ViiV Applies for Approval of First Long-Acting Injectable HIV Regimen

Dosed every four weeks, the injection, which requires a clinic visit, includes long-acting rilpivirine and cabotegravir.

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Long-acting injectable antiretroviral (ARV) treatment will likely finally become a reality for people living with HIV by the end of the year. ViiV Healthcare has applied to the Food and Drug Administration (FDA) for approval of a long-acting injectable formulation of Janssen's rilpivirine (currently sold in daily oral pill form as Edurant) and ViiV's cabotegravir, which is dosed every four weeks through an intramuscular injection (into the muscle, as opposed to under the skin) that requires a clinic visit.

The new drug application is based on findings from the Phase III ATLAS and FLAIR studies presented at the 2019 Conference on Retroviruses and Opportunistic Infections (CROI) in March in Seattle. Together, the trials included more than 1,100 HIV-positive participants from 16 nations. The studies found that 48 weeks of monthly injectable long-acting Edurant and cabotegravir suppressed HIV as effectively as a standard daily oral triple-ARV regimen.

The long-acting injectable regimen proved well tolerated and was associated with a high level of satisfaction, with participants greatly preferring it over daily oral treatment. Injection-site reactions, including pain, were common but generally mild or moderate and resolved quickly; 1% of participants withdrew from the study as a result of such reactions.

ViiV has also filed for approval of a daily oral formulation of cabotegravir for use as a lead-in drug paired with daily oral Edurant for people preparing to start the long-acting injectable formulation of this two-drug regimen.

To read a press release about the FDA application, click here.

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