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CONTINUED VIROLOGIC AND BIOCHEMICAL IMPROVEMENT THROUGH 96 WEEKS OF ENTECAVIR TREATMENT IN HBeAg(-) CHRONIC HEPATITIS B PATIENTS (STUDY ETV-027)

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Background: Entecavir (ETV) demonstrated superior virologic, biochemical and histologic benefit compared to lamivudine (LVD) at Week 48 in HBeAg(-) chronic hepatitis B (CHB) patients. HBV DNA suppression to <300 copies/mL occurred in 90% of ETV patients and 72% of LVD patients. Efficacy and safety through 96-weeks of treatment is reported here.

Methods: 638 HBeAg(-) CHB patients were randomized 1:1 and treated with ETV 0.5 mg (n=325) or LVD 100 mg (n=313) for 1 year. At Week 52, patient management decisions were made based on Week 48 laboratory results: 85% (275/325) of ETV patients and 78% (245/313) of LVD patients achieved Response (HBV DNA <0.7 MEq/mL by bDNA assay and ALT <1.25 x ULN) and discontinued therapy. Non-responders (HBV DNA ≥0.7 MEq/mL) also discontinued therapy (3 ETV and 18 LVD patients). Eleven percent in both treatment groups (ETV 34/325, LVD 34/313) achieved Virologic Response (HBV DNA <0.7 MEq/mL but ALT ≥1.25 x ULN) and could continue blinded therapy through Week 96. A cumulative response was confirmed when two sequential measurements or last on-treatment measurement for the endpoint occurred.

Results: 26 ETV and 28 LVD patients with Virologic Response continued to a second year of therapy. Of these, 96% of ETV-treated and 64% of LVD-treated patients maintained an HBV DNA <300 copies/mL by PCR at end of dosing.

Over the course of the 96-week study, total rate for Response was 88% of ETV patients and 81% of LVD patients. The cumulative safety profile of ETV was comparable to LVD.

Conclusions: In HBeAg(-) CHB patients, treatment with ETV 0.5 mg up to 96-weeks results in a significantly better viral load reduction than LVD, with 96% of patients maintaining this endpoint through a 2nd year of treatment and with a comparable safety profile to LVD.

Cumulative Confirmed Virologic and Biochemical Endpoints for all treated patients through Week 96			
	ETV 0.5 mg N=325	LVD 100 mg N=313	p-value
HBV DNA <300 copies/mL by PCR, %	94	77	<0.0001
ALT ≤1 x ULN, %	89	84	>0.05