

## **Theravance Biopharma Announces Data from Phase 1b Study of TD-1473 Selected for Oral Late-Breaker Presentation at UEG Week 2018**

October 10, 2018

### **Presentation to Highlight Positive Data Demonstrating Localized Target Engagement and Minimal Systemic Exposure following Four Weeks of Treatment in Patients with Moderately-to-Severely Active Ulcerative Colitis**

DUBLIN, Oct. 10, 2018 /PRNewswire/ -- Theravance Biopharma, Inc. (NASDAQ: TBPH) ("Theravance Biopharma" or the "Company") today announced that the results from the Phase 1b study of TD-1473 in patients with moderately-to-severely active ulcerative colitis have been selected for oral presentation as part of the late-breaker session at United European Gastroenterology (UEG) Week 2018. The presentation will highlight data from the Phase 1b clinical trial of TD-1473 in patients with moderately-to-severely active ulcerative colitis. UEG Week 2018 is being held October 20-24, 2018, in Vienna, Austria.



TD-1473 is a novel, potent, orally administered and gut selective pan-Janus kinase (JAK) inhibitor in clinical development with the potential to treat a range of inflammatory intestinal diseases, including ulcerative colitis and Crohn's disease. In contrast to other oral JAK inhibitors under development for inflammatory bowel disease, TD-1473 is specifically designed to act locally at the site of inflammation in the intestinal wall thereby limiting systemic exposure.

Details of the oral late-breaker presentation are as follows:

- **Title:** The Intestinally Restricted, Orally Administered, Pan-JAK Inhibitor TD-1473 Demonstrates Favorable Safety, Tolerability, Pharmacokinetics, and Signal for Clinical Activity in Subjects with Moderately-to-Severely Active Ulcerative Colitis
- **Publication Number:** LB05
- **Presentation Type:** Oral Late-Breaker
- **Presenting Author:** Julian Panés, M.D.
- **Session:** Clinical Trials in IBD
- **Session Date/Time:** Monday, October 22, 2018, 2:00 – 3:30 PM (local time)
- **Presentation Location:** Room C

As previously reported, top-line results from this Phase 1b clinical trial of TD-1473 demonstrated localized biological activity and minimal systemic exposure, as well as a favorable safety and tolerability profile. Theravance Biopharma is advancing the program into a Phase 2 clinical trial in patients with moderately-to-severely active Crohn's disease, as well as a Phase 2b/3 induction and maintenance study of TD-1473 in ulcerative colitis.

#### ***About Theravance Biopharma and Janssen Strategic Collaboration***

Theravance Biopharma and Janssen Biotech Inc. and their respective affiliates have established a global co-development and commercialization agreement for TD-1473 and related back-up compounds for inflammatory intestinal diseases, including ulcerative colitis and Crohn's disease.

#### ***About Gut Selective 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 and myelofibrosis, and have demonstrated therapeutic benefit for patients with ulcerative colitis. However, these products are known to have side effects associated with their 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 oral, gut selective treatment specifically designed to distribute adequately and predominantly to the tissues of the intestinal tract, treating inflammation in those tissues while minimizing its systemic exposure. Theravance Biopharma is focused on utilizing targeted JAK inhibitors for potential treatment of a range of inflammatory intestinal diseases including ulcerative colitis and Crohn's disease, which affect roughly 900,000 and 700,000 patients in the United States, respectively.

#### ***About Theravance Biopharma***

Theravance Biopharma, Inc. ("Theravance Biopharma") is a diversified biopharmaceutical company with the core purpose of creating medicines that help improve the lives of patients suffering from serious illness.

In our relentless pursuit of this objective, we strive to apply insight and innovation at each stage of our business, including research, development and commercialization, and utilize both internal capabilities and those of partners around the world. Our research efforts are focused in the areas of inflammation and immunology. Our research goal is to design localized medicines that target diseased tissues, without systemic exposure, in order to maximize patient benefit and minimize risk. These efforts leverage years of experience in developing localized medicines for the lungs to treat respiratory disease. The first potential medicine to emerge from our research focus on immunology and localized treatments is an oral, gut selective pan-Janus kinase (JAK) inhibitor, currently in development to treat a range of inflammatory intestinal diseases. Our pipeline of internally discovered product candidates will continue to evolve with the goal of creating transformational medicines to address the significant needs of patients.

In addition, we have an economic interest in future payments that may be made by Glaxo Group or one of its affiliates (GSK) pursuant to its agreements with Innoviva, Inc. relating to certain programs, including Trelegy Ellipta.

For more information, please visit [www.theravance.com](http://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, 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 of clinical studies (including the data therefrom), the potential benefits and mechanisms of action of the Company's product and product candidates, the Company's expectations for product candidates through development, potential regulatory approval and commercialization (including their potential as components of combination therapies), product sales and the Company's expectations for its 2018 operating loss, excluding share-based compensation. 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 the conference call 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, enrolling or completing clinical studies, the potential that results from clinical or non-clinical studies indicate the Company's product candidates are unsafe or ineffective (including when our product candidates are studied in combination with other compounds), risks that product candidates do not obtain approval from regulatory authorities, the feasibility of undertaking future clinical trials for our product candidates based on policies and feedback from regulatory authorities, 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, manufacture and commercialize products, and 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 Form 10-Q filed with the Securities and Exchange Commission (SEC) on August 2, 2018 and Theravance Biopharma's other filings with the SEC. In addition to the risks described above and in Theravance Biopharma's 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:**

Theravance Biopharma

Alexander Dobbin  
Head of Investor Relations  
650-808-4045  
[investor.relations@theravance.com](mailto:investor.relations@theravance.com)

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

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