FDA Approves Cabenuva, the First Complete Long-Acting Injectable HIV Treatment

Injectable cabotegravir and rilpivirine are approved for people with viral suppression who would prefer monthly injections to daily pills.

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On January 21, the Food and Drug Administration (FDA) approved the first complete injectable HIV treatment regimen that does not require daily pills. Cabenuva, from ViiV Healthcare, is administered only once a month. It is approved for people with an undetectable viral load on their current therapy who wish to switch to a long-acting regimen.

Cabenuva consists of an extended-release formulation of the integrase inhibitor cabotegravir plus an injectable version of Janssen's non-nucleoside reverse transcriptase inhibitor rilpivirine (sold in pill form as Edurant). The FDA also approved a tablet version of cabotegravir, called Vocabria.

Cabenuva is indicated as maintenance therapy for adults living with HIV who have achieved viral suppression (a viral load less than 50) on daily oral treatment and who have no history of treatment failure and no known or suspected viral resistance to either cabotegravir or rilpivirine.

People who want to switch will take Vocabria and Edurant pills for a month to ensure that the combination is well tolerated. After that, they will receive two injections in the buttocks administered by a health care provider once a month. Vocabria and Edurant pills may also be used as a complete short-term regimen—for example, if someone has to miss a planned Cabenuva injection appointment.

"Among the scientific community, we recognize the innovation behind Cabenuva is truly meaningful. Not only is it the first, complete long-acting regimen, which allows for a dramatic reduction in the frequency of dosing, but it also was preferred by most clinical trial participants when compared to their prior daily oral regimens," David Wohl, MD, of the University of North Carolina Institute of Global Health and Infectious Diseases in Chapel Hill, said in a ViiV press release. "The FDA approval of Cabenuva underscores the value of community-centric research and I am pleased this new option will be available for those living with HIV."

Study Findings

The FDA 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 and no history of virological treatment failure. They were randomly assigned to either stay on their current oral regimen or switch to Cabenuva injections after an oral lead-in. After 48 weeks, both groups were about equally likely to maintain viral suppression (93% and 96%, respectively).

Findings from a follow-up study called ATLAS-2M showed that monthly and every-other-month dosing of the injectables is equally effective, with 94% in both groups maintaining viral suppression. ViiV plans to ask the FDA for a bimonthly indication.

In the FLAIR trial, participants new to HIV treatment were first started on a standard oral regimen of Triumeq (dolutegravir/abacavir/lamivudine) to bring down their viral load. Then they were randomized to stay on that regimen or switch to Cabenuva, again after an oral lead-in. After 48 weeks, 94% of those on the injectable regimen and 93% of those who remained on Triumeq had an undetectable viral load. Follow-up findings presented last year showed that outcomes were similar for people who switched directly from Triumeq to Cabenuva without the oral lead-in.

Cabenuva is safe and generally well tolerated. The most common side effect is injection site reactions, such as pain, redness or swelling. Other adverse events, including fever, fatigue, headache, and muscle pain, nausea, sleep disorders, dizziness and rash, were uncommon in the clinical trials. Only 4% of people taking Cabenuva serious adverse events, and 3% of adverse events led to treatment discontinuation.

Most study participants said they preferred the monthly injections over daily pills. Reasons included greater convenience, having to think about HIV treatment only 12 times a year and not having pill bottles that could reveal their HIV status to others.

People who use Cabenuva will need to see their provider more often than they do now for periodic viral load testing. But ViiV's CUSTOMIZE study found that health care providers can successful integrate the administration of monthly injections into their clinical practice, and people with HIV can succeed on the regimen in a real-world setting.

Injectable cabotegravir alone is also being studied for pre-exposure prophylaxis (PrEP). Researchers reported last year 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.

Once-monthly Cabenuva for HIV treatment was first approved in Canada in March 2020. In December, the European Medicines Agency approved the combination. In Europe, injectable cabotegravir is sold under the brand name Vocabria (the same name as the pill version), while rilpivirine injections are sold as Rekambys. In 2019, the FDA held up approval of Cabenuva, citing concerns over its manufacturing process, but these have been resolved.

ViiV says it will start shipping Cabenuva to wholesalers and specialty distributors in February. The injectable combination will cost about $4,000 per month, a company spokesperson told the New York Times.

"This is an exciting new option for patients and providers, as it provides an alternative strategy for effective HIV treatment, Susan Swindells, MBBS, of the University of Nebraska Medical Center, said in a Janssen press release. “Cabenuva once-monthly injections showed comparable efficacy to daily oral antiretroviral treatment in maintaining viral suppression—a first in the treatment paradigm.”

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