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Theravance Biopharma Highlights Filing of EU Regulatory Submission for the Closed Triple in COPD by GlaxoSmithKline and Innoviva

Theravance Biopharma Entitled to Receive 85% Economic Interest in Closed Triple Royalties Paid by GSK as Part of Agreement with Innoviva

DUBLIN, Dec. 5, 2016 /PRNewswire/ -- Theravance Biopharma, Inc. (NASDAQ: TBPH) ("Theravance Biopharma") today announced that GlaxoSmithKline plc (GSK) and Innoviva, Inc. (Innoviva) have filed a Marketing Authorization Application (MAA) in the European Union for the Closed Triple (the combination of fluticasone furoate, umeclidinium, and vilanterol in a single ELLIPTA® inhaler) for patients with chronic obstructive pulmonary disease (COPD). The Closed Triple is one of the drug development programs for which Theravance Biopharma has an economic interest in future payments that may be made by GSK or one of its affiliates pursuant to its agreements with Innoviva (formerly Theravance, Inc.). Should the Closed Triple be approved and commercialized, Theravance Biopharma is entitled to receive an 85% economic interest in the royalties paid by GSK on worldwide net sales. Those royalties are upward-tiering from 6.5% to 10%. Additionally, Theravance Biopharma is not responsible for any costs related to the Closed Triple.

In an announcement made on December 2, 2016, GSK and Innoviva stated GSK has filed a regulatory submission with the European Medicines Agency for the once-daily, Closed Triple combination therapy. This follows the companies' announcement of the filing of a New Drug Application for the Closed Triple in the United States in November 2016. The EU regulatory submission of the Closed Triple comprises an MAA for a maintenance treatment to relieve symptoms of adult patients with COPD. It is based on data from the Closed Triple combination therapy development program, as well as data from studies with fluticasone furoate, umeclidinium, and vilanterol either alone or in combination. The announcement from GSK and Innoviva also noted that regulatory submissions of the Closed Triple therapy for COPD are anticipated in the rest of the world beginning in 2017.

The Closed Triple combination therapy represents a unique approach to COPD treatment by seeking to combine the activity of three molecules with different mechanisms of action in a single, simple-to-use delivery device. The combination treatment includes: fluticasone furoate (FF), an inhaled corticosteroid; umeclidinium (UMEC), a long-acting muscarinic antagonist (LAMA); and vilanterol (VI), a long-acting beta$_2$-adrenergic agonist (LABA). This combination has been formulated to be delivered once-daily in GSK's ELLIPTA® dry powder inhaler.

Current trends in the treatment of COPD with combination therapy support Theravance Biopharma's view that there is significant market potential for a first-in-class, once-daily Closed Triple. According to GSK, approximately one-third of COPD patients are already utilizing open triple therapy and the progressive nature of the disease indicates that COPD patients will need access to more effective therapies over time. Additionally, recently reported results from the Salford Lung Study, a Phase 3 real-world effectiveness trial of two of the components of Closed Triple (FF and VI) in COPD exacerbations, were strongly supportive of the benefits of once-daily therapy.

The ongoing clinical development program for the Closed Triple in COPD includes the IMPACT study, a large Phase 3 trial designed to evaluate the efficacy and safety of the triple combination treatment compared to dual COPD therapies (FF/VI and UMEC/VI). Results of the IMPACT study are expected to be reported by GSK in 2017[1].

The Closed Triple is also in development for the treatment of symptomatic asthma. A regulatory submission in this indication is planned for 2018 according to GSK. The Closed Triple is not approved for use anywhere in the world.

Notes:

[1] Regulatory and clinical milestones as reported by Glaxo Group Limited or one of its affiliates (GSK)

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 United States, 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 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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