ViiV's Fostemsavir Shows Promise for Those With Highly Resistant HIV

Early results from an ongoing trial show that 24 weeks after adding the drug to their HIV regimen, half were virally suppressed.

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The addition of ViiV's investigational attachment inhibitor fostemsavir (formerly BMS-663068) may prove a good option for those who, because of resistance to antiretrovirals (ARVs) or other conflicts related to the medications, remain virally unsuppressed despite being on treatment, aidsmap reports. In a recent small trial, about half of those who added fostemsavir to their ARV regimen became virally suppressed after 24 weeks.

Presenting their findings at the 16th European Conference in Milan, Italy, researchers conducted a two-cohort (one cohort was randomized, the other was not) Phase III study of the safety and efficacy of fostemsavir among heavily treatment-experienced people with HIV. The 371 enrollees had drug resistance, intolerability or a contraindication (meaning a conflict between certain ARVs and another medication or condition) to at least four out of six classes of ARVs.

The 99 participants who lacked any remaining ARVs that were fully active against their HIV were placed in the nonrandomized cohort and given fostemsavir on an open-label basis (meaning they knew they were receiving that drug) plus an optimized background ARV regimen that they started the same day as fostemsavir.

The remaining 272 participants were randomized 3 to 1 to add fostemsavir on a blinded basis (meaning they did not know whether it was a placebo or the active drug) or a blinded placebo to their current failing ARV regimen. The blinded period of the study lasted eight days, after which everyone received open-label fostemsavir.

In the two blinded arms, those who received fostemsavir experienced a 0.79log10 (83.8 percent) average drop in viral load by day 8, compared with a 0.17log10 (32.4 percent) average drop among those who received the placebo.

After 24 weeks of fostemsavir treatment, 54 percent of those in the randomized part of the study achieved a fully suppressed viral load (a viral load below 40).

Most of those who received fostemsavir experienced at least one adverse event by week 24.

Among the most frequently reported grade 2 to 4 adverse health events were transient headache (reported by 2 percent), diarrhea (2 percent) and nausea (4 percent).

The adverse events and serious adverse events occurred generally as expected among a group of individuals who had a median CD4 count of 80 and were therefore severely immunocompromised. Seventeen people died by week 24 of the study, most of them as a result of progression to AIDS.

According to ViiV, the company will likely apply to the Food and Drug Administration (FDA) for approval of fostemsavir between 2019 and 2020.

To read the aidsmap article, click here.

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