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Theravance Biopharma and Mylan Report Additional Phase 3 Data for Revefenacin (TD-4208) in Several Presentations at 2017 ATS

Presentations Review Detailed Efficacy and Safety Data from Two Replicate Pivotal Phase 3 Studies; Report Prevalence of COPD Patients with Low Peak Inspiratory Flow Rate in Ongoing 12-Month Phase 3 Safety Trial

DUBLIN and HERTFORDSHIRE, United Kingdom and PITTSBURGH, May 23, 2017 /PRNewswire/ -- Theravance Biopharma, Inc. (NASDAQ: TBPH) ("Theravance Biopharma") and Mylan N.V. (NASDAQ, TASE: MYL) ("Mylan") today announced the presentation of additional efficacy and safety data from the three-month, pivotal Phase 3 studies of revefenacin (TD-4208) at the American Thoracic Society (ATS) International Conference in Washington, D.C. Revefenacin is an investigational long-acting muscarinic antagonist (LAMA) and a proposed once-daily, nebulized bronchodilator in development for the treatment of chronic obstructive pulmonary disease (COPD).

Phase 3 Pivotal Study Presentations

Researchers presented new data from the completed three-month Phase 3 studies, which included more than 1,250 patients with moderate to very severe COPD, in two separate presentations at the 2017 ATS meeting. The first presentation, which focused on efficacy outcomes, demonstrated statistically significant and clinically meaningful improvements over placebo in trough forced expiratory volume in one second (FEV_1) and in overall treatment effect on trough FEV_1 (OTE FEV_1) after 12 weeks of dosing in each study and for each of the revefenacin doses studied (88 mcg once daily and 175 mcg once daily). The improvements in trough FEV_1, the primary efficacy endpoint, versus placebo for the intent-to-treat populations across both studies were 118 mL and 145 mL for 88 mcg and 175 mcg, respectively ($p \leq 0.001$). Additionally, the improvements in OTE FEV_1, a key secondary endpoint, versus placebo for the intent-to-treat population across both studies were 112 mL and 139 mL for 88 mcg and 175 mcg, respectively ($p \leq 0.001$).

The second presentation featured safety and tolerability data from the two completed three-month Phase 3 studies. Both doses of revefenacin had comparable rates of adverse events to placebo, low rates of serious adverse events, and no clinically meaningful differences in blood parameters or electrocardiogram (ECG) data, across all treatment groups (active and placebo). As previously reported, the most commonly reported adverse events, across both trials and across all treatment groups, were exacerbations, cough, dyspnea and headache. There were no reports of blurred vision, narrow-angle glaucoma or worsening of urinary retention. Reports of dry mouth were < 0.5% in the revefenacin treatment arms.

"These presentations build upon the topline results that we announced last October and further confirm that revefenacin may offer meaningful benefits to patients with moderate to very severe COPD," said Brett Haumann, MD, Chief Medical Officer at Theravance Biopharma. "We believe that these results position revefenacin favorably as a potentially key therapeutic option for COPD patients if approved, particularly as revefenacin would represent the first once-daily nebulized bronchodilator for COPD. We anticipate completing the ongoing Phase 3 safety trial of revefenacin in mid-2017 with the goal of filing an NDA by the end of 2017."

Mylan President Rajiv Malik commented, "We continue to be very pleased with the progress of the Phase 3 revefenacin program, and are excited to have the opportunity to showcase this important data set at ATS for the first time. According to

the GOLD Guidelines for COPD, LAMAs are a cornerstone of therapy for moderate to severe COPD, yet there are currently no nebulized LAMAs available. We believe this product has the potential to help address an unmet medical need for patients. Further, revefenacin represents a key contributor in Mylan's pipeline of promising respiratory products, and supports the growth of our respiratory franchise. If approved, we believe that we are well-positioned to support the commercial success of this product."

Revefenacin is being developed as a once-daily, nebulized bronchodilator for the treatment of patients with COPD and will be compatible with a range of jet nebulizers. The three-month Phase 3 pivotal studies were replicate, randomized, double-blind, placebo-controlled, parallel-group trials designed to provide pivotal efficacy and safety data for once-daily revefenacin over a dosing period of 12 weeks. The replicate studies enrolled a combined total of over 1,250 patients in the U.S. across a range of disease severity from moderate to very severe COPD and allowed for the concomitant use of long-acting beta agonist (LABA) and/or long-acting beta agonist/inhaled corticosteroid (LABA/ICS) products in a significant proportion (38%) of the studied population. Study investigators tested two doses (88 mcg and 175 mcg) of revefenacin inhalation solution or matched placebo administered once daily via a standard jet nebulizer in moderate to very severe COPD patients.

The revefenacin Phase 3 program also includes an ongoing 12-month, open-label, active comparator safety study in more than 1,050 patients, which is expected to be completed in mid-2017. Together, the three studies enrolled approximately 2,300 patients. Should outcomes from the safety study be supportive, Theravance Biopharma expects to file a New Drug Application (NDA) for revefenacin with the U.S. Food and Drug Administration (FDA) by the end of 2017. Theravance Biopharma and its affiliates have partnered with Mylan and its affiliates on the development and commercialization of nebulized revefenacin products for COPD and other respiratory diseases.

Additional Data Presentations

In a separate presentation at 2017 ATS, researchers reported baseline data on the prevalence of COPD patients with low peak inspiratory flow rate (PIFR) who are enrolled in the ongoing 12-month, open-label, active comparator safety study of revefenacin. Of the total population of 1,080 patients who were enrolled in the study, 448 patients had their PIFR measured using a commercially available, easy-to-use instrument (InCheck®) at the time of study randomization. Researchers categorized PIFRs of less than 40 L/min against the resistance of the Handihaler® as "low" for the means of this analysis based upon published research and reference data. Presented results showed that 24% of subjects had a low PIFR rate at the time of randomization. Analysis of patient characteristics showed that patients with a low PIFR tended to be female and exhibited evidence of more severe COPD, although a proportion of patients with less severe COPD were also found to have low PIFR.

"Patients with low PIFR may not be able to breathe in with enough force to benefit from the use of handheld COPD devices. There is growing evidence that these patients may have better short-term and long-term benefits from nebulized therapy. This is supported by a recent scientific study that reported that patients with low PIFR, regardless of disease severity, showed statistically significant lower COPD hospital readmission rates within both 30 and 90 days when using nebulized therapy as compared to a handheld product following COPD exacerbation[1]," said Dr. Haumann. "We believe that revefenacin could provide a unique benefit to patients with low PIFR and are currently evaluating this in a dedicated clinical study."

Researchers also presented results from a study highlighting the pharmacological properties of revefenacin in isolated tissue airways, from both rats and humans, to enable preclinical to clinical translation of the *in vivo* findings in rats. Study data demonstrated that revefenacin produced potent and persistent anti-muscarinic activity in the airway tissues of both rats and humans. These translational findings are consistent with clinical data from the replicate three-month Phase 3 studies of revefenacin demonstrating 24-hour bronchodilatory effects in COPD patients.

About Theravance Biopharma and Mylan Strategic Collaboration

Theravance Biopharma and Mylan N.V. and their respective affiliates have established a strategic collaboration to develop and commercialize nebulized revefenacin products for COPD and other respiratory diseases. Under the terms of the agreement, Theravance Biopharma is leading the U.S. development program for the revefenacin inhalation solution product, with all costs reimbursed by Mylan up until the approval of the first new drug application, after which costs will be shared. Mylan is responsible for ex-U.S. development and commercialization. Theravance Biopharma is eligible to receive up to $220 million in development and sales milestone payments, as well as a profit-sharing arrangement with Mylan on U.S. sales and double-digit royalties on ex-U.S. sales. Additionally, Theravance Biopharma retains worldwide rights to revefenacin delivered through other dosage forms, such as a metered dose inhaler or dry powder inhaler (MDI/DPI), and the rights to nebulized revefenacin in China.

About COPD

COPD is a growing and devastating disease that is the third leading cause of death in the U.S.[2] An estimated 12.7 million American adults are diagnosed with COPD and an almost equal number are believed to be undiagnosed.[3]There were more than 700,000 hospital discharges related to COPD in the U.S. reported in 2010. The costs of managing COPD in the U.S. were estimated to be nearly $50 billion in 2010, including $29.5 billion in direct healthcare expenditures, $8 billion in indirect morbidity costs and $12.4 billion in indirect mortality costs.[3]

About Revefenacin

Revefenacin (TD-4208) is a novel investigational once-daily nebulized LAMA in Phase 3 development for the treatment of moderate to very severe COPD. Market research by Theravance Biopharma indicates approximately 9% of the treated COPD patients in the U.S. use nebulizers for ongoing maintenance therapy.[4] LAMAs are a cornerstone of maintenance therapy for COPD and, if approved, revefenacin would provide a once-daily option for COPD patients who require, or prefer, nebulized therapy. The product's stability in both metered dose inhaler and dry powder device formulations suggest that this LAMA could also serve as a foundation for novel handheld combination products.

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 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 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: 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 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 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 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's Form 10-Q filed with the Securities and Exchange Commission (SEC) on May 9, 2017 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.

About Mylan

Mylan is a global pharmaceutical company committed to setting new standards in healthcare. Working together around the world to provide 7 billion people access to high quality medicine, we innovate to satisfy unmet needs; make reliability and service excellence a habit; do what's right, not what's easy; and impact the future through passionate global leadership. We market a growing portfolio of approximately 7,500 products around the world, including antiretroviral therapies on which approximately 50% of people being treated for HIV/AIDS in the developing world depend. We market our products in more than 165 countries and territories. We are one of the world's largest producers of active pharmaceutical ingredients. Every member of our more than 35,000-strong workforce is dedicated to creating better health for a better world, one person at a time. Learn more at mylan.com.

This press release includes statements that constitute "forward-looking statements," including with regard to revefenacin having the potential to offer meaningful benefits to patients with moderate to very severe COPD; revefenacin being positioned favorably as a potentially key therapeutic option for COPD patients if approved, particularly as revefenacin would represent the first once-daily nebulized bronchodilator for COPD; anticipated completion of the ongoing Phase 3 safety trial of revefenacin in mid-2017 with the goal of filing an NDA by the end of 2017; revefenacin having the potential to help address an unmet medical need for patients; revefenacin representing a key contributor in Mylan's pipeline of promising respiratory products, and supporting the growth of Mylan's respiratory franchise; Mylan's belief that it is well-positioned to support the commercial success of the product; the ongoing 12-month, open-label, active comparator safety study in more than 1,050 patients, which is expected to be completed in mid-2017; Theravance Biopharma expecting to file a New Drug Application (NDA) for revefenacin with the U.S. Food and Drug Administration (FDA) by the end of 2017; the possibility that revefenacin could provide a unique benefit to patients with low PIFR; and the possibility that this LAMA could also serve as a foundation for novel handheld combination products. These statements are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Because such statements inherently involve risks and uncertainties, actual future results may differ materially from those expressed or implied by such forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to: success of clinical trials and our and our partners' ability to execute on new product opportunities; any regulatory, legal or other impediments to our ability to bring our and our partners' products to market; other risks inherent in product development; the scope, timing, and outcome of any ongoing legal proceedings, including government investigations, and the impact of any such proceedings on our or our partners' business; actions and decisions of healthcare and pharmaceutical regulators, and changes in healthcare and pharmaceutical laws and regulations, in the United States and abroad; the impact of competition; strategies by competitors or other third parties to delay or prevent product introductions; the effect of any changes in our customer and supplier relationships and customer purchasing patterns; any other changes in third-party relationships; changes in the economic and financial conditions of the businesses of Mylan; uncertainties and matters beyond the control of management; and the other risks detailed in Mylan's filings with the Securities and Exchange Commission. Mylan undertakes no obligation to update these statements for revisions or changes after the date of this release.

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References

[1] Loh CH, Lovings T, Ohar J. Long acting nebulized agents decrease readmissions in patients with suboptimal peak inspiratory flow. Chest 2016;150:925A-925A.

[2]American Lung Association. "Chronic Obstructive Pulmonary Disease (COPD)" http://www.lung.org/lung-health-and-diseases/lung-disease-lookup/copd.

[3] American Lung Association. "Trends in COPD (Chronic Bronchitis and Emphysema): Morbidity and Mortality" http://www.lung.org/assets/documents/research/copd-trend-report.pdf.

[4] TBPH market research (N = 160 physicians); Refers to US COPD patients