Has Injectable HIV Treatment Only Been Delayed?

The Food and Drug Administration declined approval of ViiV Healthcare's injectable HIV regimen Cabenuva.

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In December, the Food and Drug Administration (FDA) declined to approve ViiV Healthcare's long-acting injectable antiretroviral regimen Cabenuva (cabotegravir/rilpivirine). The federal agency's surprise decision centered on concerns regarding the two-drug regimen's chemistry and manufacturing controls.

The pharmaceutical company indicated that it would work closely with the FDA to determine what's needed to get Cabenuva approved.

Cabenuva contains Janssen's non-nucleoside reverse transcriptase inhibitor rilpivirine, which is sold in daily oral pill form as Edurant, and ViiV's new integrase inhibitor cabotegravir. ViiV has also applied for approval of a daily pill form of cabotegravir to serve as an oral lead-in to the injectable regimen. The regimen requires a monthly clinic visit to receive an injection into the muscle given by a health care provider.

ViiV's FDA application was based on findings from the Phase III ATLAS and FLAIR studies, which were presented at the 2019 Conference on Retroviruses and Opportunistic Infections. ATLAS enrolled people who were already taking standard oral antiretroviral treatment, while FLAIR enrolled treatment first-timers.

Between them, the trials included more than 1,100 HIV-positive participants from 16 nations. After 48 weeks of treatment, Cabenuva suppressed the virus as effectively as a daily oral three-drug regimen.

Cabenuva proved well tolerated, and the trial participants reported high levels of satisfaction with the regimen, greatly preferring it to taking daily pills. The treatment was commonly associated with injection site reactions, including pain. But these effects were generally mild or moderate and resolved quickly. Just 1% of the trial members withdrew from the studies because of such reactions.

"We have had a lot of interest from the community about this," says Susan Swindells, MBBS, a

professor of infectious diseases at the University of Nebraska Medical Center, who led the ATLAS trial. “Many patients in my clinic are asking about it and are looking forward to having another option to consider instead of daily oral therapy.”

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