Dolutegravir/Epzicom Combo May Have Edge Over Atripla

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Dolutegravir, an experimental integrase inhibitor being developed by ViiV Healthcare and Shionogi, combined with Epzicom (abacavir plus lamivudine), appears to have an efficacy advantage over Atripla (efavirenz plus tenofovir and emtricitabine) among people starting HIV treatment for the first time.

According to a news announcement released by the companies—data from the Phase III SINGLE study have not yet been peer reviewed, either in a medical journal or at a scientific conference—88 percent of clinical trial volunteers using dolutegravir and Epzicom, compared with 81 percent of those using Atripla, had undetectable viral loads after 48 weeks of treatment, though this difference was primarily driven by a higher rate of discontinuations in the Atripla group because of side effects.

“This study represents an important milestone in the development of dolutegravir-based regimens, including a single-tablet regimen [containing dolutegravir, abacavir and lamivudine], and also for the Shionogi-ViiV Healthcare joint venture,” said John Pottage, MD, ViiV’s chief medical officer. “We look forward to receiving further safety and efficacy data from two Phase III studies in treatment-experienced patients to continue to build a comprehensive picture of the role of dolutegravir in the treatment of HIV.”

The primary goal of the study—which was met—was to determine that dolutegravir plus Epzicom was “non-inferior” to Atripla. However, the researchers also planned to look for superiority of one regimen over the other. In their analysis involving all patients randomized in the study (regardless of whether or not they remained on their assigned regimen), they documented a statistically significant difference between the two groups.

The SINGLE trial highlighted in the news announcement is a Phase III randomized, blinded and controlled study designed to compare the safety and effectiveness of dolutegravir plus Epzicom with Atripla, the leading fixed-dose combination regimen for people starting HIV treatment. For the trial, 414 study volunteers were allotted to receive dolutegravir/Epzicom; 419 received Atripla.

Overall, 2 percent of those in the dolutegravir group discontinued because of side effects, compared with 10 percent of those in the Atripla group. The most common drug related adverse events on Atripla were related to the central nervous system, occurring in 41 percent of those

receiving Atripla compared with 15 percent of those in the dolutegravir group. Gastrointestinal-related side effects were the most common side effects among those receiving dolutegravir/Epzicom, though the rates were similar in both groups—22 percent.

Full results of this study will be presented at upcoming scientific meetings. SINGLE is the second of four Phase III studies that are slated to be reported in 2012. Data from the clinical trial SPRING-2 were announced in April 2012. Data from VIKING-3 and SAILING in treatment-experienced patients will be received later this year and will provide further details regarding dolutegravir.

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