Three Years of Tenofovir Disoproxil Fumarate (TDF) Treatment in HBeAg-Negative Patients with Chronic Hepatitis B (Study 102)

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Background

- TDF (245 mg) was approved for HBeAg-negative chronic hepatitis B (CHB) in 2008 as 2.4 million patient-years of experience
- Week 48 Phase 3 data showed TDF superior to adefovir dipivoxil (ADV): 93% of HBeAg-negative TDF-treated patients (versus 63% of ADV-treated patients) had HBV DNA ≤ 400 copies/mL
- Week 96 Open-Label TDF data showed:
  - Both stable and viremic patients on ADV can effectively switch to TDF and achieve or maintain viral suppression (HBV DNA ≤ 400 copies/mL) and normal ALT levels
- Patients treated with TDF for 96 weeks maintained viral suppression and normal ALT levels

Objective

- Evaluate the efficacy and safety of up to 3 years of TDF therapy

Methods

- Patients were randomized to Double-Blind TDF or Open-Label TDF
- Randomized Double-Blind: 235 patients, 125 ADV-TDF, 112 TDF-TDF
- On-Treatment Analysis: observed data, missing=excluded

Results

- Overall HBV DNA from 4 viremic patients were genotypically evaluated and no patient had amino acid substitutions in a conserved site region

Conclusions

- At 3 years, 87% of patients remained on treatment demonstrating:
  - durable and potent antiviral activity, i.e., 99% of patients had HBV DNA <400 copies/mL
  - no resistance to TDF
  - favorable tolerability profile

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