Lower CNS Side Effects, Similar Efficacy for Doravirine Vs. Sustiva

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Merck's investigatory non-nucleoside reverse transcriptase inhibitor (NNRTI) doravirine (MK-1439) is comparable to Sustiva (efavirenz) in terms of efficacy, but is linked to fewer central nervous system (CNS) side effects, HIVandHepatitis.com reports. Presenting their findings at the HIV Drug Therapy Glasgow conference in Scotland, researchers are conducting an ongoing blinded Phase IIb trial comparing doravirine with Sustiva in treatment-naive people with HIV.

The first part of the study involved 208 participants, all of whom took Truvada (tenofovir/emtricitabine) and were randomized to take a series of different doses of either doravirine or Sustiva. The researchers chose the 100-milligram dose of doravirine based upon an analysis of data from the trial's 24-week mark, and then switched everyone taking doravirine to this dose at week 36.

The second part of the trial added 132 participants, who were randomized to receive either Sustiva or 100 mg of doravirine, plus Truvada. The researchers compared the CNS side effects between 108 people who took 100 mg of doravirine during both parts of the trial and 108 people who took Sustiva.

The researchers found that the two drugs yielded similar antiretroviral activity and immunological effects. There was little development of drug resistance among those receiving either drug, and each medication had a good safety and tolerability profile.

However, at the eight-week mark in part two of the trial, those on 100 mg of doravirine had a significantly lower rate of CNS side effects when compared with those taking Sustiva. Twenty-two percent of those on doravirine had at least one neuropsychiatric symptom, compared with 43.5 percent of those on Sustiva. Between those on doravirine versus those on Sustiva, the respective rates of CNS side effects were dizziness (9.3 percent vs. 27.8 percent), abnormal dreams (5.6 percent vs. 16.7 percent), nightmares (5.6 percent vs. 8.3 percent), insomnia (6.5 percent vs. 2.8 percent), depression (0.9 percent vs. 1.9 percent) and suicidal thoughts (0 percent vs. 0.9 percent).

To read the HIVandHepatitis story, click here.

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