Oral Cabotegravir Combo Keeps HIV Suppressed for 6 Years

As long-acting injectables near approval, daily pill versions of the same drugs show long-term benefit.

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A once-daily oral regimen of cabotegravir plus rilpivirine maintained HIV suppression for five and a half years after a six-month lead-in period, according to results presented at IDWeek 2019 this month in Washington, DC.

The LATTE trial was designed to evaluate the safety and effectiveness of cabotegravir and rilpivirine taken as once-daily pills. This set the stage for testing long-acting injectable versions of the two medications administered monthly or every other month.

Researchers tested the pill versions first because the long-acting formulations can't be easily removed from the body if they cause side effects or other problems. The Food and Drug Administration is expected to soon make a decision about approval of the monthly injectable regimen (Cabenuva).

Cabotegravir is an experimental next-generation integrase inhibitor being developed by ViiV Healthcare. Rilpivirine is an approved nonnucleoside reverse transcriptase inhibitor (NNRTI) marketed as the stand-alone Edurant pill and as a component of the Complera, Juluca and Odefsey oral coformulations.

At IDWeek, David Margolis, MD, MPH, of ViiV presented the latest results from the Phase IIb LATTE study with follow-up through 312 weeks. This study enrolled 243 previously untreated participants. Almost all were men (in part because hormonal contraception was not allowed), about two thirds were white, about 30% were African American and the median age was approximately 33.

Participants were randomly assigned to start on one of three once-daily doses (10, 30 or 60 milligrams) of oral cabotegravir plus a then-standard backbone of two nucleoside/nucleotide reverse transcriptase inhibitors (NRTIs). Six months later, if their viral load was below 50, they replaced the two NRTIs with oral rilpivirine as a maintenance regimen. A control group received Sustiva (efavirenz) plus two NRTIs.

At week 96—the end of the randomized part of the study—those originally assigned to take any

dose of cabotegravir could opt to receive the selected 30 mg oral dose plus rilpivirine in an open-label phase. Ultimately, those who maintained undetectable viral load for the full 312-week follow-up period were eligible to roll over into a study of the long-acting injectable formulations.

In 2014, Margolis presented 48-week findings showing that 82% of participants who used oral cabotegravir plus rilpivirine maintained undetectable viral load, compared with 71% of those who took Sustiva. At 96 weeks, the corresponding response rates were 76% and 63%. Looking only at those who started cabotegravir plus rilpivirine maintenance therapy, 86% maintained viral suppression.

The latest results, through the end of the open-label part of the study, showed that 66% of participants taking cabotegravir plus rilpivirine still maintained viral suppression at week 312. More of the original participants had dropped out of the study by this point—25% had no available viral load data—which accounts for most of the decline in the response rate. Just eight people experienced virological treatment failure according to the study's definition, six of them before week 144 and two between weeks 144 and 312. Most of them had evidence of new HIV mutations conferring resistance to integrase inhibitors, NNRTIs or both.

Treatment was generally safe and well tolerated at weeks 48 and 96, and this continued to be the case at week 312. Only two out of the 160 remaining participants (1%) experienced serious drug-related adverse events, and eight people (5%) stopped treatment because of adverse events, most of which did not appear to be attributable to the medications.

As follow-up in LATTE was continuing, researchers went on to test the long-acting injectable formulations of cabotegravir and rilpivirine in new groups of patients. As reported at this year's Conference on Retroviruses and Opportunistic Infections, the injectable regimen proved highly effective in Phase III clinical trials, both for first-time treatment and as a switch option for people with undetectable viral load.

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