Theravance Biopharma Highlights Submission of Landmark IMPACT Data to EMA to Support Expanded Label for Trelegy Ellipta

February 15, 2018

DUBLIN, Feb. 15, 2018 /PRNewswire/ -- Theravance Biopharma, Inc. (NASDAQ: TBPH) ("Theravance Biopharma") today highlighted the submission of the landmark IMPACT study data to the European Medicines Agency (EMA) as part of a type II variation to support an expanded label for Trelegy Ellipta in Europe for the maintenance treatment of moderate to severe chronic obstructive pulmonary disease (COPD). Trelegy Ellipta is the triple combination therapy of fluticasone furoate, umeclidinium, and vilanterol (FF/UMEC/VI) in a single ELLIPTA® inhaler. If this latest submission is approved, the labeled indication for Trelegy Ellipta would include a wider population of patients with COPD who are at risk of an exacerbation and require triple therapy.

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 Trelegy Ellipta.

Trelegy Ellipta is the first 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 simple-to-use delivery device, the ELLIPTA® dry powder inhaler.

In a press release dated February 14, 2018, GSK and Innoviva announced the submission of data from the landmark IMPACT study to the EMA to support an expanded label for Trelegy Ellipta. In the IMPACT study, Trelegy Ellipta showed superiority to the inhaled corticosteroid/long-acting beta$_2$-adrenergic agonist (ICS/LABA), Relvar/Breo (FF/VI), and long-acting muscarinic antagonist/long-acting beta$_2$-adrenergic agonist (LAMA/LABA), Anoro (UMEC/VI), on a range of clinically important endpoints, including reducing the number of exacerbations or 'flare ups' patients experienced, and improving lung function and health related quality of life.

Trelegy Ellipta was approved in Europe 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. The product is also approved for use in the US for the long-term, once-daily, maintenance treatment of COPD patients who are receiving Breo (FF/VI) and require additional bronchodilation or who are receiving Breo and Incruse (UMEC). This latest filing in Europe follows submission of a supplemental New Drug Application (sNDA) to the U.S. Food and Drug Administration (FDA) which is currently under review. Also included in the submission are data showing Trelegy Ellipta was non-inferior to UMEC and FF/VI when used in combination in terms of improving lung function, quality of life and breathlessness, further adding to the evidence base (NCT02729051).

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 US, 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 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.

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, 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) and the Company's expectations for product sales. 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 product and product candidates, 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 8, 2017and 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.

Contact Information:

Alexander Dobbin
Head of Investor Relations
650-808-4045
investor.relations@theravance.com

Tim Brons
Vida Strategic Partners (media)
646-319-8981
tbrons@vidasp.com

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