Studies demonstrate improved safety results achieved with investigational drug for hep B

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Studies presented today at The International Liver Congress 2016 in Barcelona, Spain, demonstrate that tenofovir alafenamide (TAF) improves patient safety while maintaining efficacy in patients with chronic Hepatitis B virus (HBV) infection compared to tenofovir disoproxil fumarate (Viread, TDF).

The studies demonstrate that regardless of Hepatitis B e antigen status (HBeAg*), 25mg of TAF once-daily was as effective as, and safer than, 300mg of TDF once-daily, with fewer negative changes in bone and kidney parameters.

Approximately 14 million people within the WHO EU Region are chronically infected with Hepatitis B.1 TAF is an investigational treatment for HBV and is approved as a component of a fixed-dose combination (Genvoya, E/C/F/TAF) for HIV infection. TDF is an approved treatment option for both HIV and HBV. TDF can cause severe side effects, including bone and renal toxicities.2

"These two studies demonstrate that treatment with tenofovir alafenamide is as effective and yet safer than treatment with tenofovir disoproxil fumarate," said Dr Maria Buti, Hospital General Universitari Vall d'Hebron, Barcelona, Spain, and lead author of one of the studies. "Patients with HBV require long-term treatment and we are pleased that these results could provide a potentially safer treatment regimen in the future."

The two randomised, double-blind Phase 3 trials are being conducted over a period of 96 weeks. Patients were randomised to TAF 25mg daily or to TDF 300mg daily and the primary efficacy endpoint was the percent of patients with HBV DNA below 29 IU/mL at week 48. The key safety endpoints were changes in hip and spine bone mineral density (a measure of minerals mainly calcium in bones), changes in serum creatinine (a waste product in blood that is removed by healthy kidneys) and dipstick proteinuria (protein excreted in urine). Markers of bone formation and resorption, and renal tubular function were also assessed in both studies.

In the study of HBeAg-negative patients, 94% (268 of 285) of patients receiving TAF and almost 93% (130 of 140) of patients receiving TDF achieved the primary endpoint. In the study of HBeAg-positive patients, almost 64% (371 of 581) of patients receiving TAF and almost 67% (195 of 292) of patients receiving TDF achieved the primary endpoint. Overall, the response rates in both studies met the primary endpoint of non-inferiority of TAF compared to TDF.

In both studies, patients receiving TAF experienced a significantly smaller mean percentage decrease from baseline in hip and spine bone mineral density at week 48 (p