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Theravance Biopharma Reports Positive Results From Phase 1 Clinical Trial of TD-1473, a GI-Targeted Pan-Janus Kinase (JAK) Inhibitor

Data Shows Favorable Safety and Tolerability of Single and Multiple Oral Doses of TD-1473 and Minimal Systemic Exposure in Healthy Subjects; Data Support Progression Into Phase 1b Clinical Trial in Ulcerative Colitis Patients Later This Year

DUBLIN, IRELAND -- (Marketwired) -- 06/09/16 -- Theravance Biopharma, Inc. (NASDAQ: TBPH) ("Theravance Biopharma" or the "Company") today announced positive results from the Company's Phase 1 clinical trial of TD-1473, a novel, potent, and orally administered GI-targeted pan-Janus kinase (JAK) inhibitor. TD-1473 is specifically designed to penetrate the intestinal wall and act directly at the site of inflammation with minimal systemic exposure.

Data from the study demonstrated TD-1473 to be generally safe and well tolerated as a single dose (up to 1000 mg) and as a daily dose (up to 300 mg) given for 14 days. There were no serious adverse events and the only adverse events reported in subjects dosed with TD-1473 were considered mild in severity and short in duration, with none leading to study discontinuation. Theravance Biopharma is developing TD-1473 as an investigational compound with the potential to treat a range of inflammatory intestinal diseases. Based on these study results, the Company intends to initiate a Phase 1b clinical trial of TD-1473 in patients with ulcerative colitis later in 2016.

This study also quantified the amount of TD-1473 that entered the systemic circulation following oral administration. This represents an area of interest as there are a range of safety and tolerability concerns associated with systemically available JAK inhibitors. Study results showed that across a range of doses expected to be efficacious, TD-1473 demonstrated exposures that were low relative to that reported for tofacitinib, a JAK inhibitor currently in development for ulcerative colitis. At steady state, the plasma exposures of TD-1473 at daily doses of 30 mg and 100 mg were approximately 75-fold and 15-fold lower, respectively, as compared to the plasma exposure of tofacitinib at twice daily doses of 10 mg.

Furthermore, subjects exhibited high stool concentrations of TD-1473, which were comparable to concentrations associated with efficacy in preclinical colitis models. Preclinical studies also demonstrated penetration of TD-1473 into the intestinal wall and membrane. The totality of the data generated in the program to date supports the Company's perspective that a therapeutically relevant level of TD-1473 can be delivered to and penetrate the colon wall with minimal release into the systemic circulation.

"We are encouraged by the data from this initial clinical trial of TD-1473, as they provide validation for our strategy of targeting JAK inhibition to the affected tissues within the GI tract in order to achieve desired therapeutic results with a favorable safety and tolerability profile," said Brett Haumann, MD, Chief Medical Officer at Theravance Biopharma. "We look forward to initiating the planned Phase 1b trial in patients as the next step in our efforts to develop a treatment for ulcerative colitis and other inflammatory intestinal diseases. We believe TD-1473 has the potential to provide significant improvements over current and emerging therapeutic options."

The completed Phase 1 trial was a randomized, double-blind, placebo-controlled, single ascending dose and multiple ascending dose study in healthy subjects. Additional findings from the study showed that vital sign and ECG assessments following TD-1473 administration did not demonstrate any clinically significant changes from baseline. There were also no clinically relevant changes in chemistry or hematology laboratory parameters in subjects dosed with TD-1473 relative to placebo.

Previously announced findings from a preclinical model of colitis evaluating TD-1473 and tofacitinib demonstrated that both compounds significantly reduced disease activity scores. However, at doses providing similar preclinical efficacy, the systemic exposure of TD-1473 was much lower than that of tofacitinib and TD-1473 did not reduce systemic immune cell counts, in contrast to tofacitinib. Based on these preclinical findings, Theravance Biopharma believes that TD-1473 represents a potential breakthrough approach to treating ulcerative colitis without the risk generally associated with systemically active therapies. Furthermore, the potential for an advantageous safety profile may allow TD-1473, if approved, to be positioned early in the course of the disease treatment, ahead of biologics.

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, myelofibrosis and psoriasis. However, these products are known to have side effects based on their systemic exposure. Tofacitinib is a JAK inhibitor with an ongoing development program in ulcerative colitis, as well as approval for second-line treatment of adults with moderate to severe rheumatoid arthritis.

TD-1473 is an internally-discovered JAK inhibitor that has demonstrated a high affinity for each of the JAK family of enzymes. Importantly, TD-1473 is a GI-targeted treatment specifically designed to distribute adequately and predominantly to the tissues of the GI tract, treating inflammation in those tissues while minimizing 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.

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 U.S., 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 (GSK) 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.

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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. 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 10, 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.

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