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Theravance Biopharma Receives FDA Fast Track Designation for Velusetrag (TD-5108) for Idiopathic and Diabetic Gastroparesis

Results from Ongoing Phase 2b Study in Gastroparesis Expected in Mid-2017

DUBLIN, Dec. 6, 2016 /PRNewswire/ -- Theravance Biopharma, Inc. (NASDAQ: TBPH) ("Theravance Biopharma" or the "Company") today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation to velusetrag (TD-5108) for the treatment of symptoms associated with idiopathic and diabetic gastroparesis. Velusetrag is an oral investigational drug in development for the treatment of patients with gastroparesis, and is currently being studied in a large, multinational Phase 2b study in patients with confirmed gastroparesis of either diabetic or idiopathic origin.

Gastroparesis represents a significant unmet medical need with no approved treatment options for patients with idiopathic gastroparesis and only one FDA-approved product for diabetic gastroparesis. The condition is characterized by delayed gastric emptying of food and associated with nausea, vomiting, early satiety, postprandial fullness and upper abdominal pain. In the United States, it is estimated to affect approximately six million individuals and includes two major sub-classes: those with diabetic gastroparesis (29% of the overall gastroparesis population) and those with idiopathic gastroparesis (36%).[1]

FDA's Fast Track program was established to facilitate the development and expedite the review of drugs with the potential to treat serious conditions and address an unmet medical need. Companies that receive Fast Track designation are provided the opportunity for more frequent interactions with FDA during clinical development and are eligible for accelerated approval and/or priority review, if relevant criteria are met. Additionally, companies that receive Fast Track designation are allowed to submit completed sections of their New Drug Application for the drug on a rolling basis, resulting in the potential for an expedited FDA review process.

"We are pleased to receive Fast Track designation for the velusetrag development program in gastroparesis, given its potential to treat patients with this serious medical condition. Velusetrag represents a uniquely positioned asset as the only investigational drug to be examined in a study enrolling both idiopathic and diabetic gastroparesis patients," said Brett Haumann, MD, Chief Medical Officer at Theravance Biopharma. "The valuable development and regulatory opportunities provided to the velusetrag program by Fast Track designation will augment our efforts to bring this important therapy to patients who currently have very few effective treatment options. We look forward to results from our Phase 2b study in mid-2017."

Velusetrag is being developed by Theravance Biopharma in collaboration with Alfa Wassermann (S.p.A.) ("Alfa Wassermann"). 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 Theravance Biopharma retains full rights to velusetrag in the United States, Canada, Japan and certain other countries.

About Gastroparesis

Gastroparesis is a disorder characterized by delayed gastric emptying and symptoms of gastric retention in the absence of mechanical obstruction. The prevalence of gastroparesis in the United States is estimated at approximately six million, or

1.8% of the population. Symptoms of gastroparesis are variable but typically include nausea, vomiting, early satiety, postprandial bloating/fullness or upper abdominal discomfort. In two case series, nausea was reported by more than 90% of patients with gastroparesis, vomiting by 68%-84% and bloating by 75%. Severe cases may also suffer from dehydration, electrolyte disturbances, weight loss and malnutrition. There is also a correlation between severity of symptoms and impairment of quality of life.[2]

About Velusetrag

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.

The ongoing Phase 2b study (study 0099) of velusetrag is a multicenter, double-blind, randomized, placebo-controlled, parallel-group trial that explores the efficacy and safety of velusetrag in patients with diabetic (n=100) or idiopathic (n=100) gastroparesis. Three doses of velusetrag (5, 15, and 30 mg once daily for 12 weeks) are being evaluated. The primary endpoint is the effect of velusetrag on symptoms in subjects with gastroparesis. The study also evaluates the effect of velusetrag on gastric emptying, and patient-reported outcome (PRO) measures. The study is being conducted in the United States and Europe.

A previous Phase 2 trial of velusetrag showed that all three doses of velusetrag (5, 15 and 30 mg) reduced gastric emptying time (GE $t_{1/2}$) compared to placebo in patients with either diabetic or idiopathic gastroparesis. The completed Phase 2 trial was the first study to evaluate gastric emptying, a diagnostic criterion for gastroparesis, in a patient population including both diabetic and idiopathic gastroparesis patients. Comparable studies of other investigational medicines have focused only on the diabetic population.

In addition, 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.

About Theravance Biopharma

Theravance Biopharma is a diversified biopharmaceutical company with the core purpose of creating medicines that make a difference in the lives of patients suffering from serious illness. Our pipeline of internally discovered product candidates includes potential best-in-class medicines to address the unmet needs of patients being treated for serious conditions primarily in the acute care setting. VIBATIV® (telavancin), our first commercial product, is a once-daily dual-mechanism antibiotic approved in the United States, Europe and certain other countries for certain difficult-to-treat infections. Revefenacin (TD-4208) is a long-acting muscarinic antagonist (LAMA) being developed as a potential once-daily, nebulized treatment for chronic obstructive pulmonary disease (COPD). Our neprilysin (NEP) inhibitor program is designed to develop selective NEP inhibitors for the treatment of a range of major cardiovascular and renal diseases, including acute and chronic heart failure, hypertension and chronic kidney diseases such as diabetic nephropathy. Our research efforts are focused in the areas of inflammation and immunology, with the goal of designing medicines that provide targeted drug delivery to tissues in the lung and gastrointestinal tract in order to maximize patient benefit and minimize risk. The first program to emerge from this research is designed to develop GI-targeted pan-Janus kinase (JAK) inhibitors for the treatment of a range of inflammatory intestinal diseases.

In addition, we have an economic interest in future payments that may be made by Glaxo Group Limited or one of its affiliates pursuant to its agreements with Innoviva, Inc. relating to certain drug development programs, including the Closed Triple (the combination of fluticasone furoate, umeclidinium, and vilanterol), currently in development for the treatment of COPD and asthma.

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

About Alfa Wassermann

Alfa Wassermann is a private pharmaceutical company wholly owned by and subject to the direction and coordination of Alfasigma S.p.A. Alfa Wassermann has its headquarters in Bologna, Italy with its own R&D and Manufacturing facilities. In 2015, Alfa Wassermann net sales were €429 million and the company employs over 1,500 people. 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 rifaximin-α is a gut-selective antibiotic marketed under the trade names of NORMIX®, XIFAXAN® and others, in 47 countries, including the USA. Alfa Wassermann has also developed other important products: sulodexide (VESSEL®) and parnaparin (FLUXUM®). For more information, please visit www.alfawassermann.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, expectations 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 Company's strategies, plans and objectives, the Company's regulatory strategies and timing and results of clinical studies, the potential benefits and mechanisms of action of the Company's product and product candidates and the Company's expectations for product candidates through development, potential regulatory approval and commercialization. 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 the Company's product candidates are unsafe or ineffective, the feasibility of undertaking future clinical trials for our product candidates based on FDA policies and feedback, dependence on third parties to conduct clinical studies, delays or failure to achieve and maintain regulatory approvals for product candidates, risks of collaborating with or relying on third parties to discover, develop and commercialize products, risks associated with establishing and maintaining sales, marketing and distribution capabilities 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 9, 2016. 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.

References:

[1] American Gastroenterological Association. "Technical Review on the Diagnosis and Treatment of Gastroparesis." http://www.gastrojournal.org/article/S0016-5085(04)01634-8/fulltext. Published online July 27, 2005.

[2] Journal of Neurogastroenterology and Motility. "Prevalence of Hidden Gastroparesis in the Community: The Gastroparesis 'Iceberg'." http://www.jnmjournal.org/journal/view.html?doi=10.5056/jnm.2012.18.1.34. Published online January 16, 2012.

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