# Theravance Biopharma Highlights Expanded COPD Indication for Trelegy Ellipta in Europe

November 12, 2018

DUBLIN, Nov. 12, 2018 /PRNewswire/ -- Theravance Biopharma, Inc. (NASDAQ: TBPH) ("Theravance Biopharma") today highlighted that the European Commission authorized an expanded label for once-daily Trelegy Ellipta (fluticasone furoate/umeclidinium/vilanterol 'FF/UMEC/VI'), recognizing the product's effect on exacerbations and making it the first single-inhaler triple therapy indicated for patients with moderate to severe chronic obstructive pulmonary disease (COPD) not adequately treated with dual bronchodilation or with an inhaled corticosteroid (ICS) and a long-acting β2-agonist (LABA).

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 ICS; UMEC, a long-acting muscarinic antagonist (LAMA); and VI, a LABA. This combination has been formulated to be delivered once-daily in GSK's ELLIPTA® dry powder inhaler.

In a press release dated November 9, 2018, GSK and Innoviva announced that the European Commission authorized the expanded label for Trelegy Ellipta in Europe. According to the companies, the expanded indication reflects evidence supporting its potential benefits in a broader group of patients than originally indicated, giving them the option of taking a once-daily, single-inhaler triple therapy for the first time. The label update is based on data from the landmark InforMing the PAthway of COPD Treatment (IMPACT) study which showed Trelegy Ellipta was superior to both the ICS/LABA Relvar/Breo Ellipta (FF/VI) and LAMA/LABA Anoro Ellipta (UMEC/VI) in patients with moderate to severe COPD on multiple clinically important endpoints, including reducing exacerbations and improving lung function and health related quality of life.

The new indication for Trelegy Ellipta is 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 or a combination of a LABA and a LAMA (for effects on symptom control and prevention of exacerbations see section 5.1). It was originally approved in the European Union (EU) in November 2017 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 (for effects on symptom control see section 5.1).

The European Summary of Product Characteristics is available at: https://www.medicines.org.uk/emc/medicine/34357.

**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, gut-selective 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 characteristics, 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 and their differentiation from other products or potential products), 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-Q filed with the Securities and Exchange Commission (SEC) on November 7, 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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