

Theravance Biopharma Highlights Positive Top-Line Results From Pivotal Phase 3 FULFIL Study of the Closed Triple Announced by GlaxoSmithKline and Innoviva

Theravance Biopharma Entitled to Receive 85% Economic Interest in Royalties Paid by GSK as Part of Agreement With Innoviva; Regulatory Submissions Planned for the Closed Triple in U.S. and EU by End of 2016

DUBLIN, IRELAND -- (Marketwired) -- 06/20/16 -- Theravance Biopharma, Inc. (NASDAQ: TBPH) ("Theravance Biopharma") today announced that GlaxoSmithKline plc (GSK) and Innoviva, Inc. (Innoviva) have disclosed positive top-line results from the pivotal Phase 3 FULFIL study of the Closed Triple (the combination of fluticasone furoate, umeclidinium, and vilanterol) in patients with chronic obstructive pulmonary disease (COPD). Data demonstrated superiority for the Closed Triple as compared to Symbicort® Turbohaler® in improving lung function and health-related quality of life in COPD patients. 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 successfully developed 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, GSK is responsible for all development costs related to the Closed Triple with no costs being borne by Theravance Biopharma.

In an announcement made on June 20, 2016, GSK and Innoviva stated that the FULFIL study met its two co-primary endpoints, demonstrating statistically significant improvements compared with twice-daily Symbicort Turbohaler (budesonide/formoterol 400/12mcg) in both lung function as measured by trough FEV₁ (171mL, 95% confidence interval [148, 194] p < 0.001), and health-related quality of life as measured by the St. George's Respiratory Questionnaire (SGRQ) (-2.2 units, 95% confidence interval [-3.5, -1.0] p < 0.001), at the end of the 24-week study period. The proportion of patients who responded with the minimum clinically important difference in SGRQ (-4 units) was 50% on FF/UMEC/VI and 41% on budesonide/formoterol. Additionally, GSK and Innoviva announced that the safety profile for the Closed Triple at both 24 weeks and the 52-week extension was consistent with the known profile of the individual medicines and their combinations. GSK has indicated that findings from the FULFIL study support its plans to submit regulatory filings for the approval of the Closed Triple for the treatment of COPD in both the U.S. and EU by the end of 2016.

Additional top-line FULFIL study results announced by GSK and Innoviva include:

- | Most common adverse events across both treatment arms at 24 and 52 weeks were nasopharyngitis, headache and COPD worsening.
- | At 24 weeks, the incidence of investigator-reported serious adverse events was 5.4% and 5.7% for FF/UMEC/VI and budesonide/formoterol, respectively. This included worsening of COPD (1.3% and 2.3%); pneumonia (1.0% and 0.3%); and cardiac disorders (0.3% and 1.0%), respectively.
- | At 52 weeks, the incidence of investigator-reported serious adverse events was 10.0% for FF/UMEC/VI and 12.7% for budesonide/formoterol, respectively. This included worsening of COPD (2.4% and 9.1%); pneumonia (1.9% and 1.8%); and cardiac disorders (1.4% and 0.9%), respectively.

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 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 beta₂-adrenergic agonist (LABA). This combination has been formulated to be delivered once-daily in GSK's Ellipta® dry powder inhaler.

The FULFIL study compared FF/UMEC/VI with budesonide and formoterol, an ICS/LABA combination delivered twice-daily in the Turbohaler dry powder inhaler. GSK and Innoviva intend to submit full results from the FULFIL study, including data from secondary endpoints and the 52-week extension study, for presentation at a scientific congress.

In addition to the FULFIL study, the ongoing clinical development program for the Closed Triple in COPD includes the

IMPACT study, a second Phase 3 trial designed to evaluate the effectiveness and safety of the combination treatment compared to existing COPD therapies. Results of the IMPACT study are expected in 2017¹.

Notes:

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

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.

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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 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 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. 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 May 10, 2016. 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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