



## Corporate Press Release

### **Tranzyme Pharma and Norgine Announce Top-line Data from ULISES 007, the First of Two Phase 3 Pivotal Trials**

***-- Preliminary Analysis Indicates Study Did Not Meet Primary Endpoint --***

***-- Tranzyme to Host Conference Call Today at 8:00 am ET --***

**RESEARCH TRIANGLE PARK, N.C. and AMSTERDAM, NETHERLANDS** (March 12, 2012) – Tranzyme Pharma (NASDAQ: TZYM) and Norgine B.V. today announced top-line results of the primary analysis of ULISES 007, the first of two Phase 3 pivotal trials evaluating TZP-101. The trial failed to meet its primary and secondary efficacy endpoints.

“These results are surprising and disappointing. While we are still planning to analyze the data from the second phase 3 trial ULISES 008, which we expect by the end of the second quarter, we are stopping all other NDA activities for TZP-101,” said Vipin K. Garg, Ph.D., President and Chief Executive Officer, Tranzyme Pharma. “We are now focusing on our oral drug TZP-102 which is currently in a phase 2b trial for the treatment of diabetic gastroparesis. In this trial, we are looking for improvement in upper GI symptoms over a twelve-week treatment period.”

The results of ULISES 007 show that TZP-101, at both 160 and 480 micrograms/kg doses, was not statistically different from placebo for the primary endpoint, the time to recovery of GI function as defined by the time from the end of surgery to GI2. GI2 is defined as the later of first bowel movement and tolerance of solid food. Key summary data include:

- Median time to GI2 was approximately 80 hours in all arms.
- Median duration of therapy was approximately 3.5 days in all arms.
- Both doses of TZP-101 were well tolerated.

#### **Conference Call Details**

Tranzyme will host a conference call today at 8:00 am ET. To participate in the live call, please dial (877) 670-9784 (U.S. and Canada) or (970) 315-0430 (international), five to ten minutes prior to the start of the call. A live audio webcast will also be available in the "Investors" section of the Tranzyme Pharma website, [www.tranzyme.com](http://www.tranzyme.com).

A replay of the conference call will be available from today at 11:00 am ET through March 19, 2012. Investors may listen to the replay by dialling (855) 859-2056 (U.S. and Canada) or (404) 537-3406 (international), with the conference id 61643444. The webcast will also be archived for on-demand listening for 30 days at [www.tranzyme.com](http://www.tranzyme.com).

### **Study Design**

ULISES (TZP-101 Safety and Efficacy Study) 007 is one of two Phase 3 pivotal, double-blind, multinational, placebo-controlled studies to evaluate the efficacy and safety of IV TZP-101 administered postoperatively to accelerate GI recovery in subjects who have undergone partial bowel resection. The study was designed to randomize approximately 330 patients to once-daily IV administration of 160 micrograms/kg of TZP-101, 480 micrograms/kg of TZP-101, or placebo. Top-line results in the second pivotal trial, ULISES 008 (identical in design and population to ULISES 007), are expected to be announced by the end of the second quarter 2012.

### **About Tranzyme Pharma**

Tranzyme Pharma is a late-stage biopharmaceutical company focused on discovering, developing and commercializing novel, mechanism-based therapeutics for the treatment of upper gastrointestinal (GI) motility disorders. While approximately 40 percent of people in the U.S. are affected by these persistent and recurring conditions which disrupt the normal movement of food throughout the GI tract, currently there are a limited number of safe and effective treatment options. Tranzyme is developing TZP-102, an oral ghrelin agonist with potent prokinetic properties for treating the symptoms associated with chronic GI motility disorders. This product candidate targets a significant underserved market. Enrolment in a multinational, phase 2b trial is ongoing; top-line data is expected by year-end 2012. By leveraging its proprietary drug discovery technology, Tranzyme is committed to pursuing first-in-class medicines to address areas of significant unmet medical needs.

Further information about Tranzyme Pharma can be found on the Company's web site at [www.tranzyme.com](http://www.tranzyme.com).

### **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 2011, Norgine's net product sales were €250 million. 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 therapeutic 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<sup>®</sup> for the treatment of constipation and faecal impaction, MOVIPREP<sup>®</sup> a bowel cleansing preparation, KLEAN-PREP<sup>®</sup> for large bowel preparation prior to colonoscopy or surgery, XIFAXAN<sup>®</sup> for the treatment of traveller's diarrhoea and ORAMORPH<sup>®</sup> 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, UK and Dreux, France. For more information: [www.norgine.com](http://www.norgine.com)

### **Forward-Looking Statements**

Statements in this press release may include statements which are not historical facts and are considered forward-looking within the meaning of Section 27A of the Securities Act and Section 21E of the Securities Exchange Act, which are usually identified by the use of words such as "anticipates," "believes," "estimates," "expects," "intends," "may," "plans," "projects," "seeks," "should," "will," and variations of such words or similar expressions. We intend these forward-looking statements to be covered by the safe harbour provisions for forward-looking statements contained in Section 27A of the Securities Act and Section 21E of the Securities Exchange Act and are making this statement for purposes of complying with those safe harbour provisions. These forward-looking statements reflect our current views about our plans, intentions, expectations, strategies and prospects, which are based on the information currently available to

us and on assumptions we have made. Although we believe that our plans, intentions, expectations, strategies and prospects as reflected in or suggested by those forward-looking statements are reasonable, we can give no assurance that the plans, intentions, expectations or strategies will be attained or achieved. Furthermore, actual results may differ materially from those described in the forward-looking statements and will be affected by a variety of risks and factors that are beyond our control including, without limitation, risks related to enrolment and successful completion of our trials, risk of unforeseen side effects, risks related to our collaborations and risks related to regulatory approval of new drug candidates. Further information on these and other factors that could affect the company's financial results is contained in our public filings with the Securities and Exchange Commission (SEC) from time to time, including our Form 10-K which was filed with the SEC on February 28, 2012, and subsequent filings with the SEC. Existing and prospective investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. We assume no obligation to update publicly any forward-looking statements, whether as a result of new information, future events or otherwise.

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