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Theravance Biopharma, Inc. and Mylan Partner to Develop and Commercialize a Novel LAMA Compound, TD-4208, for COPD

Phase 3 registrational studies of TD-4208 are anticipated to begin in 2015

GEORGE TOWN, Grand Cayman and PITTSBURGH, Feb. 2, 2015 /PRNewswire/ -- Theravance Biopharma, Inc. (NASDAQ: TBPH) and Mylan Inc. (NASDAQ: MYL) today announced that the two companies will partner on the development and, subject to FDA approval, commercialization of TD-4208, a novel investigational once-daily nebulized long-acting muscarinic antagonist (LAMA) for chronic obstructive pulmonary disease (COPD) and other respiratory diseases.

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] Once-daily LAMAs are currently the cornerstone of maintenance therapy for patients with COPD, but existing LAMAs are only available in handheld devices. Approximately 9% of the treated COPD patients in the U.S. either need or prefer a nebulized product for delivery of their ongoing maintenance therapy and a further 30% of COPD patients use nebulized treatment on an intermittent basis.[3] In the nebulizer segment, there is no once-daily or twice-daily muscarinic antagonist therapy available.

TD-4208 has shown positive top-line results in COPD patients in multiple Phase 2 studies, and the FDA recently agreed to the design of the Phase 3 registrational program, which is anticipated to begin this year. Theravance Biopharma and Mylan believe that TD-4208 has the potential to be a best-in-class once-daily single-agent nebulized product for COPD patients who require, or prefer, nebulized therapy.

"This exciting development and commercialization collaboration leverages Mylan's expertise in manufacturing and marketing complex respiratory products and Theravance Biopharma's respiratory clinical development capabilities. The addition of TD-4208 to our pipeline is highly complementary with our existing respiratory portfolio, including our marketed nebulized COPD product, Perforomist® Inhalation Solution, and reinforces Mylan's leadership in nebulized respiratory therapy," said Mylan CEO Heather Bresch.

"Partnering with a world leader in nebulized respiratory therapies enables us to expand the breadth of our TD-4208 development program and extend our commercial reach beyond the acute care setting where we currently market VIBATIV® (telavancin). Funding of the Phase 3 registrational program by Mylan strengthens our company's capital position and enhances our financial flexibility to advance other high-value pipeline assets alongside TD-4208," said Rick E Winningham, Chairman and Chief Executive Officer, Theravance Biopharma. "We look forward to working with Mylan to bring this potential first-in-class, once-daily nebulized therapy to COPD patients."

Under the terms of the agreement, Mylan and Theravance Biopharma will co-develop nebulized TD-4208 for COPD and other respiratory diseases. Theravance Biopharma will lead the U.S. registrational development program and Mylan will be responsible for reimbursement of Theravance Biopharma's costs for that program up until the approval of the first new drug application, after which costs will be shared. In addition, Mylan will be responsible for commercial manufacturing. In the U.S., Mylan will lead commercialization and Theravance Biopharma will retain the right to co-promote the product under a profit-sharing arrangement. Outside the U.S. (excluding China), Mylan will be responsible for development and commercialization and pay Theravance Biopharma a royalty on net sales. Theravance Biopharma retains worldwide rights to TD-4208 delivered through other dosage forms, such as a metered dose inhaler or dry powder inhaler (MDI/DPI).

In addition to funding the U.S. registrational development program, Mylan will pay Theravance Biopharma an initial payment of $15 million in cash and has agreed to make a $30 million equity investment in Theravance Biopharma by purchasing newly issued Ordinary Shares at a price of $18.92 per share, which is equal to a 10% premium over the 5-day trailing volume-weighted average price ending January 30. Under the terms of the agreement, Theravance Biopharma is eligible to receive potential development and sales milestone payments totaling $220 million in the aggregate, with $175 million associated with TD-4208 monotherapy and $45 million for future potential combination products.

Mylan and Theravance Biopharma believe that TD-4208 has the potential to be the only FDA-approved once-daily nebulized LAMA product for COPD patients in the near term and it may offer longer-term opportunities for combination with other nebulized products. In addition, the patent portfolio for TD-4208 is currently expected to provide a TD-4208 nebulized product with exclusivity in the U.S. until at least 2025, which does not include any potential patent term extensions. Given the short- and long-term potential of this differentiated product, and in an effort to optimize its uses of capital, Mylan has decided to redeploy resources from the development of its combination nebulized ICS/LABA product (Combo) to TD-4208.

About TD-4208

TD-4208 is an investigational long-acting muscarinic antagonist (LAMA) in development for the treatment of chronic obstructive pulmonary disease (COPD). In September 2014, Theravance Biopharma announced positive top-line results from its Phase 2b dose-ranging study of TD-4208. TD-4208 met the primary efficacy endpoint (change from baseline in trough FEV_1 [forced expiratory volume in one second] following the last dose on Day 28) with statistically significant responses at once-daily doses of 88, 175 and 350 mcg. The lowest dose of 44 mcg once-daily produced a sub-therapeutic response that was not statistically different from placebo.

In November 2014, Theravance Biopharma announced positive top-line results from the once- versus twice-daily (QD versus BID) study of TD-4208. The study compared 175 mcg once-daily against 44 mcg twice-daily in a 3-period, 7-day placebo-controlled crossover study conducted in 64 COPD patients. The study met its primary endpoint and demonstrated that the lower dose (44 mcg) administered twice-daily did not produce greater bronchodilation than the higher dose (175 mcg) administered once-daily. The frequency of adverse events was low and consistent across all three treatments including placebo. There was one death in the study that was assessed by the study investigator as unrelated to study medication.

Conference Call Today at 8:00 am ET

Theravance Biopharma will hold a conference call today at 8:00 am ET to discuss the content of this press release. To participate in the live call by telephone, please dial (855) 296-9648 from the U.S., or (920) 663-6266 for international callers. To listen to the conference call live via the internet, please visit Theravance Biopharma's website at www.theravance.com, under the Investor Relations section, Presentations and Events. To listen to the live call please go to Theravance Biopharma's website 15 minutes prior to its start to register, download, and install any necessary audio software.

A replay of the conference call will be available on Theravance Biopharma's website through March 4, 2015. An audio replay will also be available through 11:59 p.m. ET on February 9, 2015 by dialing (855) 859-2056 from the U.S., or (404) 537-3406 for international callers, and entering confirmation code 79259295.

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. and Europe for difficult-to-treat infections. TD-4208 is a long-acting muscarinic antagonist (LAMA) being developed as a potential once-daily, nebulized treatment for COPD. Axelopran (TD-1211) is a 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 - our core areas of therapeutic focus - and infectious disease. In addition, we have an economic interest in future payments that may be made by GSK pursuant to its agreements with Theravance, Inc. relating to certain drug programs, including the combination of umeclidinium, vilanterol and fluticasone furoate (or 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 and the conference call will contain 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 strategies, plans and objectives of Theravance Biopharma, the status and timing of clinical studies, data analysis and communication of results, the potential benefits and mechanisms of action of TD-4208, the enabling capabilities of Theravance Biopharma's approach to drug discovery and Theravance Biopharma's proprietary insights, expectations for TD-4208 through development and commercialization, the timing of seeking regulatory approval of TD-4208 and the duration of intellectual property protection for TD-4208. 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: the disruption of operations during the transition period following the spin-off of Theravance Biopharma from Theravance, Inc., including the diversion of management's and employees' attention from the business, adverse impacts upon the progress of discovery and development efforts, disruption of relationships with collaborators and increased employee turnover, delays or difficulties in commencing or completing clinical studies, the potential that results from clinical or non-clinical studies indicate TD-4208 is unsafe or ineffective, dependence on third parties to conduct clinical studies, delays or failure to achieve and maintain regulatory approvals for TD-4208, and risks of collaborating with third parties to develop and commercialize TD-4208. 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 November 12, 2014. 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 health care. 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 1,300 generic pharmaceuticals and several brand medications. In addition, we offer a wide range of antiretroviral therapies, upon which approximately 40% of HIV/AIDS patients in developing countries depend. We also operate one of the largest active pharmaceutical ingredient manufacturers and currently market products in approximately 140 countries and territories. Our workforce of more than 25,000 people is dedicated to improving the customer experience and increasing pharmaceutical access to consumers around the world. Learn more at mylan.com.

Private Securities Litigation Reform Act of 1995 — A Caution Concerning Forward-Looking Statements

This press release includes statements that constitute "forward-looking statements," including with regard to sales of products; product development, studies and potential; product markets; 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; risks inherent in legal and regulatory processes; risks associated with international operations; 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. 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.

2. 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.

[3.] Market research conducted by Theravance Biopharma, Inc.

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