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Abstracts of the 2022 Annual Meeting of the ALEH (Asociación Latinoamericana para el Estudio del Hígado)

P1- HIGH VIRAL SUPPRESSION AND IMPROVED SAFETY PROFILE OF TENOFOVIR ALAFENAMIDE RELATIVE TO TENOFOVIR DISOPROXIL FUMARATE IN CHRONIC HEPATITIS B PATIENTS TREATED FOR 5 YEARS

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Introduction and Objectives: Tenofovir Alafenamide (TAF) is a preferred treatment in the most recent EASL and AASLD HBV Guidelines, especially in patients with risk factors for TDF-associated renal and bone effects. In 2 identically-designed double-blind (DB), randomized (2:1), Phase 3 studies (HBeAg-negative patients [N = 425] and HBeAg-positive patients [N = 873]), TAF demonstrated antiviral efficacy non-inferior to that of TDF with superior renal and bone safety. After completing three years of DB treatment, all patients were eligible to receive open-label (OL) TAF through Year eight. Here we present study results for Year five.

Materials and Methods: Efficacy was assessed by serial virologic, biochemical, and serologic assessments, while safety data included changes in renal function and changes in hip and spine bone mineral density. Resistance testing and phenotyping were performed annually through Year 5.

Results: Of 1298 randomized and treated patients, 1157 (89%; 775 TAF; 382 TDF) entered OL, at year 5, 999 (77%; 675 TAF, 136 TDFTAF OL 3y, 188 TDF-TAF OL 2y) patients remained on treatment. High rates of virologic control were achieved and maintained in patients receiving TAF throughout and for TDF patients who switched to TAF at Weeks 96 or 144. Rates of ALT normalization and serologic responses were also comparable among groups. Eight patients are undergoing phenotypic testing to assess resistance. Adverse events (AEs) leading to discontinuation were low and similar among groups. Renal and bone outcomes were improved following the switch to OL TAF from TDF.

Conclusions: After five years of treatment, virologic suppression rates remained high, and TAF was safe and well tolerated, with improved renal and bone safety in patients switching from TDF.

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P-2 DE NOVO LIPOGENESIS MARKERS ARE INVOLVED IN METABOLIC ASSOCIATED FATTY LIVER DISEASE PROGRESSION IN BTBR OB/OB MICE

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