

NEWS

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Tranzyme Pharma Initiates Dosing of Patients in a Multi-National Phase IIb Clinical Trial for the Treatment of Severe Gastroparesis

RESEARCH TRIANGLE PARK, N.C. and SHERBROOKE, Québec (October 30, 2007) - Tranzyme Pharma today announced the initiation of a Phase IIb clinical trial of its potent intravenous ghrelin agonist, TZP-101, for the management of severe gastroparesis. TZP-101 is a first-in-class prokinetic agent under development for the treatment of selected GI motility disorders. In July 2007, Tranzyme initiated enrollment in a Phase IIb clinical trial for post-operative ileus.

The severe gastroparesis Phase IIb trial, now underway in the US, Denmark and Sweden, is a multicenter, randomized, double-blind, placebo-controlled, dose-ranging study to assess the efficacy and safety of TZP-101 in subjects suffering from severe diabetic gastroparesis. The study has an adaptive randomization design, and could potentially enroll up to 100 subjects. The primary objective of this study is to assess the impact of TZP-101 on symptoms as defined by a change from baseline in a validated gastroparesis symptom scoring assessment.

In July 2007, TZP-101 received fast track designation from the FDA for the treatment of severe gastroparesis based on Tranzyme's positive Phase IIa clinical data. In the Phase IIa study, TZP-101 not only demonstrated a statistically significant increase in gastric emptying (measured by scintigraphy) but also improved symptoms in 10 patients with long-standing diabetes, poor glycemic control, and significant gastropathy. Postprandial fullness, the most frequent and severe symptom observed with these patients, was reduced 37% by TZP-101. This state-of-the-art simultaneous controlled investigation, carried out during euglycemic hyperinsulinemic clamp (in highly selective homogenous patients), demonstrated for the first time that TZP-101 both accelerates gastric emptying of solid food and improves symptoms characteristic of gastroparesis. These observations clearly suggest that TZP-101 is a potential break-through drug for the management of severe gastroparesis.

Severe gastroparesis is a cause of significant patient morbidity. Frequent hospitalizations, emergency room and physician office visits may result from the difficulties in managing this disorder and its diabetes-associated metabolic complications. The impact on people's lives, and the economic and resource burdens that gastroparesis places on the healthcare system, stresses the importance of developing an effective and safe treatment for this indication. Most current drug treatments are only moderately effective at best, and may cause neurological side effects.

“As of today, no efficient treatment for diabetic gastroparesis exists. The ability of TZP-101 to address both gastric emptying and symptoms of gastroparesis will potentially make this drug a unique first-in-class treatment for this extremely difficult medical condition,” said Dr. Niels Ejskjaer, principal investigator from the Aarhus University Hospital, Denmark.

About TZP-101

TZP-101 is a potent, small molecule ghrelin receptor agonist that Tranzyme is developing for the treatment of severe gastroparesis and post-operative ileus. The safety and pharmacokinetic profile of TZP-101 has been characterized in 50 healthy subjects across multiple dose levels. The prokinetic properties of the compound have been well established in various animal models of postoperative ileus and more recently in diabetic patients with severe gastroparesis. In addition to TZP-101, Tranzyme is developing an oral ghrelin agonist, TZP-102, for the treatment of mild-to-moderate gastroparesis and other chronic GI motility disorders.

About Severe Gastroparesis

Gastroparesis is a paralysis of upper gastrointestinal tract function characterized by delayed gastric emptying in the absence of a mechanical cause of obstruction. Disease severity ranges from mild to moderate to severe. Symptoms include post-prandial fullness, bloating, nausea, vomiting, and upper abdominal pain. Severe gastroparesis, or gastroparesis with gastric failure, is characterized by refractory symptoms that are not controlled despite medical therapy. Patients suffering from severe gastroparesis are often unable to maintain nutrition, or medication via oral delivery. Because of their unremitting symptoms, they may be dependent on gastric suctioning and enteral/parenteral nutrition. Gastroparesis is a major complication of diabetes. The World Health Organization estimates that 180 million people have diabetes. Approximately 5% of Type 1 and 25% of Type 2 diabetic patients, or 13 million worldwide, are believed to suffer from gastroparesis. In addition, there may be a nearly equal number of patients who suffer from gastroparesis due to other causes.

About Tranzyme Pharma

Tranzyme Pharma is a clinical-stage biopharmaceutical company which discovers and develops breakthrough small molecule drugs for diseases where there is a high unmet medical need. Tranzyme has developed a pipeline of novel drugs for the treatment of gastrointestinal and metabolic diseases. Tranzyme’s proprietary chemistry technology and discovery capabilities provide competitive advantages in developing drugs being sought by pharmaceutical companies. For more information, please visit: www.tranzyme.com.

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