Theravance Biopharma Highlights Positive Headline Results from IMPACT Study of Trelegy Ellipta Announced by GlaxoSmithKline and Innoviva

September 20, 2017

Single Inhaler Triple Therapy Met Study Primary Endpoint Demonstrating Reduction in Exacerbations Compared with Dual Therapies Anoro Ellipta and Relvar/Breo Ellipta in Patients with COPD

Theravance Biopharma Entitled to Receive 85% Economic Interest in Trelegy Ellipta Royalties Paid by GlaxoSmithKline as Part of Agreement with Innoviva

DUBLIN, Sept. 20, 2017 /PRNewswire/ -- Theravance Biopharma, Inc. (NASDAQ: TBPH) ("Theravance Biopharma") today highlighted that GlaxoSmithKline plc (GSK) and Innoviva, Inc. (Innoviva) have reported positive headline results from the landmark Phase 3 IMPACT study of Trelegy Ellipta, the first and only FDA approved once-daily single inhaler triple therapy comprising an inhaled corticosteroid (ICS), long-acting muscarinic antagonist (LAMA) and long-acting beta agonist (LABA). Trelegy Ellipta is a drug development program for which Theravance Biopharma has an economic interest in future payments that may be made by 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%. Theravance Biopharma is not responsible for any costs related to Trelegy Ellipta.

Trelegy Ellipta (fluticasone furoate/umeclidinium/vilanterol, FF/UMEC/VI) is approved in the US for the long-term, once-daily, maintenance treatment of patients with chronic obstructive pulmonary disease (COPD) who are receiving Breo (fluticasone furoate/vilanterol, FF/ VI) and require additional bronchodilation or who are receiving Breo and Incruse (umeclidinium, UMEC).

In an announcement dated September 20, 2017, GSK and Innoviva stated the IMPACT study, which involved 10,355 patients, met its primary endpoint demonstrating statistically significant reductions in the annual rate of on-treatment moderate/severe exacerbations for FF/UMEC/VI (100/62.5/25mcg) when compared with two, once-daily dual COPD therapies from GSK's existing portfolio. The study showed a:

- 15% reduction for FF/UMEC/VI compared with Relvar/Breo Ellipta (FF/VI,100/25mcg); 0.91 vs 1.07 per year; p<0.001
- 25% reduction for FF/UMEC/VI compared with Anoro Ellipta (UMEC/VI, 62.5/25mcg); 0.91 vs 1.21 per year; p<0.001

In addition, statistically significant improvements were observed across all pre-specified key secondary endpoints and associated treatment comparisons:

- Change from baseline trough FEV_1 at week 52 for FF/UMEC/VI compared with FF/VI was 97mL; p<0.001 and for FF/UMEC/VI compared with UMEC/VI was 54mL; p<0.001
- Change from baseline St. George's Respiratory Questionnaire at week 52 for FF/UMEC/VI compared with FF/VI was -1.8 units; p<0.001 and for FF/UMEC/VI compared with UMEC/VI was -1.8 units; p<0.001
- Analysis of time to first on-treatment moderate/severe COPD exacerbation demonstrated a 14.8% reduction in risk for FF/UMEC/VI compared with FF/VI; p<0.001, and a 16.0% reduction in risk for FF/UMEC/VI compared with UMEC/VI; p<0.001

GSK and Innoviva also noted that based on review of the headline data, the safety profile of FF/UMEC/VI was consistent with the known profile of the individual medicines and their dual combinations. The most common adverse events across the treatment groups were viral upper respiratory tract infection, worsening of COPD, upper respiratory tract infection, pneumonia and headache. The incidences of the most frequent serious adverse events were worsening of COPD: 11%, 11% and 13% for FF/UMEC/VI, FF/VI and UMEC/VI, respectively; and pneumonia: 4%, 4% and 3% for FF/UMEC/VI, FF/VI and UMEC/VI, respectively. According to GSK and Innoviva, full results from the IMPACT study will be presented at upcoming scientific meetings and in peer-reviewed publications.

About IMPACT

The InforMing the PAthway of COPD Treatment (IMPACT) study was a randomized, double-blind, 3-arm parallel group, multicenter study evaluating FF/UMEC/VI (100mcg/62.5mcg/25mcg) versus FF/VI (100mcg/25mcg) and UMEC/VI (62.5mcg/25mcg), all given once daily via the Ellipta dry powder inhaler. The total duration of the study was approximately 55 weeks consisting of a 2-week run-in period, 52-week treatment period and a 1-week safety follow-up period. Patients had moderate to very severe symptomatic COPD with a history of exacerbation in the prior 12 months. In the study, 10,355 patients were treated in over 1,035 study centers globally.

The primary efficacy endpoint was the annual rate of on-treatment moderate and severe exacerbations. This was compared for FF/UMEC/VI versus

FF/VI and, FF/UMEC/VI versus UMEC/VI. Other endpoints included lung function and patient reported outcomes, including health related quality of life measures.

About Theravance Biopharma

Theravance Biopharma, Inc. 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. 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 drug development 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 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 and results of clinical studies, the potential benefits and mechanisms of action of the Company's product and product candidates and the Company's expectations for product candidates through development, potential regulatory approval and commercialization. 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 or completing clinical studies, the potential that results from clinical or non-clinical studies indicate the Company's product candidates are unsafe or ineffective, 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 and commercialize products, 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 Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission (SEC) on August 9, 2017. In addition to the risks described above and in Theravance Biopharma's other 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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