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Theravance and Alfa Wassermann Announce Initiation of Phase 2 Study With Velusetrag for Gastroparesis

SOUTH SAN FRANCISCO, CA and BOLOGNA, ITALY -- (Marketwire) -- 01/08/13 -- Theravance, Inc. (NASDAQ: THRX) and Alfa Wassermann S.p.A. announced today the initiation of a Phase 2 proof-of-concept study with velusetrag, Theravance's investigational 5-HT4 agonist, for the treatment of patients with diabetic or idiopathic gastroparesis.

"We are pleased to be advancing the clinical development of velusetrag in a Phase 2 gastroparesis study," said Mathai Mammen, M.D., Ph.D., Senior Vice President of Research and Early Clinical Development of Theravance. "Today, patients have limited options for treating this serious, debilitating, and chronic condition."

About Phase 2 Study 0093

Study 0093 is a multicenter, randomized, double-blind, incomplete block, three-period fixed sequence crossover, Phase 2 study. This proof-of-concept study will assess three oral doses of velusetrag (5, 15, and 30 mg) or placebo, administered once daily in three periods of 1-week duration each, with a 1-week washout period between treatment periods, in approximately 32 patients with diabetic or idiopathic gastroparesis. The primary endpoint of the study is gastric emptying time. Secondary endpoints include safety and tolerability assessments.

About Gastroparesis

Gastroparesis is a serious, debilitating disorder of gastrointestinal (GI) motility with few therapeutic options currently available to patients. It is characterized by delayed gastric emptying in the absence of a mechanical obstruction. Symptoms experienced by patients with gastroparesis include early satiety, nausea, vomiting, and bloating. The impact of these symptoms, and the uncertainty of knowing when a symptom will occur, can make living with this condition very difficult.

About Velusetrag

Velusetrag, also known as TD-5108, is a highly selective agonist with high intrinsic activity at the human 5-HT4 receptor. An oral, investigational medicine dosed once daily, velusetrag has completed a 400-patient Phase 2 proof-of-concept study in chronic idiopathic constipation, demonstrating statistically significant prokinetic activity at all three doses tested; at the two lowest doses, velusetrag was generally well tolerated with a low incidence of adverse events. Velusetrag has also been shown to accelerate gastric emptying in healthy volunteers. Velusetrag was discovered by Theravance through the application of its multivalent drug design in a research program dedicated to finding new treatments for gastrointestinal motility disorders.

About Partnership

In October 2012, Theravance and Alfa Wassermann entered into a development and commercialization agreement for velusetrag, in development for gastrointestinal motility disorders. Under the agreement, the companies will collaborate in the execution of a two-part Phase 2 program, funded by Alfa Wassermann, to test the efficacy, safety and tolerability of velusetrag in the treatment of patients with gastroparesis. Alfa Wassermann has an exclusive option to develop and commercialize velusetrag in the European Union, Russia, China, Mexico and certain other countries. Theravance retains full rights to velusetrag in the United States, Canada, Japan and certain other countries.

About Theravance

Theravance is a biopharmaceutical company with a pipeline of internally discovered product candidates and strategic collaborations with pharmaceutical companies. Theravance is focused on the discovery, development and commercialization of small molecule medicines across a number of therapeutic areas including respiratory disease, bacterial infections, and central nervous system (CNS)/pain. Theravance's key programs include: RELVAR™ or BREO™ (FF/VI), ANORO™ (UMEC/VI) and MABA (Bifunctional Muscarinic Antagonist-Beta2 Agonist), each partnered with GlaxoSmithKline plc, and its oral Peripheral Mu Opioid Receptor Antagonist program. By leveraging its proprietary insight of multivalency to drug discovery, Theravance is pursuing a best-in-class strategy designed to discover superior medicines in areas of significant unmet medical need. For more information, please visit Theravance's web site at www.theravance.com.

Theravance, Inc.

RELVAR™ or BREO™ (FF/VI) and ANORO™ (UMEC/VI) are investigational medicines and are not currently approved anywhere in the world. RELVAR™, BREO™ and ANORO™ are trademarks of the GlaxoSmithKline group of companies. T use of these brand names has not yet been approved by any regulatory authority.

About Alfa Wassermann
Alfa Wassermann is a private pharmaceutical group with Head Quarters in Bologna, Italy with its own research, development and manufacturing facilities. It has a growing number of affiliate companies in both Europe as well as in emerging markets such as Russia, China and Mexico. Its main product is rifaximin, a gut-selective antibiotic, which has been prescribed for 24 years under the Trade Name Normix®, Xifaxan® and others (approved in 33 countries, including the US). The company has also developed other important products: Sulodexide (Vessel®), a heparinoid for thromboembolic diseases, and Parnaparin (Fluxum®), a low molecular weight heparin for the treatment and prophylaxis of deep-vein thrombosis. For more information, please visit Alfa Wassermann's web site at www.alfawassermann.it.

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This press release contains certain "forward-looking" statements as that term is defined in the Private Securities Litigation Reform Act of 1995 regarding, among other things, statements relating to goals, plans, objectives and future events. Theravance intends such forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 21E of the Securities Exchange Act of 1934 and the Private Securities Litigation Reform Act of 1995. Examples of such statements include statements relating to the status and timing of clinical studies, statements regarding the potential benefits and mechanisms of action of drug candidates, statements concerning the enabling capabilities of Theravance's approach to drug discovery and its proprietary insights and statements concerning expectations for product candidates through development and commercialization. These statements are based on the current estimates and assumptions of the management of Theravance as of the date of this press release and are subject to risks, uncertainties, changes in circumstances, assumptions and other factors that may cause the actual results of Theravance to be materially different from those reflected in its forward-looking statements. Important factors that could cause actual results to differ materially from those indicated by such forward-looking statements include, among others, risks related to delays or difficulties in commencing or completing clinical and non-clinical studies, the potential that results of clinical or non-clinical studies indicate product candidates are unsafe or ineffective, our dependence on third parties in the conduct of our clinical studies, delays or failure to achieve regulatory approvals for product candidates, risks of relying on third-party manufacturers for the supply of our product and product candidates and risks of collaborating with third parties to develop and commercialize products. These and other risks are described in greater detail under the heading "Risk Factors" contained in Theravance's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission (SEC) on October 31, 2012 and the risks discussed in our other period filings with SEC. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Theravance assumes no obligation to update its forward-looking statements.

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