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Theravance Biopharma Highlights Submission of Regulatory Application in Japan for Once-Daily Single Inhaler Triple Therapy FF/UMEC/VI for Patients with COPD

May 29, 2018

DUBLIN, May 29, 2018 /PRNewswire/ -- Theravance Biopharma, Inc. (NASDAQ: TBPH) ("Theravance Biopharma") today highlighted that a regulatory application for once-daily fluticasone furoate/umeclidinium/vilanterol (FF/UMEC/VI 100/62.5/25 mcg) under the proposed brand name Trelegy Ellipta has been submitted to the Japanese Ministry of Health, Labour and Welfare (MHLW) for the treatment of adults with chronic obstructive pulmonary disease (COPD). Trelegy Ellipta is the triple combination therapy of FF/UMEC/VI in a single ELLIPTA® inhaler.

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 (ICS); UMEC, a long-acting muscarinic antagonist (LAMA); and 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.

In a [press release](#) dated May 29, 2018, GSK and Innoviva announced the submission of a New Drug Application (NDA) to the Japanese MHLW for Trelegy Ellipta for the treatment of adult COPD patients. The proposed indication is for the relief of various symptoms with COPD (chronic bronchitis, pulmonary emphysema) (in the case where concurrent use of ICS, LABA and long-acting inhaled anticholinergic drug is required). According to the companies, this is the first NDA filing to be made in Japan for a triple COPD therapy in a single inhaler.

The regulatory submission is primarily based on data from the Phase III IMPACT study which included 378 patients from Japan. In the overall study population, FF/UMEC/VI was superior to the ICS/LABA Relvar/Breo Ellipta (FF/VI) and the LAMA/LABA Anoro Ellipta (UMEC/VI) on multiple clinically important endpoints, including reducing exacerbations and improving lung function and health related quality of life. Similar trends were observed in the Japanese population for the primary endpoint as well as across multiple secondary and supportive efficacy endpoints.

Trelegy Ellipta is approved in the US for 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. 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.

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.

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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 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's Form 10-Q filed with the Securities and Exchange Commission (SEC) on May 9, 2018 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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