

NEWS

For Immediate Release – July 12, 2007

Tranzyme Pharma Receives FDA Fast Track Designation for its Novel Ghrelin Agonist, TZP-101, for the Treatment of Severe Gastroparesis

RESEARCH TRIANGLE PARK, N.C. and SHERBROOKE, Québec (July 12, 2007) - Tranzyme Pharma, a leading biopharmaceutical company developing small molecule drugs for the treatment of gastrointestinal and metabolic diseases, today announced that the company has received fast track designation for its novel ghrelin agonist, TZP-101, for the treatment of severe gastroparesis. Tranzyme is developing TZP-101 as a first-in-class prokinetic agent for the treatment of severe gastroparesis and post-operative ileus (POI).

Under the FDA Modernization Act of 1997, the Fast Track Program mandates the FDA to facilitate development and expedite review of a drug intended to treat a serious or life-threatening condition that demonstrates the potential to address an unmet medical need. Support of this fast track designation was based on positive Phase IIa data from a clinical study of TZP-101 in diabetic patients with severe gastroparesis, as well as from pre-clinical studies demonstrating that TZP-101 has the potential to address this unmet medical need.

“The Food and Drug Administration’s fast track designation for TZP-101 highlights the large unmet medical need for a treatment for severe gastroparesis,” said Gordana Kosutic, M.D., VP of Clinical and Regulatory Affairs for Tranzyme Pharma. “In 2005, an estimated 150,000 patients were hospitalized with a diagnosis code of gastroparesis; these patients had gastroparesis listed as either a primary or secondary diagnosis at the time of discharge. Many of these patients are diabetics who have inadequate blood glucose control. Currently, no satisfactory treatment exists for this severe condition. Metoclopramide, the only drug approved by the FDA for gastroparesis, is associated with unwanted adverse events including extrapyramidal reactions and tardive dyskinesia.”

About Gastroparesis

Gastroparesis is a disorder characterized by delayed emptying of food from the stomach. Gastroparesis results from dysfunction of the nerves of the stomach, leading to postprandial fullness, bloating, early satiety, nausea and vomiting. Gastroparesis exists in mild to moderate (chronic) and severe (acute) forms. In severe cases, patients may require hospitalization to treat pain, nausea, vomiting, and malnutrition. In particular, gastroparesis has serious implications in diabetic patients, where failure to tolerate food and oral medications may rapidly lead to metabolic instability and the need for immediate treatment or hospitalization. Gastroparesis

affects an estimated 1.2 million diabetics in the US. In 2005 there were 150,000 hospitalizations in the United States where gastroparesis was the primary or the secondary diagnosis. The incidence of gastroparesis has increased dramatically as the incidence of diabetes and obesity has increased.

About TZP-101

TZP-101 is a potent, small molecule ghrelin receptor agonist that Tranzyme is developing as an intravenous drug 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. A Phase IIa pilot clinical trial testing its efficacy in diabetic patients with severe gastroparesis has been completed. Tranzyme recently reported initial data showing that TZP-101 significantly accelerates gastric emptying and improves symptoms characteristic of gastroparesis. Tranzyme plans to initiate full Phase II development of TZP-101 for both severe gastroparesis and POI in 3Q 2007.

TZP-101 is a new chemical entity originating from Tranzyme's internal chemistry-based drug discovery program.

About Tranzyme

Tranzyme Pharma is a 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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