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Theravance and Alfa Wassermann Enter Into Agreement to Develop and Commercialize Velusetrag for Gastroparesis

SOUTH SAN FRANCISCO, Calif. and BOLOGNA, Italy, Oct. 2, 2012 (GLOBE NEWSWIRE) -- Theravance, Inc. (Nasdaq:THRX) and Alfa Wassermann S.p.A. announced today that they have entered into an exclusive development and commercialization agreement in certain countries for velusetrag, Theravance's investigational 5-HT4 agonist in development for gastrointestinal motility disorders.

Under the agreement, the companies will collaborate in the execution of a two-part Phase 2 program to test the efficacy, safety and tolerability of velusetrag in the treatment of patients with gastroparesis. If the results of the studies are sufficiently favorable, Alfa Wassermann will have the right to exercise an exclusive option for the development and commercialization of velusetrag in the EU, Russia, China, Mexico and certain other countries. Theravance retains full rights to velusetrag in the US, Canada, Japan and certain other countries.

Financial terms of the transaction include funding of the Phase 2 program by Alfa Wassermann, a $10 million option fee payable to Theravance by Alfa Wassermann if it exercises its option following completion of the Phase 2 program, and potential development, regulatory and sales milestone payments of up to $53.5 million. Theravance is entitled to receive royalties on net sales by Alfa Wassermann ranging from the low teens to 20%.

"Gastroparesis represents one of the most significant unmet medical needs in gastroenterology and we look forward to moving quickly with Alfa Wassermann to bring this potential medicine to patients who have limited alternatives today," said Rick E Winningham, Chairman and Chief Executive Officer of Theravance.

"We are pleased to enter this agreement with Theravance, with its strong record in partnering, as we strengthen our long term gastroenterology portfolio through development initiatives in innovative indications and further build our affiliate platform for the EU and emerging markets, where we are increasing our direct presence," said Stefano Golinelli, Chief Executive Officer, Alfa Wassermann.

About Gastroparesis

Gastroparesis is a serious, debilitating disorder of 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.

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 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), umeclidinium bromide/vilanter (UMEC/VI) and MABA (Bifunctional Muscarinic Antagonist-Beta$_2$ 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.

Relvar™ and Breo™ are trademarks of the GlaxoSmithKline group of companies. The use of these brand names has not ye 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 Exchange Act and the Private Securities Litigation Reform Act of 1995. Examples of such statements include statements relating to the status and timing of clinical studies, data analysis and communication of results, statements regarding the potential benefits and mechanisms of action of drug candidates, statements concerning the timing of seeking regulatory approval of our product candidates, statements concerning enabling capabilities of Theravance's approach to drug discovery and its proprietary insights, statements concerning expectations for product candidates through development and commercialization and projections of revenue, expenses and other financial items. 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 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 August 1, 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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