



Theravance Biopharma Highlights Marketing Authorization in Europe for Trelegy Ellipta as Once-Daily Single Inhaler Triple Therapy for the Treatment of COPD

November 16, 2017

Launch of Trelegy Ellipta in Europe Expected Before End of Year

DUBLIN, Nov. 16, 2017 /PRNewswire/ -- Theravance Biopharma, Inc. (NASDAQ: TBPH) ("Theravance Biopharma") today highlighted that the European Commission has granted marketing authorization for Trelegy Ellipta, the triple combination therapy of fluticasone furoate, umeclidinium, and vilanterol in a single ELLIPTA[®] inhaler, as a maintenance treatment for appropriate patients with chronic obstructive pulmonary disease (COPD). Trelegy Ellipta is a product in which Theravance Biopharma has an economic interest in future payments that may be made by GlaxoSmithKline (GSK) or one of its affiliates pursuant to its agreements with Innoviva (formerly Theravance, Inc.). 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%, resulting in cash flows to Theravance Biopharma of approximately 5.5% to 8.5% of worldwide net sales of Trelegy Ellipta. Theravance Biopharma is not responsible for any costs related to the product.



In an announcement dated November 16, 2017, GSK and Innoviva stated that the European Commission authorization for Trelegy Ellipta is for adult patients with moderate to severe COPD who are not adequately treated by a combination of an inhaled corticosteroid and a long-acting beta2-agonist. The companies noted that following this marketing authorization, the first European launch of Trelegy Ellipta is expected to take place before the end of the year. Additionally, GSK and Innoviva reported that regulatory applications have been submitted and are undergoing assessment in a number of other countries.

In September 2017, Trelegy Ellipta was approved by the United States Food and Drug Administration (FDA) for COPD patients with chronic bronchitis and/or emphysema, who are on a fixed-dose combination of fluticasone furoate and vilanterol for airflow obstruction and reducing exacerbations in whom additional treatment of airflow obstruction is desired or for patients who are already receiving umeclidinium and a fixed-dose combination of fluticasone furoate and vilanterol. Subsequently, GSK stated it anticipated launch of Trelegy Ellipta in the US in the middle of November.

"This marketing authorization for Trelegy Ellipta represents a key milestone for the COPD patient population as it expands access to this unique and first-in-class once-daily triple therapy to appropriate COPD patients in Europe," said Rick E Winningham, chairman and chief executive officer of Theravance Biopharma. "With the US and European launches of Trelegy planned by year end, our economic interest in worldwide net sales serves as an important strategic asset to the Company, and we look forward to it supporting our continued growth."

Trelegy Ellipta is a combination therapy that represents a unique approach to COPD treatment by combining 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 beta₂-adrenergic agonist (LABA). This combination has been formulated to be delivered once-daily in GSK's ELLIPTA[®] dry powder inhaler.

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[®] (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[®] 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.

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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 2017 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 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, risks associated with establishing and maintaining sales, marketing and distribution capabilities with appropriate technical expertise and supporting infrastructure, and risks of developing an institutional customer mix for VIBATIV[®] (telavancin) that meet the Company's plan for the product. 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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