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Theravance Biopharma Highlights Positive Results From Pivotal Phase 3 FULFIL Study of the Closed Triple Announced by GlaxoSmithKline and Innoviva at ERS International Congress

DUBLIN, IRELAND -- (Marketwired) -- 09/07/16 -- Theravance Biopharma, Inc. (NASDAQ: TBPH)

Statistically Significant Benefits in Lung Function, Health-Related Quality of Life and Annual Rate of Exacerbations Observed for Closed Triple as Compared to Symbicort® Turbohaler®

Theravance Biopharma Entitled to Receive 85% Economic Interest in Closed Triple Royalties Paid by GSK as Part of Agreement With Innoviva

GSK's Regulatory Submissions on Track for the Closed Triple in U.S. and Europe by end of 2016

Theravance Biopharma, Inc. (NASDAQ: TBPH) (Theravance Biopharma) today announced that GlaxoSmithKline plc (GSK) and Innoviva, Inc. (Innoviva) have presented additional positive data from the pivotal Phase 3 FULFIL study of the Closed Triple (the combination of fluticasone furoate, umeclidinium, and vilanterol or FF/UMEC/VI) in patients with chronic obstructive pulmonary disease (COPD). Data presented at the European Respiratory Society (ERS) International Congress demonstrated clinically meaningful and statistically significant benefits for the Closed Triple as compared to Symbicort® Turbohaler® (budesonide/formoterol) in improving lung function and health-related quality of life, as well as reducing the annual rate of moderate/severe exacerbations, in COPD patients. GSK has indicated that its plans are on track for regulatory submissions for the Closed Triple for the treatment of COPD in both the U.S. and Europe by the end of 2016.

The Closed Triple is one of the drug development programs 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.). Should the Closed Triple be approved and commercialized, 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%. Additionally, Theravance Biopharma is not responsible for any costs related to the Closed Triple.

In an announcement made on September 6, 2016, GSK and Innoviva stated that new data from the FULFIL study was being presented at ERS. The FULFIL study compared FF/UMEC/VI with budesonide and formoterol, an ICS/LABA combination delivered twice-daily in the Turbohaler dry powder inhaler. Key highlights from the data presentation included:

- The study met its two co-primary endpoints. At 24 weeks, there was a clinically meaningful and statistically significant benefit for FF/UMEC/VI in both lung function, measured as mean change from baseline in trough FEV_1 (171mL, 95% confidence interval [148, 194] $p < 0.001$) and health-related quality of life, measured as mean change from baseline in St. George's Respiratory Questionnaire (SGRQ) total score (-6.6 units for closed triple versus -4.3 units for budesonide/formoterol, difference of -2.2 units, 95% confidence interval [-3.5, -1.0] $p < 0.001$). Additionally, the proportion of patients who responded with the minimum clinically important difference in SGRQ (-4 units) was 50% on closed triple and 41% on budesonide/formoterol (odds ratio: 1.41; $p < 0.001$).

- Treatment benefit with closed triple therapy was also observed in the subset of patients who received treatment for up to 52 weeks, with a statistically significant improvement of 179mL in trough FEV_1 and a numerical improvement of -2.7 units in SGRQ total score at Week 52 with closed triple therapy compared with budesonide/formoterol.

- The study also showed a statistically significant and clinically meaningful reduction in the annual rate of moderate/severe exacerbations with closed triple therapy compared to budesonide/formoterol. Closed triple therapy showed a 35% reduction versus budesonide/formoterol based on data up to 24 weeks (p=0.002) and a 44% reduction in the subset of patients that received treatment for up to 52 weeks (p=0.006).

- The safety profile of the closed triple combination up to 24 weeks and in the subset of patients up to 52 weeks was consistent with the known profile of the individual medicines and their combinations. Up to both 24 weeks and 52 weeks, the most common adverse events in both treatment arms were nasopharyngitis, headache and COPD worsening.

- The incidence of investigator-reported serious adverse events for closed triple and budesonide/formoterol, respectively, was 5.4% and 5.7% up to 24 weeks, and 10.0% and 12.7% up to 52 weeks. Up to 24 weeks, the incidence of pneumonia was 1.0% in the closed triple arm and 0.3% in the budesonide/formoterol arm. Up to 52 weeks, it was 1.9% in the closed triple arm and 1.8% in the budesonide/formoterol arm.

The Closed Triple combination therapy represents a unique approach to COPD treatment by seeking to combine the activity of three molecules with different mechanisms of action in a single, simple-to-use delivery device. The combination treatment includes: fluticasone furoate (FF), an inhaled corticosteroid; umeclidinium (UMEC), a long-acting muscarinic antagonist (LAMA); and vilanterol (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.

Current trends in the treatment of COPD with combination therapy support Theravance Biopharma's view that there is significant market potential for a first-in-class, once-daily Closed Triple. According to GSK, approximately one-third of COPD patients are already utilizing open triple therapy and the progressive nature of the disease indicates that COPD patients will need access to more effective therapies over time. Additionally, recently reported results from the Salford Lung Study, a Phase 3 real-world effectiveness trial of two of the components of Closed Triple (FF and VI) in COPD exacerbations, were strongly supportive of the benefits of once-daily therapy.

In addition to the FULFIL study, the ongoing clinical development program for the Closed Triple in COPD includes the IMPACT study, a large Phase 3 trial designed to evaluate the efficacy and safety of the triple combination treatment compared to dual COPD therapies (FF/VI and UMEC/VI). Results of the IMPACT study are expected to be reported by GSK in 2017[1].

The Closed Triple is also in development for the treatment of symptomatic asthma. GSK has stated that a pivotal Phase 3 trial of the Closed Triple in asthma is expected to be initiated by the end of 2016, with a regulatory submission planned for 2018.

Notes:
[1]Regulatory and clinical milestones as reported by Glaxo Group Limited or one of its affiliates (GSK)

About FULFIL

FULFIL (Lung FUnction and quality of LiFe assessment in COPD with closed trIpLe therapy) was a randomized, double-blind, double-dummy, parallel group multicenter study evaluating once-daily FF/UMEC/VI (100mcg/62.5mcg/25mcg) inhalation powder versus twice-daily budesonide/formoterol (400mcg/12mcg) via the Turbohaler dry powder inhaler. In the study, 1,810 patients were treated across 162 study centers globally (911 on FF/UMEC/VI and 899 on budesonide/formoterol). The population included symptomatic COPD patients (COPD assessment test ≥ 10) with either an FEV_1 of less than 50% predicted, or FEV_1 of 50% to less than 80% of predicted and two moderate or one severe exacerbation in the prior year.

The co-primary endpoints were: change from baseline in trough FEV_1 and SGRQ total score after 24 weeks of treatment. Other endpoints included the effect of FF/UMEC/VI on the annual rate of moderate/severe exacerbations compared with budesonide/formoterol, and the safety profile of FF/UMEC/VI compared with budesonide/formoterol over 24 weeks and 52 weeks of treatment. To provide additional longer term safety data, a sub-set of 430 patients remained on blinded study treatment for up to a total of 52 weeks.

About Theravance Biopharma

Theravance Biopharma is a diversified biopharmaceutical company with the core purpose of creating medicines that make a difference in 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 GI-targeted 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 the Closed Triple (the combination of fluticasone furoate, umeclidinium, and vilanterol), currently in development for the treatment of COPD and 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: strategies, plans and objectives, regulatory strategies and timing of clinical studies, the potential benefits and mechanisms of action of product candidates, and expectations for product candidates through development, potential regulatory approval and commercialization (including their potential as components of combination therapies). 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 that product candidates are unsafe or ineffective (including when product candidates are studied in combination with other compounds),the feasibility of undertaking future clinical trials for 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, and risks of collaborating with or relying on third parties to discover, develop and commercialize products. 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 August 9, 2016 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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