

## **Theravance Biopharma Highlights Initiation of Phase 3 Study of the Closed Triple in Patients with Asthma 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. 19, 2016 /PRNewswire/ -- Theravance Biopharma, Inc. (NASDAQ: TBPH) ("Theravance Biopharma") today announced that GlaxoSmithKline plc (GSK) and Innoviva, Inc. (Innoviva) have initiated a Phase 3 study of the Closed Triple (the triple combination therapy of fluticasone furoate, umeclidinium, and vilanterol in a single ELLIPTA<sup>®</sup> inhaler) in patients with asthma. 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 19, 2016, GSK and Innoviva stated GSK has started a Phase 3 study designed to investigate the effects of the once-daily Closed Triple when compared to therapy with the once-daily dual combination therapy of Relvar/Breo<sup>®</sup> (fluticasone furoate and vilanterol) as a treatment for patients with asthma. In the Phase 3 study, termed CAPTAIN (Clinical study of Asthma Patients receiving Triple therapy through A single INhaler), the primary endpoint is the change from baseline in trough Forced Expiratory volume in 1 second (FEV<sub>1</sub>) at 24 weeks of treatment and the key secondary endpoint is the annualized rate of moderate/severe asthma exacerbations. Other secondary endpoints are assessing health-related quality of life and symptom control.

The Closed Triple combination therapy combines 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<sub>2</sub>-adrenergic agonist (LABA). This combination has been formulated to be delivered once-daily in GSK's ELLIPTA<sup>®</sup> dry powder inhaler.

The Closed Triple is also being developed for the treatment of chronic obstructive pulmonary disease (COPD). GSK and Innoviva recently announced the filing of a New Drug Application in the United States and a Marketing Authorization Application in the EU for the once-daily Closed Triple for patients with COPD. The Closed Triple is not currently approved for use anywhere in the world.

#### ***About the Phase 3 CAPTAIN Study***

CAPTAIN (Clinical study of Asthma Patients receiving Triple therapy through A single INhaler) is a superiority study to demonstrate the add-on benefit of UMEC at two dosage strengths of 62.5 mcg and 31.25 mcg in a single inhaler when compared to doses of FF/VI that are already approved in asthma. It is a randomized, double-blind, active controlled, six-arm parallel group, global multicenter study evaluating FF/UMEC/VI (100/31.25/25, 100/62.5/25, 200/31.25/25 and 200/62.5/25

micrograms) versus FF/VI (100/25 and 200/25 micrograms, both approved doses in asthma) given once daily in the morning to patients whose asthma is inadequately controlled despite treatment with maintenance asthma medication. The study aims to randomize 2,250 patients, with 375 patients randomly assigned to each of the six treatment arms.

### **About Asthma**

Asthma is a chronic lung disease that inflames and narrows the airways. Asthma affects 242 million people worldwide. Despite medical advances, more than half of patients continue to experience poor control and significant symptoms.

The causes of asthma are not completely understood but likely involve an interaction between a person's genetic make-up and the environment. Key risk factors are inhaled substances that provoke allergic reactions or irritate the airways.

### **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<sup>®</sup> (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](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 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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