February 17, 2017

Theravance Biopharma Presents Positive Clinical Data on TD-1473 at the 12th Congress of the European Crohn's and Colitis Organization

Further Data from Phase 1 Trial Reaffirms Favorable Tolerability of Single and Multiple Oral Doses of TD-1473 and Minimal Systemic Exposure in Healthy Subjects

DUBLIN, Feb. 17, 2017 /PRNewswire/ -- Theravance Biopharma, Inc. (NASDAQ: TBPH) ("Theravance Biopharma" or the "Company") today announced the presentation of positive clinical data for TD-1473, a novel, potent, and orally administered pan-Janus kinase (JAK) inhibitor designed to be intestinally restricted, at the 12th Congress of the European Crohn's and Colitis Organization (ECCO). In a poster presentation, the Company reported further data from its completed Phase 1 study of single-ascending and multiple-ascending doses of TD-1473. Results of the study were first announced in June 2016. Theravance Biopharma is developing TD-1473 as an investigational compound with the potential to treat a range of inflammatory intestinal diseases and is currently conducting a Phase 1b study of the compound in patients with moderate to severe ulcerative colitis. The 12th Congress of ECCO is being held in Barcelona, Spain, February 15-18, 2017.

The findings presented at ECCO reaffirm previously announced results from the Phase 1 study which demonstrated TD-1473 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. Newly presented data demonstrated that no moderate, severe or serious treatment emergent adverse events (TEAEs) were reported in subjects dosed with TD-1473, and no TEAEs of any severity led to study discontinuation. TEAEs were higher in subjects receiving placebo than in subjects receiving TD-1473 in both the single-ascending and multiple-ascending dose portions of the study.

Additionally, the study data presented demonstrated that TD-1473 exhibited a pharmacokinetic (PK) profile consistent with the Company's goal of designing the compound to penetrate the intestinal wall from within and act directly at the site of inflammation with minimal systemic exposure. Across a range of doses, the observed systemic concentrations of TD-1473 were consistent with low bioavailability and intestinal restriction. For all doses in both the single-ascending and multiple-ascending groups, the amount of TD-1473 that was excreted in the urine was less than 0.5% of the administered dose. TD-1473 is designed to be intestinally restricted, which potentially represents a key competitive advantage for the compound based on the range of safety and tolerability concerns associated with systemically available JAK inhibitors.

"The latest data presented at ECCO align with and build upon the top-line results from the study. We believe that the totality of the data generated in the program to date strongly suggests that a therapeutically relevant level of TD-1473 can be delivered to and penetrate the colon wall from within with minimal release into the systemic circulation," said Brett Haumann, MD, Chief Medical Officer at Theravance Biopharma. "We are currently conducting a Phase 1b trial of TD-1473 designed to evaluate the safety, tolerability, pharmacokinetics and pharmacodynamics of TD-1473 in patients with moderate to severe ulcerative colitis over 28 days, as well as to measure the drug levels in the blood following oral administration. This trial will also provide the first indication of the early effect of TD-1473 on a range of relevant ulcerative colitis biomarkers, histological improvements and measures of endoscopic and clinical improvement."

The Company's ongoing Phase 1b trial is a randomized, double-blind, study in patients with moderate to severe ulcerative colitis. Forty patients are being randomized to receive one of three doses of TD-1473 or placebo for 28 days in sequential fashion. The primary objectives of the study 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 is 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 several 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 in mid-2017.

About Intestinally Restricted Pan-Janus Kinase (JAK) 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 myelofibrosis, 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 designed to be an intestinally restricted treatment that distributes 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 help improve 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 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, expectations 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, potential regulatory approval 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 or relying on third parties to discover, develop and commercialize products, risks associated with establishing and maintaining sales, marketing and distribution capabilities with appropriate technical 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 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.

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