

Theravance Biopharma Submits Investigational New Drug (IND) Application for TD-0714, an Inhibitor of Neprilysin (NEP)

Phase 1 Trial of Potential Best-in-Class Neprilysin Inhibitor Planned for Q4 2015; Compound Designed for Broad Use in Major Cardiovascular and Renal Diseases

DUBLIN, IRELAND -- (Marketwired) -- 10/13/15 -- Theravance Biopharma, Inc. (NASDAQ: TBPH) ("Theravance Biopharma" or the "Company") today announced that it has submitted an investigational new drug (IND) application to the U.S. Food and Drug Administration (FDA) to conduct the first-in-human study of TD-0714. The Company is actively engaged in a research and development program designed to create a best-in-class selective neprilysin (NEP) inhibitor 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. TD-0714 is currently the NEP inhibitor program's lead drug candidate and pending FDA's acceptance of the filing, Theravance Biopharma will initiate a Phase 1 single-ascending dose study investigating the safety, tolerability, pharmacokinetics, and pharmacodynamics of the compound in healthy subjects. Trial initiation is planned for the fourth quarter of 2015.

TD-0714 is an internally-discovered selective inhibitor of NEP, the enzyme responsible for degradation of natriuretic peptides ANP, BNP and CNP. By inhibiting NEP, TD-0714 elevates the levels of these peptides, which may exert protective cardiac and renal effects including vasodilation, diuresis, natriuresis, reversal of maladaptive changes in heart, blood vessels and kidney, prevention of fibrosis, and prevention of end-organ damage.

Theravance Biopharma has specifically designed TD-0714 to possess certain key features, including low renal clearance, the potential to be administered once daily, and the flexibility to be combined with other approved and investigational drugs. The Company has conducted experiments to validate these potentially important product features in its preclinical research and will evaluate them, along with other key drug characteristics, in its planned Phase 1 clinical program.

"We are excited about the potential to create a best-in-class NEP inhibitor that may serve as the cornerstone of multiple combination products. We believe that the combination of our NEP inhibitor with best-in-class Angiotensin Receptor Blockers, other RAAS blockers and drugs with cGMP elevating mechanisms can create products that may help patients with a range of cardiovascular and renal diseases," said Mathai Mammen, Senior Vice President, Research and Development of Theravance Biopharma. "We believe we have the most advanced non-renally cleared NEP inhibitor program in development and look forward to the opportunity to initiate a first-in-human Phase 1 study of TD-0714 later this year. We believe that the unique characteristics of TD-0714 position the compound as a highly valuable asset, and we are in active discussions with a number of potential collaborators regarding this program."

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. Revefenacin (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 August 13, 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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