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Theravance Biopharma Announces Initiation of Phase 2b Study of Velusetrag (TD-5108) for the Treatment of Gastroparesis

GEORGE TOWN, GRAND CAYMAN -- (Marketwired) -- 03/12/15 -- Theravance Biopharma, Inc. (NASDAQ: TBPH) ("Theravance Biopharma" or the "Company") today announced the initiation of a Phase 2b study of velusetrag (TD-5108), an investigational drug for the treatment of patients with gastroparesis and other gastrointestinal motility disorders.

Gastroparesis is a significant medical condition characterized by delayed gastric emptying of food and associated with nausea, vomiting, early satiety, postprandial fullness and upper abdominal pain. The Phase 2b study (study 0099) is a multicenter, double-blind, randomized, placebo-controlled, parallel-group trial which will explore the efficacy and safety of multiple doses of velusetrag in patients with diabetic (n=100) or idiopathic (n=100) gastroparesis. Three dose levels of velusetrag (5, 15, and 30 mg once daily) will be evaluated and compared to placebo for 12 weeks of therapy. The primary endpoint will be the effect of velusetrag on symptoms in subjects with gastroparesis. The study will also evaluate the effect of velusetrag on gastric emptying, and the psychometric properties of the Gastroparesis Rating Scale (GRS), a daily patient-reported outcome (PRO) measure. The study will be conducted primarily in the US but will also include some European centers.

"Gastroparesis is a chronic and debilitating condition that causes significant patient suffering, and for which there are few therapeutic options. We believe that velusetrag may represent an important approach to treating this disease, which affects close to six million patients in the US alone," said Brett Haumann, MD, Senior Vice President, Clinical Development. "Advancing velusetrag in the US is a key component of Theravance Biopharma's core strategy to develop products used or initiated in and around acute care centers and to leverage our existing commercial infrastructure. To expand our reach in specialty markets outside the US, we are pleased to have established a strategic partnership with Alfa Wassermann, and continue to work closely with our partner to advance this potential new therapeutic option."

Velusetrag is being developed by Theravance Biopharma in collaboration with Alfa Wassermann (S.p.A.) ("Alfa Wassermann") in a Phase 2 program to test the efficacy, safety and tolerability of velusetrag in the treatment of patients with gastroparesis. Positive top-line results from the Phase 2 proof-of-concept study under this partnership (study 0093) were announced in April 2014. Based on the study results (including gastric emptying, safety and tolerability), the Company and Alfa Wassermann agreed to advance velusetrag into a definitive Phase 2b study. Under the terms of the agreement, Alfa Wassermann pays for the majority of the Phase 2 clinical costs and has an exclusive option to develop and commercialize velusetrag in the European Union, Russia, China, Mexico and certain other countries, while the Company will retain full rights to velusetrag in the United States, Canada, Japan and certain other countries.

About Gastroparesis and Velusetrag

Gastroparesis is a disorder characterized by delayed gastric emptying and symptoms of gastric retention in the absence of mechanical obstruction. Approximately 36% and 29% of patients with gastroparesis have no known cause (i.e., idiopathic) or are diabetic, respectively. Post-prandial fullness, early satiety, bloating, abdominal discomfort (due to slow small bowel transit), nausea and vomiting are present in 46% to 97% of both diabetic and idiopathic gastroparesis patients with varying degrees of severity. Additional symptoms include weight loss and subsequent nutritional deficits.

The prevalence of gastroparesis in the US is estimated at 5.8 million, or 1.8% of the population. Among patients with diabetes, 14% of Type I and 9% of Type II diabetics (approximately 2 million individuals) seek care for gastroparesis. It is estimated that there are 188,000 US hospital discharges annually with a diagnosis of gastroparesis.

Velusetrag is an oral, once-daily investigational medicine discovered internally and developed for gastrointestinal motility disorders. It is a highly selective agonist with high intrinsic activity at the human 5-HT4 receptor.

5-hydroxytryptamine receptor 4 (5-HT_4) agonists are established as gastrointestinal (GI) prokinetic agents for the treatment of GI tract dysfunction, such as chronic constipation. Velusetrag (or TD-5108) is a 5-HT_4 receptor agonist that demonstrates high in vitro intrinsic activity and selectivity for the 5-HT_4 receptor and has no significant affinity for all other receptor types, ion channels, or enzymes tested. Velusetrag is being evaluated for the treatment of GI motility disorders.

Velusetrag was shown to decrease gastric emptying time in normal volunteers after multiple doses. A Phase 2 study of velusetrag in 34 subjects with diabetic or idiopathic gastroparesis exhibited improvement in gastric emptying half times (GE $t_{1/2}$) at doses of 5, 15, and 30 mg. The proportion of subjects demonstrating at least a 20% change from baseline in GE $t_{1/2}$

was statistically significant for those subjects receiving velusetrag 30 mg and was noteworthy for those subjects receiving velusetrag 5 and 15 mg, compared to placebo. Similar treatment effects were observed in both diabetic and idiopathic gastroparetic subjects treated with velusetrag. Velusetrag has also been studied in patients with chronic idiopathic constipation (CIC), where velusetrag achieved statistically and clinically significant increases in stool frequency, including weekly frequency of spontaneous bowel movements (SBM) and weekly frequency of SBMs resulting in a sensation of complete evacuation (CSBM), versus subjects receiving placebo, in a Phase 2 study of 401 subjects during a 1 month study.

About Theravance Biopharma

The mission of Theravance Biopharma (NASDAQ: TBPH) is to create value from a unique and diverse set of assets: an approved product; a development pipeline of mid- and late-stage assets; and a productive research platform designed for long-term growth.

Our pipeline of internally discovered product candidates includes potential best-in-class opportunities in underserved markets in the acute care setting, representing multiple opportunities for value creation. VIBATIV® (telavancin), our first commercial product, is a once-daily dual-mechanism antibiotic approved in the US and Europe for certain difficult-to-treat infections. TD-4208 is an investigational long-acting muscarinic antagonist (LAMA) being developed as a potential once-daily, nebulized treatment for COPD. Axelopran (TD-1211) is an investigational potential once-daily, oral treatment for opioid-induced constipation (OIC). Our earlier-stage clinical assets represent novel approaches for potentially treating diseases of the lung and gastrointestinal tract and infectious disease. In addition, we have an economic interest in future payments that may be made by GSK pursuant to its agreements with Theravance, Inc. relating to certain drug development programs, including the combination of fluticasone furoate, umeclidinium, and vilanterol (or the "Closed Triple").

With our successful drug discovery and development track record, commercial infrastructure, experienced management team and efficient corporate structure, we believe that we are well positioned to create value for our shareholders and make a difference in the lives of patients.

For more information, please visit www.theravance.com.

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 Biopharma 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 strategies, plans and objectives of Theravance Biopharma, the status and timing of clinical studies, data analysis and communication of results, the potential benefits and mechanisms of action of product candidates, the enabling capabilities of Theravance Biopharma's approach to drug discovery and Theravance Biopharma's proprietary insights, expectations for product candidates through development and commercialization, and the timing of seeking regulatory approval of product candidates. These statements are based on the current estimates and assumptions of the management of Theravance Biopharma as of the date of the press release and are subject to risks, uncertainties, changes in circumstances, assumptions and other factors that may cause the actual results of Theravance Biopharma to be materially different from those reflected in the 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 from clinical or non-clinical studies indicate product candidates are unsafe or ineffective, dependence on third parties to conduct clinical studies, delays or failure to achieve and maintain regulatory approvals for product candidates, risks of collaborating with third parties to discover, develop and commercialize products and risks associated with establishing distribution capabilities for telavancin with appropriate technical expertise and supporting infrastructure. Other risks affecting Theravance Biopharma are described under the heading "Risk Factors" contained in Theravance Biopharma's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission (SEC) on November 12, 2014. In addition to the risks described above and in Theravance Biopharma's other filings with the SEC, other unknown or unpredictable factors also could affect Theravance Biopharma's results. No forward-looking statements can be guaranteed and actual results may differ materially from such statements. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Theravance Biopharma assumes no obligation to update its forward-looking statements on account of new information, future events or otherwise, except as required by law.

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.com.

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