Monthly Injectable Treatment

Given every four weeks, the combo injection of cabotegravir and Edurant (rilpivirine) will likely face an FDA decision by early 2020.

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Treating HIV with monthly combination injections of long-acting formulations of ViiV Healthcare's cabotegravir and Janssen's rilpivirine (Edurant) suppresses the virus as effectively as a standard daily oral antiretroviral (ARV) regimen, according to a pair of advanced clinical trials. Consequently, the injectable regimen is poised for Food and Drug Administration approval, likely by early 2020.

This would mark the first time an approved HIV regimen does not involve taking daily oral medications. However, the intramuscular injections would require monthly clinic visits.

In one of the two Phase III trials, 616 participants whose HIV was already fully suppressed on daily oral ARVs were randomized to stay on their current regimen or to switch to monthly long-acting cabotegravir and rilpivirine. In the other trial, following a lead-in period when they all started first-time HIV treatment with oral therapy, 566 participants were randomized to receive either the long-acting injectable regimen or a daily oral regimen.

After one year of treatment, a comparably high proportion of those in the long-acting treatment groups and those in the daily oral ARV groups had a fully suppressed viral load.

Injection-site reactions, which tended to be mild and resolve quickly, were common among those in the long-acting treatment group.

Anthony Mills, MD, chief executive officer of the Men's Health Foundation in Los Angeles, is encouraged by the very high level of satisfaction reported by those in the long-acting injectable ARV treatment groups.

The two trials, he says, "clearly demonstrate the interest and excitement in the HIV community to support the introduction of a long-acting injectable regimen."

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