Besifovir Is as Effective as Viread in Treating Hepatitis B

The experimental drug is apparently safer to bones and kidneys.

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The investigational guanosine nucleotide analogue prodrug besifovir has shown promise as an alternative to Viread (tenofovir disoproxil fumarate, or TDF) in treating hepatitis B virus (HBV), aidsmap reports.

Researchers conducted a Phase III trial comparing besifovir, formerly known as LB80380 and ANA380, with Viread among 187 people with chronic HBV. The participants were randomized to receive either 150 milligrams of besifovir or 300 mg of Viread to be taken daily for 48 weeks. After that time, they received besifovir through week 192 on an open-label basis. Additionally, participants received 660 mg of L-carnitine daily throughout the study.

Findings were presented at the 52nd International Liver Congress in Amsterdam.

About 60 percent of the participants were hepatitis B “e” antigen positive (HBeAg). About 20 percent had compensated cirrhosis, the milder form of cirrhosis; those with decompensated cirrhosis, the more advanced form of the severe liver disease, were excluded from the study.

At the 48-week mark, 81 percent of those on besifovir were virally suppressed, with a viral load below 400, compared with 85 percent of those on Viread. Sixty-four percent of those on besifovir and 69 percent of those on Viread had a viral load below 116.

Among the HBeAg-negative individuals, 97 percent of those on besifovir and 100 percent of those on Viread had a viral load below 100. The viral suppression rates among the HBeAg-positive individuals were 70 percent for those on Viread and 75 percent for those on besifovir.

Twenty-nine participants received a liver biopsy. Among this group, 78 percent of those on besifovir and 36 percent of those on Viread experienced a reduction of two or more points in their liver inflammation activity. At the outset of the study, a respective 17 percent and 9 percent of those given besifovir and Viread had stage 6 liver fibrosis on the 6-point Ishak scale. Those proportions shifted to 11 percent and 18 percent, respectively, after 48 weeks of treatment.

Besifovir proved generally safe and well tolerated, with one individual experiencing a serious

adverse drug reaction of muscle spasms that may have been treatment related. One individual on besifovir terminated treatment after developing liver cancer. One person taking Viread stopped treatment because of elevated creatine phosphokinase.

The only adverse health event that was reported by more than 5 percent of participants was stomach pain, experienced by 7 percent of those on Viread, compared with 2 percent of those on besifovir.

Measures of kidney and bone health were superior among those taking besifovir.

The researchers deemed besifovir non-inferior to, or as effective as, Viread in treating HBV.

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