Theravance Biopharma Highlights Approval of Expanded Indication in the US for Once-Daily Trelegy Ellipta for Treatment of COPD Patients

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DUBLIN, April 25, 2018 /PRNewswire/ -- Theravance Biopharma, Inc. (NASDAQ: TBPH) ("Theravance Biopharma") today highlighted that the US Food and Drug Administration (FDA) has approved an expanded indication for Trelegy Ellipta. This expanded approval in the US allows Trelegy Ellipta to be used as a treatment for a broader population of chronic obstructive pulmonary disease (COPD) patients with airflow limitation or who have experienced an acute worsening of respiratory symptoms. Trelegy Ellipta is the triple combination therapy of fluticasone furoate, umeclidinium, and vilanterol (FF/UMEC/VI) in a single ELLIPTA® inhaler.

(PRNewsfoto/Theravance Biopharma, Inc.)

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.

Trelegy Ellipta is the first COPD treatment to provide a combination of three molecules in a single inhaler that only needs to be taken once a day. The unique combination treatment includes: FF, an inhaled corticosteroid; UMEC, a long-acting muscarinic antagonist (LAMA); and 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.

In a press release dated April 24, 2018, GSK and Innoviva announced that the US FDA has approved an expanded indication for Trelegy Ellipta to include the long-term, once-daily, maintenance treatment of airflow obstruction in patients with COPD, including chronic bronchitis and/or emphysema. It is also indicated to reduce exacerbations of COPD in patients with a history of exacerbations. It is not indicated for relief of acute bronchospasm or for the treatment of asthma.

The approval is based on a supplemental New Drug Application (sNDA) supported by data from the landmark InforMing the PAthway of COPD Treatment (IMPACT) study which showed Trelegy Ellipta was superior to the inhaled corticosteroid/long-acting beta$_2$-adrenergic agonist (ICS/LABA), Relvar/Breo Ellipta (FF/VI), and long-acting muscarinic antagonist/long-acting beta$_2$-adrenergic agonist (LAMA/LABA), Anoro Ellipta (UMEC/VI), on multiple clinically important endpoints, including reducing exacerbations and improving lung function and health related quality of life.

Trelegy Ellipta was originally approved for use in the US in September 2017 for the long-term, once-daily, maintenance treatment of COPD patients who are receiving Breo and require additional bronchodilation or who are receiving Breo and Incruse (UMEC). The product is also approved in Europe as a maintenance treatment in adult patients with moderate to severe COPD who are not adequately treated by a combination of an ICS and a LABA. A type II variation to support an expanded label in Europe was submitted to the European Medicines Agency (EMA) in February 2018 and is currently under review. Regulatory applications for Trelegy Ellipta have been submitted and are undergoing assessments in a number of other countries.

The boxed warning has also been removed from the Trelegy Ellipta prescribing information, in line with the recent updates to the ICS/LABA class. Labelling changes to ICS/LABA combination medicines were implemented following a review of safety data submitted to the FDA by three companies including GSK and approved on December 20, 2017.

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, intestinally restricted 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.

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'sForm 10-K filed with the Securities and Exchange Commission (SEC) on February 28, 2018and 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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