Randomized Placebo-Controlled Phase III Study to Assess the Safety and Efficacy of Rifabutin Triple Therapy (RHB-105) for Helicobacter Pylori (H. pylori) Infection in Dyspepsia Patients

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Rationale: Both Maastricht V and the Kyoto H. pylori consensus recommend eradication therapy for patients with active Hp infections including those with dyspepsia. Standard triple therapy fails to eradicate H. pylori in up to 30% of infected patients. RHB-105 is a new “all-in-one” capsule formulation, comprising a dual antibiotic (rifabutin and amoxicillin) and PPI (omeprazole) drug combination under investigation for the treatment of H. pylori infections.

Methods: This was a Phase III, randomized, double-blind, placebo-controlled study of RHB-105 in adult patients with dyspepsia positive for H. pylori infection. The primary endpoint was H. pylori eradication confirmed by ¹³C UBT testing 28-35 days after end of treatment.

Results: Seventy seven subjects received RHB-105 and 41 received FDA mandated placebo for assessment of safety. The H. pylori eradication rate (based on ¹³C UBT) in the protocol defined, modified intent-to-treat (mITT) patient population was 89.4% (59/66 subjects). This rate was statistically significantly superior to 70%, p-value 0.001, which was the reported effectiveness of standard of care (SOC) treatment. Placebo patients and RHB-105 failures underwent physician choice non-rifabutin Hp therapy with eradication rate of 61% (19/31 subjects). The AE profile, laboratory values, and other safety assessments did not indicate any safety concerns.

Conclusions: RHB-105, a novel “three in one” investigational formulation appeared safe, well-tolerated and more effective than historical SOC treatment regimens as well as physician selected SOC therapy in eradication of H. pylori. A confirmatory Phase III study for this new therapeutic agent is in development.