October 4, 2016

Theravance Biopharma Announces First Subject Dosed in Phase 1b Clinical Trial of TD-1473 in Patients With Moderate to Severe Ulcerative Colitis

Intestinally Restricted Pan-Janus Kinase (JAK) Inhibitor Designed to Act Directly at Site of Inflammation in the Intestinal Wall With Minimal Systemic Exposure

DUBLIN, IRELAND -- (Marketwired) -- 10/04/16 -- Theravance Biopharma, Inc. (NASDAQ: TBPH) ("Theravance Biopharma" or the "Company") today announced dosing of the first patient in a Phase 1b clinical trial of TD-1473 in patients with moderate to severe ulcerative colitis. TD-1473 is a novel, potent, orally administered and intestinally restricted pan-Janus kinase (JAK) inhibitor in clinical development, with the potential to treat a range of inflammatory intestinal diseases. Importantly, TD-1473 is specifically designed to act directly at the site of inflammation in the intestinal wall with minimal systemic exposure.

The Phase 1b trial is a multi-center, randomized, double-blind, multi-dose, placebo-controlled study in 40 patients with moderate to severe ulcerative colitis. Patients will be randomized to receive one of three doses of TD-1473 or placebo for 28 days in sequential fashion. The primary objectives of the study will include evaluation of the safety and tolerability of TD-1473 administered for 28 days, as well as assessment of the compound's plasma exposure following administration. A key secondary objective of the trial will be the evaluation of the effect of TD-1473 on levels of a range of key ulcerative colitis biomarkers, including C-reactive protein (CRP) and fecal calprotectin (FC). Additionally, investigators will evaluate a number of exploratory objectives, including changes in partial Mayo score and improvement in disease activity through endoscopic and histologic assessments. The Company expects data from the Phase 1b trial to be available in mid-2017.

Theravance Biopharma recently announced positive results from a Phase 1 clinical trial of TD-1473 in healthy volunteers demonstrating the compound to be generally 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. Furthermore, findings from the Phase 1 trial related to systemic exposure and stool concentrations of TD-1473 support 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.

"The start of our Phase 1b clinical trial is the latest development milestone for our TD-1473 program, which we believe represents a potentially transformative approach to treating inflammatory intestinal diseases. The totality of the data generated in the program to date provides support for our strategy of targeting JAK inhibition to affected tissues within the intestinal 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. "In addition to safety and tolerability objectives, this Phase 1b study includes exploratory endpoints aimed at assessing potential efficacy measures in ulcerative colitis patients. By providing initial insight into the impact of TD-1473 on such outcomes as clinical response and mucosal healing, this trial will help guide future studies of this unique, intestinally restricted pan-JAK inhibitor."

About Intestinally Restricted 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 diseases, such as rheumatoid arthritis, myelofibrosis and psoriasis, and have demonstrated therapeutic benefit for patients with ulcerative colitis. However, these products are known to have side effects associated with systemic exposure.

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 an intestinally restricted treatment specifically designed to distribute adequately and predominantly to the tissues of the intestinal tract, treating inflammation in those tissues while minimizing systemic exposure. Theravance Biopharma is focused on utilizing targeted JAK inhibitors for potential treatment of a range 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 intestinally restricted 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.

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, designs 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 and designs 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 August 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.

Contact Information:

Renee Gala
Chief Financial Officer
650-808-4045
investor.relations@theravance.com

Tim Brons
Vida Strategic Partners (media)
646-319-8981
tbrons@vidasp.com

Source: Theravance Biopharma