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Theravance Biopharma and Mylan Announce Positive Results from 12-Month Phase 3 Safety Study of Revefenacin (TD-4208) in Patients with Chronic Obstructive Pulmonary Disease (COPD)

These Data, Combined with Positive Results from Two Phase 3 Efficacy Studies, Support NDA Filing Planned for Fourth Quarter of 2017

DUBLIN and HERTFORDSHIRE, England and PITTSBURGH, July 19, 2017 /PRNewswire/ -- Theravance Biopharma, Inc. (NASDAQ: TBPH) ("Theravance Biopharma") and Mylan N.V. (NASDAQ, TASE: MYL) ("Mylan") today announced positive results from a 12-month Phase 3 safety study of revefenacin (TD-4208), 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). The study of 1,055 patients with COPD demonstrated that revefenacin was generally well-tolerated, and no new safety issues were identified. Rates of adverse events (AEs) and serious adverse events (SAEs) were low and comparable to those seen in the standard of care treatment arm.

"The data from this 12-month safety study build on our observations from the previous three-month efficacy studies and suggest that revefenacin has a favorable safety and tolerability profile when dosed chronically, either as a standalone therapy or when taken as an add-on to other COPD therapies including combinations of ICS and LABA," said Brett Haumann, MD, Chief Medical Officer at Theravance Biopharma. "As of today, there are no approved nebulized LAMAs, despite a significant number of COPD patients needing or preferring nebulized therapy for the treatment of their disease. Having achieved positive efficacy and tolerability data in our Phase 3 program, we and our partner Mylan believe that revefenacin is well positioned to address this important patient need. We remain on schedule to submit the NDA in the fourth quarter of 2017, which is the next step towards our goal of delivering the first once-daily nebulized bronchodilator to the COPD patient community."

Mylan President Rajiv Malik commented, "Our revefenacin collaboration with Theravance Biopharma continues to deliver results at every step along the development path. We are very pleased with the top-line results from the 12-month safety trial and now feel we have all the data necessary to support a successful NDA filing. Should revefenacin receive approval from the FDA, we look forward to introducing this nebulized LAMA, to ensure the treatment has the greatest possible impact on the lives of patients with COPD."

The Phase 3 safety study of revefenacin was a randomized, active-controlled parallel group trial designed to evaluate the safety and tolerability of two doses of revefenacin (88 mcg or 175 mcg, inhaled once daily via a nebulizer) over a dosing period of 52 weeks, as compared to standard of care. Tiotropium (Spiriva®), administered via a handheld device, served as the active comparator standard of care treatment arm in the study. 50% of patients in the study were using other COPD therapies, including long-acting beta-agonists (LABA) or LABA/inhaled corticosteroids (ICS). Data from the trial demonstrated low rates of AEs and SAEs for both doses of revefenacin, comparable to tiotropium. Mortality rates were low, balanced across each arm of the study, and deemed by investigators as not related to study treatment. The most commonly reported adverse events were exacerbations, nasopharyngitis, upper respiratory tract infections, and cough. Rates of COPD exacerbations were numerically lowest in the 175 mcg arm. The numerical frequency of anti-muscarinic side effects such as dry mouth and constipation was lowest in the revefenacin arms. Theravance Biopharma and Mylan plan to present more detailed results from the study at upcoming scientific conferences.

The companies previously reported positive results from two pivotal Phase 3 efficacy studies of revefenacin, which included

more than 1,250 patients with moderate to very severe COPD. In these studies, revefenacin 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. The data from these studies, combined with the results announced today, will support the submission of the new drug application (NDA) for revefenacin with the U.S. Food and Drug Administration (FDA), anticipated in the fourth quarter 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. The companies are developing revefenacin as a once-daily, nebulized bronchodilator for the treatment of patients with COPD that will be compatible with a range of jet nebulizers.

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 related to the registrational program 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 has the potential to be a best-in-class once-daily single-agent product 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 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 intestinal 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.

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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, 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 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 offer a growing portfolio of more than 7,500 marketed 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 the anticipated filing of a NDA with FDA for revefenacin in the fourth quarter of 2017; suggestions that revefenacin has a favorable safety and tolerability profile; that Theravance Biopharma and Mylan believe that revefenacin is well positioned to address an important patient need; Theravance Biopharma and Mylan remaining on schedule to submit the NDA in the fourth quarter of 2017, which is the next step towards their goal of delivering the first once-daily nebulized bronchodilator to the COPD patient community; Theravance Biopharma and Mylan having all the data necessary to support a successful NDA filing; Mylan looking forward to introducing the nebulized LAMA, to ensure the treatment has the greatest possible impact on the lives of patients with COPD; Theravance Biopharma and Mylan planning to present results from the study at upcoming conferences; revefenacin being compatible with a range of jet nebulizers; revefenacin having the potential to be a best-in-class once-daily single-agent product for COPD patients who require, or prefer, nebulized therapy; and the product's stability in both metered dose inhaler and dry powder device formulations, suggesting 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 or our partners' ability to execute on new product opportunities; any regulatory, legal or other impediments to our or our partners' ability to bring 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' businesses; 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 or our partners' 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 or its partners; 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. Accessed on September 29, 2016.

[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. Accessed on September 29, 2016.

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

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