

Theravance Biopharma Announces First Subject Dosed in Phase 1 Clinical Trial of TD-1473, a GI-Targeted Pan-Janus Kinase (JAK) Inhibitor

First-in-Human Study for Potentially Best-in-Class Treatment for Range of Inflammatory Intestinal Diseases

DUBLIN, IRELAND -- (Marketwired) -- 12/10/15 -- Theravance Biopharma, Inc. (NASDAQ: TBPH) ("Theravance Biopharma" or the "Company") today announced dosing of the first subject in a Phase 1 clinical trial of TD-1473, a novel, potent, and orally administered GI-targeted pan-Janus kinase (JAK) inhibitor. The Company is developing TD-1473 as an investigational compound with the potential to treat a range of inflammatory intestinal diseases.

TD-1473 is an internally-discovered JAK inhibitor that has demonstrated a high affinity for each of the JAK family of enzymes (JAK1, JAK2, JAK3 and TYK2). Through the inhibition of these enzymes, TD-1473 interferes with the JAK/STAT signaling pathway and, in turn, modulates the activity of a wide range of pro-inflammatory cytokines. Importantly, TD-1473 is a GI-targeted treatment specifically designed to distribute adequately and exclusively to the tissues of the GI tract and to minimize systemic exposure.

The Phase 1 trial is a randomized, double-blind, placebo-controlled, single ascending dose (SAD) and multiple ascending dose (MAD) study in healthy subjects. The primary objective of the study will be evaluation of the safety and tolerability of single ascending doses and multiple ascending doses of TD-1473 in healthy subjects. A key secondary objective of the trial will be the characterization of pharmacokinetics related to TD-1473, which will help determine the amount of TD-1473 that enters systemic circulation following oral administration.

"In the past month we have advanced two novel, potentially best-in-class programs from our internal discovery and research engine into Phase 1 clinical trials. This is a true testament to the talent and dedication of our research team as we work to identify and develop the Company's next wave of impactful medicines," said Mathai Mammen, M.D., Ph.D., Senior Vice President, Research and Development of Theravance Biopharma. "We are excited about the therapeutic potential of TD-1473, and in particular about our targeted approach which seeks to maximize the therapeutic potential of JAK inhibition in the affected areas of the gastrointestinal tract, while minimizing the safety and tolerability concerns associated with systemic JAK blockade. Our ability to create a pan-JAK inhibitor that is targeted specifically to the GI tract may enable us to offer patients with ulcerative colitis and other inflammatory intestinal diseases a treatment option that significantly improves upon currently available therapeutics."

Findings from a preclinical study in models of colitis evaluating TD-1473 and tofacitinib demonstrated that both compounds significantly reduced colitis manifestations. However, at doses providing similar reductions in colitis manifestations, the systemic exposure of TD-1473 was much lower than that of tofacitinib. This suggests that TD-1473 may be able to provide an effective treatment for colitis with reduced potential for systemically-mediated adverse events. Tofacitinib is a pan-JAK inhibitor approved for second-line treatment of adults with moderate to severe rheumatoid arthritis with ongoing clinical studies to evaluate its effectiveness in treating ulcerative colitis.

About Gastrointestinal (GI)-Targeted Pan-Janus (JAK) Kinase Inhibition

JAK inhibitors function by inhibiting the activity of one or more of the Janus kinase family of enzymes (JAK1, JAK2, JAK3, TYK2) that play a key role in cytokine signaling. Inhibiting these JAK enzymes interferes with the JAK/STAT signaling pathway and, in turn, modulates the activity of a wide range of pro-inflammatory cytokines. JAK inhibitors are currently approved for the treatment of rheumatoid arthritis and are also being evaluated as potential therapies for ulcerative colitis. However, these non-targeted products are known to have side effects based on their systemic exposure.

Theravance Biopharma is focused on utilizing targeted JAK inhibitors for potential treatment of inflammatory intestinal diseases including ulcerative colitis, which affects roughly 700,000 patients in the United States. While currently available treatments for ulcerative colitis have systemic safety liabilities and limited efficacy, Theravance Biopharma believes that the company's targeted approach to JAK inhibition has the potential to treat the inflammation in the tissues of the GI tract while minimizing the risk of systemic side effects.

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 chronic obstructive pulmonary disease (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 Glaxo Group Limited or one of its affiliates ("GSK") 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 November 12, 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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