

PRESS RELEASE

For Immediate Release – October 1, 2008

Tranzyme Pharma Announces Positive Phase IIb Results with Its Ghrelin Agonist, TZP-101, for Postoperative Ileus (POI)

Phase III Initiation Targeted Q1 2009

RESEARCH TRIANGLE PARK, N.C. (October 1, 2008) - Tranzyme Pharma today announced positive Phase IIb results for its first-in-class, highly potent and selective ghrelin agonist, TZP-101, for the management of postoperative ileus (POI). Results demonstrated that TZP-101 was both safe and highly effective in reducing the duration of ileus following surgery in patients undergoing open bowel resection.

Over 200 patients were enrolled in an adaptive, multinational, double-blind, placebo-controlled Phase IIb clinical trial designed to assess the time to recovery of gastrointestinal (GI) function. Either TZP-101 or placebo was administered intravenously within the first hour after surgery, followed by once-daily dosing for up to seven days. The primary study endpoint was time to first bowel movement (BM), also known as “GI1”. Given its pharmacoeconomic importance, a key secondary endpoint was the percentage of patients that achieved GI recovery within 72 hours of surgery.

For the primary endpoint, TZP-101 was superior to placebo at all doses tested. For the two most effective doses, 80µg/kg and 480µg/kg, Cox proportional hazard ratios were 1.57; P=0.056, and 1.67; P=0.029 respectively. After accounting for covariates, including country, type of surgery, age and opioid consumption, the dose and drug effect for the primary endpoint persisted. In the Kaplan-Meier “GI1” analysis, median times to first BM were 70.5 and 68.0 hours for the 80µg/kg and 480µg/kg dose groups, respectively, *versus* 89.6 hours for placebo. Further, nearly 2/3 (64%) of patients in both the 80µg/kg and 480µg/kg dose groups had a BM within 72 hours, *versus* only 25% in placebo; (P=0.001 for both dose groups).

Statistical significance was also achieved in another important secondary endpoint, time to recovery of GI function as defined by the later of the first BM and first solid food intake, referred to as “GI2”. In the Kaplan-Meier analysis, median times for the “GI2” endpoint were identical to “GI1”, 70.5 and 68.0 hours for the 80µg/kg and 480µg/kg groups, respectively, *versus* 91.3 hours for placebo. The “GI2” Cox proportional hazard ratio for 80µg/kg=1.65; P=0.034 and for 480µg/kg=1.61; P=0.044.

In June, the Company completed a “Thorough QT/QTc” study of TZP-101 with no adverse signals identified. In the current Phase IIb study, TZP-101 was well tolerated

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without any identified safety concerns. As expected, the most frequently observed adverse events in this post-surgical population were nausea (26.5%) and vomiting (16.1%) in the placebo group. In contrast, for the two most effective study doses, fewer than 5% of TZP-101 patients experienced nausea or vomiting, consistent with the strong GI prokinetic activity of TZP-101.

“The ability of TZP-101 to increase the percentage of patients achieving recovery within 72 hours is particularly impressive and represents a major advancement in the management of postoperative ileus, a condition which carries significant associated morbidity and costs,” stated Anthony Senagore, MD, MBA. Dr. Senagore, a TZP-101 study investigator, is Professor of Surgery, Michigan State University College of Human Medicine, and Vice President of Research and Medical Education for Spectrum Health.

“We are extremely pleased with the outcome of this study and look forward to advancing TZP-101 into a Phase III trial early next year,” said Gordana Kosutic, MD, the Company’s VP, Clinical and Regulatory Affairs.

About Postoperative Ileus

Postoperative ileus is a transient impairment of GI motility following abdominal or other surgery and is often protracted and exacerbated by multiple factors including the use of opioids for pain management. Symptoms of POI can include abdominal distention, pain, nausea and vomiting, and inability to pass stools and tolerate a solid diet. Delays in resuming a normal diet may lead to poor healing and increased risk of infection through a cascade of events, and patients are at greater risk for pulmonary complications since POI may result in reduced patient mobility. POI is associated with an increased length of hospital stay and is the most common cause of delayed hospital discharge after abdominal surgery. In the United States alone, 2.4 million patients undergo open abdominal surgery each year and are at high risk for POI (Source: Premier Database). No unrestricted treatments for POI have been approved by the US Food and Drug Administration to date.

About TZP-101

TZP-101, Tranzyme’s intravenous ghrelin agonist, is a product of the Company’s internal drug discovery efforts. TZP-101 is being evaluated clinically for use in acute care settings, including POI and gastroparesis. In addition to the recently completed POI trial, a Phase IIb gastroparesis trial is nearing completion. The safety and pharmacokinetic profiles of TZP-101 have been extensively characterized in healthy subjects across multiple dose levels, and the prokinetic properties of the compound have been well established in various animal models, with or without concomitant opioids. In addition to TZP-101, Tranzyme is developing an oral ghrelin agonist, TZP-102, for the out-patient treatment of gastroparesis and other chronic GI motility disorders, such as GERD and functional dyspepsia.

About Tranzyme Pharma

Tranzyme Pharma is a clinical stage biopharmaceutical company engaged in the discovery and development of first-in-class small molecule therapeutics for the treatment of both acute care (hospital-based) and chronic indications with significant unmet medical needs.

Tranzyme has developed a pipeline of novel drugs through its proprietary MATCH™ drug discovery technology which accelerates the progression of compounds from discovery to commercial track by generating small molecule drug candidates that display the favorable characteristics exhibited by large biomolecules, such as tight receptor binding for high potency and exquisite target selectivity, while maintaining the benefits typically associated with small molecule drugs including oral bioavailability, cost of synthesis, and ease of formulation. For more information, please visit: www.tranzyme.com.

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