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Theravance Biopharma and Mylan Initiate Phase 3 Program for Revefenacin (TD-4208) for Treatment of Chronic Obstructive Pulmonary Disease (COPD)

Potential First Once-Daily, Nebulized LAMA in COPD

DUBLIN, IRELAND and HERTFORDSHIRE, UNITED KINGDOM and PITTSBURGH, PA -- (Marketwired) -- 09/14/15 -- Theravance Biopharma, Inc. (NASDAQ: TBPH) ("Theravance Biopharma") and Mylan N.V. (NASDAQ: MYL) ("Mylan") today announced the initiation of a Phase 3 program for revefenacin (TD-4208), an investigational long-acting muscarinic antagonist (LAMA) in development for the treatment of chronic obstructive pulmonary disease (COPD). The Phase 3 program, designed to support the registration of the product in the U.S., includes two replicate three-month efficacy studies and a single 12-month safety study.

"Despite the fact that once-daily LAMAs are the first-line therapy for patients with moderate-to-severe COPD, there still are no nebulized LAMA treatments available today. This unmet need is significant when one considers that approximately 9% of COPD patients in the U.S. currently use nebulizers for ongoing maintenance therapy, and a total of 41% of U.S. COPD patients use nebulizers for bronchodilator therapy at some time during the course of their disease,"[1] said Brett Haumann, MD, Senior Vice President, Clinical Development at Theravance Biopharma. "Based on data that we've generated to date, we believe that revefenacin possesses the product profile that could uniquely and effectively address this market need. We look forward to conducting this Phase 3 program in collaboration with our partner Mylan to generate the data required to support a regulatory filing for the product."

"The initiation of this Phase 3 program is an important milestone for Mylan as we continue to further build out our global respiratory pipeline. Revefenacin is highly complementary to our currently marketed nebulized COPD product, Perforomist® Inhalation Solution, as well as other respiratory products in our pipeline. We are excited by the potential to offer healthcare professionals, and ultimately patients, an even more robust respiratory portfolio if revefenacin is approved," said Mylan President Rajiv Malik. "Theravance Biopharma has done an excellent job advancing revefenacin to this stage of development and we look forward to contributing our expertise and leadership in the area of nebulized respiratory therapy as we work together to bring this important product to market."

The revefenacin development program includes two Phase 3 efficacy studies and one Phase 3 safety study, examining 2 doses (88 mcg and 175 mcg) of revefenacin inhalation solution administered once-daily via nebulizer in moderate to severe patients with COPD. The Phase 3 efficacy studies are 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, with a primary endpoint of trough forced expiratory volume in one second (FEV_1) on day 85. The Phase 3 safety study is an open-label, active comparator study of 12 months duration. Together, the three studies will enroll approximately 2,300 patients. Theravance Biopharma expects the results to be available from the two efficacy studies in 2016, with the results of the safety study available in 2017. More information about the trials is available at www.clinicaltrials.gov.

About Theravance Biopharma and Mylan Partnership

Theravance Biopharma and Mylan N.V. and its affiliates have partnered 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 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 LAMA in development for the treatment of COPD. Theravance Biopharma has completed a successful Phase 2b program with revefenacin, administered once-daily via nebulizer for up to 28 days in a moderate-to-severe COPD population. Market research by Theravance Biopharma indicates approximately 9% of the treated COPD patients in the U.S. use nebulizers for ongoing maintenance therapy.[1] LAMAs are a cornerstone of maintenance therapy for COPD, but are only available in handheld devices that may not be suitable for every patient. 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
The mission of Theravance Biopharma (NASDAQ: TBPH) is to create value from a unique and diverse set of assets: an approved product; a development pipeline of late-stage assets; and a productive research platform designed for long-term growth.

Our pipeline of internally discovered product candidates includes potential best-in-class opportunities in underserved markets in the acute care setting, representing multiple opportunities for value creation. 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 an investigational long-acting muscarinic antagonist (LAMA) being developed as a potential once-daily, nebulized treatment for COPD. Axelopran (TD-1211) is an investigational potential once-daily, oral treatment for opioid-induced constipation (OIC). Our earlier-stage clinical assets represent novel approaches for potentially treating diseases of the lung and gastrointestinal tract and infectious disease. In addition, we have an economic interest in future payments that may be made by GlaxoSmithKline plc pursuant to its agreements with Theravance, Inc. relating to certain drug development programs, including the combination of fluticasone furoate, umeclidinium and vilanterol (the "Closed Triple").

With our successful drug discovery and development track record, commercial infrastructure, experienced management team and efficient corporate structure, we believe that we are well positioned to create value for our shareholders and make a difference in the lives of patients.

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 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, risks of collaborating with 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 expertise and supporting infrastructure. 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 August 13, 2015. 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.

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 around 1,400 generic pharmaceuticals and several brand medications. In addition, we offer a wide range of antiretroviral therapies, upon which nearly 50% of HIV/AIDS patients in developing countries depend. We also operate one of the largest active pharmaceutical ingredient manufacturers and currently market products in about 145 countries and territories. Our workforce of approximately 30,000 people 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 Phase 3 program and included studies, product, pipeline and portfolio development and potential, approvals and sales of products and the company's strategy, future growth and performance. 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: the impacts of competition; changes in economic and financial conditions of the company's business; strategies by competitors or other third parties to delay or prevent product introductions; actions taken by regulatory or governmental agencies with respect to our or our competitors' current or future products; success of clinical trials and our ability to execute on new product opportunities; other risks inherent in product development and legal and regulatory processes; changes in third-party relationships uncertainties and matters beyond the control of management; and the other risks detailed in the company's filings with the Securities and Exchange Commission. The company undertakes no obligation to update these statements for revisions or changes after the date of this release.

References

1. Market research conducted by Theravance Biopharma, Inc.
2. American Lung Association. "Chronic Obstructive Pulmonary Disease (COPD) Fact Sheet." http://www.lung.org/lung-disease/copd/resources/facts-figures/COPD-Fact-Sheet.html. Accessed on January 26, 2015.
3. American Thoracic Society. "Center for Patients & Families: The Basics of Lung Disease/Lung Disease 101 Fact Sheet." http://patients.thoracic.org/?page_id=8. Accessed on January 26, 2015.

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