

# Press Release

For Immediate Release February 23, 2011

## Tranzyme Pharma and Norgine Initiate Dosing in Phase 3 Pivotal Study of Novel Intravenous GI Motility Drug Ulimorelin

**RESEARCH TRIANGLE PARK, N.C. and AMSTERDAM, NETHERLANDS** (February 23, 2011) Tranzyme Pharma and Norgine B.V., have initiated dosing of ulimorelin in the first of two, Phase 3 pivotal studies - ULISES (**UL**imorelin **S**afety and **E**fficacy **S**tudy). Ulimorelin is Tranzyme's intravenous promotility agent in development for the management of postoperative ileus (POI) in hospital and acute care settings. POI is the temporary cessation of normal bowel motility after surgery preventing transit of intestinal contents and tolerance of oral intake. Approximately 300 bowel surgery patients will be enrolled at sites across the US and Europe in each of the two studies, ULISES 007 and ULISES 008. The objective is to evaluate the efficacy and safety of two, once-daily, dosage regimens of ulimorelin (160 and 480 $\mu$ g/kg) in accelerating gastrointestinal (GI) recovery in patients undergoing partial bowel resection. The primary endpoint of the study is the time to GI recovery defined as the time to the latest of first bowel movement and first intake of solid food.

“Currently there are limited options for restoring GI function shortly after surgery, which is a critical component for post-surgical recovery” said Vipin K. Garg, PhD, President and CEO of Tranzyme. “We are committed to finding new and safe therapeutics for critical, unmet medical needs, and the commencement of this Phase 3 program is a vital step towards achieving that goal.”

There are an estimated 360,000 bowel resection surgeries performed annually in the United States. In many cases POI results in an extended length of stay in the hospital, having a negative impact on the patient experience and placing a considerable economic burden on hospitals and healthcare providers worldwide.

### About Ulimorelin

Ulimorelin is an intravenous ghrelin agonist currently in clinical development for the management of POI in acute care settings. Ulimorelin was discovered using Tranzyme's proprietary drug discovery technology, and is being co-funded by, and co-developed with specialty pharmaceutical firm Norgine B.V. based in the Netherlands. Norgine, in turn, holds the commercial rights for ulimorelin in Europe, Oceania, Middle East, and North and South Africa.

### About Norgine

Norgine is an independent, successful European specialty pharmaceutical company that has been established for over 100 years and has a presence in all major European markets. In 2009, Norgine's net product sales were €253 million, the 23rd year of double-digit growth at constant exchange rates. The company employs over 1,200 people.

Norgine's focus is the development and marketing of pharmaceutical products that address significant unmet clinical needs in areas such as gastroenterology, hepatology and supportive care. The company currently markets a range of products in various markets in its key therapeutic areas e.g., MOVICOL® for the

treatment of constipation and fecal impaction, MOVIPREP® a bowel cleansing preparation, KLEAN-PREP® for bowel preparation prior to colonoscopy, XIFAXAN® for the treatment of travelers' diarrhea and ORAMORPH® for the treatment of moderate to severe pain associated with cancer.

Norgine is active in research and development and currently has products in various stages of clinical development. Norgine manufactures most of its own products in Hengoed, Wales and Dreux in France.

## **About Tranzyme Pharma**

Tranzyme Pharma is a clinical-stage biopharmaceutical company focused on discovering, developing and commercializing novel, first-in-class small molecule therapeutics for the treatment of acute (hospital-based) and chronic gastrointestinal motility disorders. All of Tranzyme's product candidates have been discovered using its proprietary drug discovery (chemistry) technology, MATCH™, which enables the construction of synthetic libraries of drug-like, macrocyclic compounds in a predictable and efficient manner.

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