Cabenuva, citing concerns over its manufacturing process. ViiV has worked with the FDA to address these concerns, and approval in the United States is expected in early 2021.

The EMA approval is supported by findings from Phase III clinical trials. The ATLAS study enrolled more than 600 HIV-positive participants with a fully suppressed viral load for at least six months and no history of virological treatment failure. They were randomly assigned to either stay on their current oral regimen or switch to the injectables after an oral lead-in. As previously reported, both groups were about equally likely to maintain viral suppression (93% and 96%, respectively, at 48

weeks).

Findings from a follow-up study called ATLAS-2M, presented earlier this year, showed that monthly and every-other-month dosing of the injectables were equally effective, with 94% in both groups maintaining viral suppression.

The FLAIR study, which enrolled more than 600 people starting HIV treatment for the first time, also showed that injectable cabotegravir and rilpivirine are highly effective. Participants were first started on a standard oral regimen of Triumeq (dolutegravir/abacavir/lamivudine) to bring down their viral load. They were then randomized to stay on that regimen or switch to cabotegravir and rilpivirine, starting with a four-week oral lead-in before starting the injections. As previously reported, 94% of those on the injectable regimen and 93% of those who remained on Triumeq had undetectable viral load at 48 weeks

Follow-up findings presented this fall showed that outcomes were similar for people who switched directly from Triumeq to the injectables and those who first used cabotegravir and rilpivirine pills for a month, indicating that the oral lead-in may not be necessary.

Injectable cabotegravir and rilpivirine are safe and generally well tolerated. What's more, although some participants in the clinical trials experienced injection site reaction such as pain or swelling, a majority said they preferred the monthly injections over daily pills.

"Daily antiretrovirals have transformed the lives of people living with HIV. However, taking daily medication can pose challenges for some people; it may act as a constant reminder of HIV or be a cause of fear that their HIV status will be disclosed," Antonio Antela, MD, PhD, of University Hospital Santiago de Compostela in Spain, said in a ViiV press release. "The long-acting regimen of cabotegravir and rilpivirine was as effective as treatment with current daily antiviral therapy in the clinical trials in maintaining viral suppression, is generally well tolerated, and could change the treatment experience for some people living with HIV that may have challenges with daily HIV therapies."

Injectable cabotegravir alone is also being studied as pre-exposure prophylaxis (PrEP). Researchers recently reported that cabotegravir injections given every other month were more effective for HIV prevention than daily oral Truvada (tenofovir disoproxil fumarate/emtricitabine) both for cisgender men and trans women who have sex with men in the HPTN 083 study and for cisgender women in the HPTN 084 study.

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