



## Theravance Biopharma Enters Global Collaboration with Janssen for TD-1473 in Inflammatory Intestinal Diseases

February 7, 2018

**Theravance Biopharma Together with Janssen will Jointly Develop and Commercialize TD-1473, a Novel, Potent, Orally Administered and Intestinally Restricted pan-Janus Kinase (JAK) Inhibitor**

**Theravance Biopharma Eligible to Receive up to \$1 Billion in Potential Payments, Including \$100 Million Upfront Phase 2b/3 Study in Ulcerative Colitis and Phase 2 Study in Crohn's Disease to Begin in 2018**

DUBLIN, Feb. 7, 2018 /PRNewswire/ -- Theravance Biopharma Ireland Limited, a subsidiary of Theravance Biopharma, Inc. (NASDAQ: TBPH) ("Theravance Biopharma") today announced that it has entered into a global co-development and commercialization agreement with Janssen Biotech, Inc., one of the Janssen Pharmaceutical Companies of Johnson & Johnson, for TD-1473 and related back-up compounds for inflammatory intestinal diseases, including ulcerative colitis and Crohn's disease. Under the terms of the agreement, Theravance Biopharma will receive an upfront payment of \$100 million and will be eligible to receive up to an additional \$900 million in potential payments, if Janssen elects to remain in the collaboration following the completion of certain Phase 2 activities, as described below. Theravance Biopharma together with Janssen will jointly develop and commercialize TD-1473 in inflammatory intestinal diseases, with the two companies sharing profits in the US and expenses related to a potential Phase 3 program (67% to Janssen; 33% to Theravance Biopharma). Theravance Biopharma would receive double-digit tiered royalties on ex-US sales.



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. In contrast to other oral JAK inhibitors under development for inflammatory bowel disease, TD-1473 is specifically designed to act directly at the site of inflammation in the intestinal wall thereby limiting systemic exposure.

"Internally, we have been very excited about the potential of TD-1473 to serve as a transformational medicine designed to offer the proven therapeutic activity of JAK inhibitors without the safety concerns associated with systemic JAK exposure. We believe this transaction can accelerate the development of TD-1473 and maximize the potential value of the program to Theravance Biopharma," said Rick E Winningham, Chairman and Chief Executive Officer of the Theravance Biopharma group. "Janssen's expertise and experience from multiple clinical development programs in both ulcerative colitis and Crohn's disease, across a range of mechanisms of action, will be important in the development, regulatory, and commercial path forward for this program."

In 2018, Theravance Biopharma plans to initiate a large, Phase 2b/3 adaptive design induction and maintenance study in ulcerative colitis with TD-1473. The company is also now planning to initiate a Phase 2 study in Crohn's disease in 2018. Following completion of the Phase 2 Crohn's study and the Phase 2b induction portion of the ulcerative colitis study, Janssen can elect to enter into an exclusive license arrangement by paying Theravance Biopharma a fee of \$200 million. After Phase 2, Janssen would lead subsequent development of TD-1473 in Crohn's disease. Theravance Biopharma will lead development of TD-1473 in ulcerative colitis through completion of the Phase 2b/3 program. If TD-1473 is commercialized, Theravance Biopharma has the option to co-commercialize in the US, and Janssen would have sole commercialization responsibilities outside the US. Theravance Biopharma would be eligible to receive up to an additional \$700 million in development and commercialization milestone payments.

"The opportunity to apply Janssen's unrivaled expertise in inflammatory bowel disease at this stage of the development of TD-1473 is very exciting," said Brett Haumann, MD, Chief Medical Officer of the Theravance Biopharma group. "Janssen has an extremely impressive record in developing therapies using efficient clinical designs and has developed unparalleled biomarker datasets that can inform patient stratification to optimize clinical response to TD-1473. We look forward to collaborating together with the team at Janssen to successfully develop this promising treatment for patients with ulcerative colitis, Crohn's disease, and other intestinal inflammatory diseases."

### Conference Call Today at 8:00 am ET

Theravance Biopharma will hold a conference call to discuss the collaboration today at 8:00 am ET. To participate in the live call by telephone, please dial (855) 296-9648 from the US, or (920) 663-6266 for international callers, using the confirmation code 1998809. Those interested in listening to the conference call live via the internet may do so by visiting Theravance Biopharma's website at [www.theravance.com](http://www.theravance.com), under the Investor Relations section, Presentations and Events. Please go to the website 15 minutes prior to the start of the call to register, download, and install any necessary audio software.

A replay of the conference call will be available on Theravance Biopharma's website for 30 days through March 9, 2018. An audio replay will also be available through 8:00 pm ET on February 14, 2018 by dialing (855) 859-2056 from the US, or (404) 537-3406 for international callers, and then entering confirmation code 1998809.

### **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 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 intestinally restricted 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 is a diversified biopharmaceutical company with the core purpose of creating medicines that help improve 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<sup>®</sup> (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. Revedfenacin (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 programs, including Trelegy Ellipta (the combination of fluticasone furoate, umeclidinium, and vilanterol in a single ELLIPTA<sup>®</sup> inhaler, previously referred to as the Closed Triple), currently approved in the US and Europe for the treatment of appropriate COPD patients and in development for the treatment of COPD in several other countries. The product is also currently in development for the treatment of asthma.

For more information, please visit [www.theravance.com](http://www.theravance.com).

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*This press release contains and the conference call will contain 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, and the Company's expectations for product candidates through development, potential regulatory approval and commercialization (including their potential as components of combination therapies). 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), 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, 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 November 8, 2017 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.*

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