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Tranzyme Pharma Expands Clinical Program of its Novel Ghrelin Agonist, TZP-101, to Include Patients with Gastroparesis

RESEARCH TRIANGLE PARK, **N.C.** and **SHERBROOKE**, **Québec** (September 21, 2006) -Tranzyme Pharma announced today that the Company has amended the IND for its novel small molecule ghrelin agonist, TZP-101, to include patients with gastroparesis. Tranzyme has been developing TZP-101 as a potent prokinetic agent for the treatment of post-operative ileus (POI). Under the amended IND, Tranzyme has initiated a single-dose study in diabetic patients suffering from gastroparesis. This new study will provide a lead-in to more detailed Phase II evaluation of TZP-101 in both POI and gastroparesis.

Gastroparesis is a gastrointestinal disorder characterized by delayed emptying of the stomach. It exists in acute and chronic forms and is a common disorder among patients with diabetes. Patients presenting with acute episodes of gastroparesis require immediate hospitalization to manage pain, nausea, vomiting, glucose dysregulation, fluid and electrolyte imbalance, and potential malnutrition. The most potent product for treating gastroparesis, Propulsid® (cisapride), achieved \$1 billion in global sales, but was withdrawn from the market in 2000 due to adverse side effects.

"The Company is making significant progress in the development of TZP-101," said Gordana Kosutic, M.D., VP, Clinical & Regulatory Affairs for Tranzyme Pharma. "Recent investigator initiated clinical studies of the native ghrelin peptide have shown that ghrelin accelerates gastric emptying in patients with gastroparesis. Since gastroparesis is highly prevalent among diabetics, we chose to target this patient population in this proof of principal study. The results from this study will give us preliminary data on the efficacy of TZP-101 in reversing delayed gastric emptying."

In a previous Phase I single-dose study, Tranzyme reported that TZP-101 demonstrated excellent tolerability and safety, and a desirable pharmacokinetic profile in healthy subjects. The Company plans to initiate full Phase II development of TZP-101 in early 2007. In addition to the ongoing clinical testing of TZP-101, Tranzyme is developing a second generation ghrelin agonist, TZP-102, as an oral product. Tranzyme expects to initiate Phase I clinical testing of TZP-102 in the second half of 2007 for the treatment of mild to moderately severe gastroparesis.

"TZP-101 and TZP-102 are promising first-in-class drugs with tremendous commercial potential", said Vipin K. Garg, Ph.D., President & CEO of Tranzyme Pharma. "Unlike TZP-101, most prokinetic agents under development and on the market target the central nervous system with potentially serious side effects. The amended IND represents a significant milestone for Tranzyme Pharma as TZP-101 is the Company's first product to be dosed in patients."

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