TheraVida Announces Positive Top-Line Phase 2 Results for Tolenix™ (THVD-201) in Patients with Overactive Bladder and Urge Urinary Incontinence

MOUNTAIN VIEW, Calif., Jan. 3, 2013 /PRNewswire/ -- TheraVida, Inc., a clinical-stage biopharmaceutical company developing novel combination drug products, announced positive results from a Phase 2 clinical trial of its lead product candidate Tolenix™ (THVD-201) for the treatment of overactive bladder (OAB) and urge urinary incontinence (UUI). Tolenix™ is a twice-daily (BID) proprietary combination of tolterodine, a muscarinic antagonist used to treat OAB, and pilocarpine, a muscarinic agonist approved to treat dry mouth (xerostomia).

The objectives of the randomized, double-blinded, multiple-crossover Phase 2 trial were to assess the safety and efficacy of Tolenix™ in reducing the frequency of micturition (urination) and incontinence episodes per day, as compared to both placebo control and active control Detrol® (tolterodine tartrate). In addition, common side effects of muscarinic antagonist therapies, such as dry mouth, were carefully assessed in the 138 patients enrolled in the trial. This international Phase 2 clinical trial was conducted in South Korea, Australia, and New Zealand.

Patients receiving Tolenix™ (2mg tolterodine plus 9mg pilocarpine, administered BID) experienced statistically significant improvements in their OAB and UUI symptoms over placebo control, as well as efficacy similar in magnitude to the maximum dose of active control Detrol® (2mg tolterodine, administered BID). Patients receiving Tolenix™ exhibited no significant safety issues, and demonstrated statistically significant and clinically meaningful improvements in their saliva production and dry mouth side effects, as compared to active control Detrol®. TheraVida intends to present detailed efficacy and tolerability results from the Phase 2 trial of Tolenix™ at an upcoming scientific meeting.

"Results from this Phase 2 clinical trial clearly demonstrate that Tolenix™ has the ability to provide patients with bladder control, while reducing dry mouth side effects typically associated with OAB medications such as Detrol®," said Roger Flugel, Ph.D., Chief Executive Officer at TheraVida. "Dry mouth side effects are a primary reason why patients stop taking medicines to treat their OAB and urgency-related micturition symptoms. We believe there is a significant opportunity for a new OAB treatment option for currently diagnosed patients and the aging population. Tolenix™ has the potential to improve the overall tolerability, compliance, and satisfaction for patients with OAB and UUI."

This Phase 2 study also demonstrated a favorable therapeutic index, which may enable higher dosing of Tolenix™ in some patients. A higher dose of Tolenix™ (3mg tolterodine plus 13.5mg pilocarpine, administered BID) was studied in a 12-week open-label extension period, in a subset of patients in this Phase 2 trial. In this extension period, the higher dose of Tolenix™ exhibited the potential to provide greater bladder control, while minimizing dry mouth side effects.

TheraVida intends to conduct additional international clinical trials of Tolenix™ in patients with OAB and UUI.

About Overactive Bladder (OAB)
OAB is primarily a disease of aging, characterized by an increase in urinary frequency, urinary incontinence and nocturia (waking at night to urinate). OAB is a common disorder, affecting approximately 16% to 17% of the population worldwide, with a prevalence similar to diabetes or asthma. As the world population continues to age, the prevalence of OAB is expected to increase.

About Tolenix™ (THVD-201)
Tolenix™ is a novel, patent-protected therapeutic that combines the muscarinic antagonist tolterodine with a modified-release formulation of the muscarinic agonist (salivary stimulant) pilocarpine. Tolenix™ incorporates a unique and proprietary combination drug technology developed by TheraVida that can be applied to any of the standard muscarinic antagonist therapies used to treat OAB, to overcome problematic dry mouth typically associated with this class of pharmacological agents. TheraVida combination drug products such as Tolenix™ have the potential for greater efficacy, improved tolerability, and better patient compliance, when compared to tolterodine alone for the treatment of OAB and UUI.

About TheraVida

TheraVida, Inc., is applying its unique and patent-protected combination drug technology to develop products that offer patients therapeutic benefits with significantly better side effect, safety, and efficacy profiles when compared with predecessor, standard-of-care therapies. The company's lead product Tolenix™ (THVD-201) is being developed for the treatment of overactive bladder (OAB) and urge urinary incontinence (UUI) and is advancing into Phase 3 clinical studies. For further information, please visit www.theravida.com

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