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Theravance Biopharma and Mylan to Present Additional Data for Revefenacin (TD-4208) in Several Presentations at 2017 ATS

Presentations Will Include Detailed Efficacy and Safety Data from Two Replicate Pivotal Phase 3 Studies

DUBLIN and HERTFORDSHIRE, England and PITTSBURGH, May 17, 2017 /PRNewswire/ -- Theravance Biopharma, Inc. (NASDAQ: TBPH) ("Theravance Biopharma") and Mylan N.V. (NASDAQ, TASE: MYL) ("Mylan") today announced that data from several studies of revefenacin (TD-4208) will be presented at the American Thoracic Society (ATS) International Conference, which is being held in Washington, D.C., May 19-24, 2017. 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).

Seeing is believing™

Presented findings will include a detailed review of the positive efficacy results and the safety data from two replicate completed pivotal Phase 3 studies of revefenacin, following the initial announcement of top-line results from the trials in October 2016. Additionally, researchers will present results of an analysis of the prevalence of COPD patients with low peak inspiratory flow rate (PIFR) who were enrolled in the ongoing 12-month, Phase 3 safety study of revefenacin, which is expected to be completed in mid-2017.

Details of the revefenacin *poster* presentations at 2017 ATS are as follows:

Poster #P365: Safety and Tolerability of Revefenacin, a Novel Once-Daily Nebulized Long-Acting Muscarinic Antagonist: Results of Two 12-Week, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Phase 3 Trials in Participants with Moderate to Very Severe Chronic Obstructive Pulmonary Disease

Monday, May 22, 2017, 9:15 a.m. Eastern
Session: Long Acting Bronchodilator Therapy in COPD I

Poster #P1090: Efficacy of Revefenacin, a Novel Once-Daily Nebulized Long-Acting Muscarinic Antagonist: Results of Two 12-Week, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Phase 3 Trials in Participants with Moderate to Very Severe Chronic Obstructive Pulmonary Disease

Tuesday, May 23, 2017, 9:15 a.m. Eastern
Session: Long Acting Bronchodilator Therapy in COPD II

Poster #P1271: Prevalence and Characteristics of Patients with COPD and Low Peak Inspiratory Flow Rate Recruited in a Phase 3 Development Program for Revefenacin, a Nebulized Once-Daily Long-Acting Muscarinic Antagonist

Tuesday, May 23, 2017, 9:15 a.m. Eastern
Session: Advancing Understanding of Obstructive Lung Disease: Medications and Mechanisms of Delivery

Poster #P1219: Pharmacological Studies with Revefenacin (TD-4208) in Rat Isolated Trachea and Human Isolated Bronchus: Animal to Human Translation of Potent and Long Acting Muscarinic Receptor Antagonistic Properties in Airway Tissues

Tuesday, May 23, 2017, 9:15 a.m. Eastern

Session: Advances in Translational COPD

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.[1] An estimated 12.7 million American adults are diagnosed with COPD and an almost equal number are believed to be undiagnosed.[2] 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.[2]

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.[3] 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 clinical studies, potential products 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.

References

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

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

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

To view the original version on PR Newswire, visit:http://www.prnewswire.com/news-releases/theravance-biopharma-and-mylan-to-present-additional-data-for-revefenacin-td-4208-in-several-presentations-at-2017-ats-300459191.html

SOURCE Mylan N.V.; Theravance Biopharma, Inc.

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