Canada Is the First to Approve Long-Acting HIV Regimen Cabenuva

The FDA recently held up the U.S. approval based on concerns over the monthly injectable regimen's manufacturing.

March 23, 2020 By Benjamin Ryan

HIV treatment has entered an exciting new era as Canada has become the first nation in the world to approve ViiV Healthcare's monthly long-acting injectable antiretroviral (ARV) regimen Cabenuva (cabotegravir/rilpivirine)—the first complete regimen for treating the virus that does not require daily pills.

In late December, the Food and Drug Administration (FDA) held up approval of the regimen, citing concerns over its manufacturing process. In turn, ViiV indicated it was working closely with the FDA to address those concerns and ultimately bring Cabenuva to market in the United States.

ViiV first applied for FDA approval of Cabenuva in April 2019.

Health Canada approved Cabenuva for people with HIV to swith to if they have a fully suppressed viral load (below 50) thanks to a standard oral ARV regimen.

Cabenuva contains Janssen's non-nucleoside reverse transcriptase inhibitor rilpivirine (sold in daily oral pill form as Edurant) and ViiV's new integrase inhibitor cabotegravir.

Health Canada has also approved a daily pill form of cabotegravir, to be sold under the brand name Vocabria. People transitioning onto Cabenuva will first take a daily oral regimen of Edurant and Vocabria for one month.

Because the long-acting versions of cabotegravir and rilpivirine can linger in the body for months, it's important that people starting the regimen receive monitoring during the oral drug lead-in phase. That way, if any troublesome side effects arise during that first month, an individual can simply discontinue the daily drugs, which will quickly dissipate in the body.

People with HIV should not take Cabenuva if tests indicate that their virus shows signs of resistance to either of the drugs in the regimen.

Since the dawn of the combination ARV era in 1996, successfully treating HIV has always required

taking daily pills. Cabenuva requires a monthly shot into the muscle given by a health care professional.

Cabenuva's approval is based on the Phase III ATLAS and FLAIR studies, which between them included more than 1,100 participants from 16 nations. ATLAS found that switching from a daily oral ARV regimen to Cabenuva was as effective at suppressing HIV after 48 weeks as continuing on an oral regimen. FLAIR studied people starting ARV treatment for the first time.

The results of the studies were published on March 20 in The New England Journal of Medicine.

The most common adverse health events in both studies, seen in at least 2% of the participants, included injection-site reactions, fever, fatigue, headache, musculoskeletal pain, nausea, sleep disorders, dizziness, rash and diarrhea.

During the 48-week treatment period, 4% of participants randomized to receive Cabenuva discontinued the regimen due to adverse health events.

About nine out of 10 of the participants who switched to Cabenuva said they preferred monthly injectable treatment to daily oral therapy.

Signs indicate that injectable HIV treatment will only become more convenient in the coming years. A recent presentation of results from the ATLAS-2M trial at the 2020 Conference on Retroviruses and Opportunistic Infections earlier this month indicated that a version of Cabenuva containing higher doses of cabotegravir and rilpivirine was as effective at suppressing HIV when injected every eight weeks as the standard regimen given every four weeks.

To read a press release about the approval, click here.

To read the study abstract, click here.

To read a press release about the FDA's decision with regard to Cabenuva, click here.

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