

NEWS

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Tranzyme Pharma Initiates Dosing of Patients in a Multi-National Phase IIb Clinical Trial with its Novel Ghrelin Agonist, TZP-101, for Post-Operative Ileus

RESEARCH TRIANGLE PARK, N.C. and SHERBROOKE, Québec (July 26, 2007) - Tranzyme Pharma, a leading biopharmaceutical company developing small molecule drugs for the treatment of gastrointestinal and metabolic diseases, today announced the initiation of a Phase IIb clinical trial of its investigational drug, TZP-101, for the management of post-operative ileus (POI). TZP-101 is a potent ghrelin agonist that Tranzyme is developing as a first-in-class prokinetic agent for the treatment of POI and severe gastroparesis.

The POI Phase IIb trial, now underway in the USA, Romania and Lithuania, is a multicenter, randomized, double-blind, placebo-controlled, dose-ranging study to assess the efficacy and safety of TZP-101 when administered as a 30 minute i.v. infusion to subjects undergoing major open abdominal surgery. The study has an adaptive randomization design, and could potentially enroll up to 250 patients. The primary objective of this study is to assess the impact of TZP-101 on postoperative time to recovery of gastrointestinal (GI) function as defined by the time to first bowel movement. In addition to efficacy monitoring, routine clinical, laboratory and ECG monitoring will be performed to evaluate patient safety.

POI is a cause of significant morbidity in patients subjected to abdominal and other types of surgery and increases the duration and cost of hospitalization. The economic and resource burden that POI places on the healthcare system stresses the importance of developing an effective and safe treatment for this indication.

“TZP-101 offers the potential to treat POI through a novel mechanism of action,” said Vipin K. Garg, Ph.D, President and CEO of Tranzyme Pharma. “We are pleased to initiate this Phase II program which results from our internal research efforts and our proprietary chemistry-based drug discovery platform.”

“It is exciting for Tranzyme that the TZP-101 program has now entered the more advanced phase of the clinical development process,” said Gordana Kosutic, M.D., VP of Clinical and Regulatory Affairs for Tranzyme Pharma. “Tranzyme’s pre-clinical data have clearly shown that TZP-101 restores motility of the gastrointestinal tract whether caused by surgical manipulations of the GI tract or aggravated by the use of drugs such as opioids. The ability of TZP-101 to treat several underlying causes of post-operative ileus will potentially make this drug a unique first-in-class treatment for this medical condition.”

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 post-operative ileus and severe gastroparesis. 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 chronic GI motility disorders.

About Post-Operative Ileus

Post-operative ileus is a transient impairment of GI motility following abdominal or other surgery. Common symptoms include abdominal distention or bloating, pain, nausea and vomiting, and inability to pass stools and tolerate a solid diet. A delay in resuming a normal diet may lead to poor healing through a cascade of events. A greater risk for pulmonary complications also exists, since POI may result in reduced patient mobility. POI is associated with an increased length of hospital stay. It has been reported that POI is the most common cause of delayed hospital discharge after abdominal surgery. In the United States alone, it is estimated that 22 million patients undergo surgical procedures requiring pain management and of these patients, 2.4 million undergo high risk open surgery each year (Source: Premier Database). No treatments for POI have been approved by the US Food and Drug Administration to date.

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: <http://www.tranzyme.com>.

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