



Theravance Biopharma and Mylan to Report New Data from Phase 3 Studies of YUPELRI™ (revefenacin) in Oral Presentation at European Respiratory Society International Congress 2018

September 11, 2018

Presentation to Highlight COPD Exacerbation Rates Observed in Phase 3 Program of YUPELRI in Patients with Moderate to Very Severe COPD

DUBLIN and HERTFORDSHIRE, England and PITTSBURGH, Sept. 11, 2018 /PRNewswire/ -- Theravance Biopharma, Inc. (NASDAQ: TBPH) ("Theravance Biopharma") and Mylan N.V. (NASDAQ: MYL) ("Mylan") today announced that new data from the Phase 3 YUPELRI™ (revefenacin) inhalation solution clinical program will be featured in an oral presentation at the European Respiratory Society (ERS) International Congress 2018, being held in Paris, France on September 15-19, 2018. The presented data will highlight chronic obstructive pulmonary disease (COPD) exacerbation rates observed in the Phase 3 clinical program of YUPELRI in patients with moderate to very severe COPD.



YUPELRI is an investigational long-acting muscarinic antagonist (LAMA) currently under review by the U.S. Food and Drug Administration (FDA) for the treatment of COPD. The Prescription Drug User Fee Act (PDUFA) date for YUPELRI is November 13, 2018. If approved, YUPELRI would be the first once-daily, long-acting nebulized bronchodilator for the treatment of COPD. YUPELRI is designed to be compatible with any standard jet nebulizer.

Details of the oral presentation at the ERS International Congress 2018 are as follows:

Presentation #OA1655: COPD Exacerbations in the Phase 3 Revefenacin Clinical Trial Program

Sunday, September 16, 2018, 2:45 – 4:45 p.m. (local time)
Session: Oral Presentation: Clinical Trials in COPD: New Results
Location: Room 7.3P (Hall 7.3)

About YUPELRI

YUPELRI (revefenacin) inhalation solution is a novel investigational once-daily nebulized LAMA under FDA review 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.¹ LAMAs are a cornerstone of maintenance therapy for COPD and, if approved, YUPELRI would be the only once-daily, long-acting single-agent product for COPD patients who require, or prefer, nebulized therapy. YUPELRI'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, Inc. ("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.

In our relentless pursuit of this objective, we strive to apply insight and innovation at each stage of our business, including research, development and commercialization, and utilize both internal capabilities and those of partners around the world. Our research efforts are focused in the areas of inflammation and immunology. Our research goal is to design localized medicines that target diseased tissues, without systemic exposure, in order to maximize patient benefit and minimize risk. These efforts leverage years of experience in developing localized medicines for the lungs to treat respiratory disease. The first potential medicine to emerge from our research focus on immunology and localized treatments is an oral, intestinally restricted pan-Janus kinase (JAK) inhibitor, currently in development to treat a range of inflammatory intestinal diseases. Our pipeline of internally discovered product candidates will continue to evolve with the goal of creating transformational medicines to address the significant needs of patients.

In addition, we have an economic interest in future payments that may be made by Glaxo Group or one of its affiliates (GSK) pursuant to its agreements with Innoviva, Inc. relating to certain programs, including Trelegy Ellipta.

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 (including the data therefrom), 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), product sales and the Company's expectations for its 2018 operating loss, excluding share-based compensation. 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, enrolling 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), risks that product candidates do not obtain approval from regulatory authorities, the feasibility of undertaking future clinical trials for our product candidates based on policies and feedback from regulatory authorities, 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, manufacture and commercialize products, 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 August 2, 2018 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 more than 40% of people being treated for HIV/AIDS globally 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 approximately 35,000-strong workforce is dedicated to creating better health for a better world, one person at a time. Learn more at Mylan.com. We routinely post information that may be important to investors on our website at investor.mylan.com.

This press release includes statements that constitute "forward-looking statements", including with regard to: the outcome of clinical studies; that, if approved, YUPELRI would be the first once-daily, long-acting nebulized bronchodilator for the treatment of COPD; if approved, YUPELRI would be the only once-daily, long-acting single-agent product for COPD patients who require, or prefer, nebulized therapy; and that YUPELRI'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. 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.

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¹ TBPH market research (N = 160 physicians); Refers to US COPD patients



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