

Theravance Biopharma Receives FDA Fast Track Designation for TD-8954 for Use With Enteral Feeding in Critically Ill Patients

DUBLIN, IRELAND -- (Marketwired) -- 08/06/15 -- Theravance Biopharma, Inc. (NASDAQ: TBPH) ("Theravance Biopharma" or the "Company") today announced that the U.S. Food and Drug Administration (FDA) granted Fast Track Designation to TD-8954 for short-term use with enteral feeding to achieve early nutritional adequacy in critically ill patients at high nutritional risk. TD-8954 is a selective 5-HT₄ receptor agonist being evaluated for potential use in the treatment of gastrointestinal motility disorders, including enteral feeding intolerance (EFI). Importantly, there are currently no FDA-approved therapies for EFI, leaving the approximately one million Americans who suffer from the disorder without adequate treatment options.

TD-8954 is currently in Phase 2 clinical development having most recently completed a study in critically ill patients with EFI to evaluate the safety, tolerability and pharmacodynamics of a single dose of TD-8954 administered intravenously compared to metoclopramide. Theravance Biopharma is preparing for further discussions with FDA regarding potential designs for the next TD-8954 study in EFI patients.

"This Fast Track designation provides key development and regulatory advantages to the TD-8954 program, adding important value to a product that we believe has significant potential to deliver therapeutic benefit to critically ill patients with gastrointestinal motility disorders, including EFI," said Brett Haumann, Senior Vice President, Clinical Development of Theravance Biopharma. "This regulatory milestone comes at an opportune time for Theravance Biopharma as we continue to assess accelerated development pathways for this program through conversations with FDA, as well as potential collaboration with prospective partners. We look forward to making additional progress in these discussions and optimally positioning this novel therapeutic for success."

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 (NDA) for the drug on a rolling basis, resulting in the potential for an expedited FDA review process.

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 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 U.S., Europe and certain other countries 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 GlaxoSmithKline plc pursuant to its agreements with Theravance, Inc. relating to certain drug development programs, including the combination of fluticasone furoate, umeclidinium and vilanterol (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.

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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 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 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 third parties to discover, develop and commercialize product and product candidates and risks associated with establishing and maintaining sales, marketing and distribution capabilities with appropriate 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 May 13, 2015 and under the heading "Risk Factors" contained in the Form S-3 Registration Statement filed by Theravance Biopharma with the SEC on June 26, 2015. 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.

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