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

September 17, 2018

Reduction in Rates of COPD Exacerbations Observed in COPD Patients Treated with YUPELRITM Compared to Placebo and Tiotropium (Spiriva® HandiHaler®)

DUBLIN and HERTFORDSHIRE, England and PITTSBURGH, Sept. 17, 2018 /PRNewswire/ -- Theravance Biopharma, Inc. (NASDAQ: TBPH) ("Theravance Biopharma") and Mylan N.V. (NASDAQ: MYL) ("Mylan") today announced that positive new data from the companies' Phase 3 clinical program for YUPELRI ™ (revefenacin) inhalation solution were featured in an oral presentation at the European Respiratory Society (ERS) International Congress 2018, which is being held in Paris, France on September 15-19, 2018. Presented data showed reductions in the rates of chronic obstructive pulmonary disease (COPD) exacerbations ranging from 15% to 18% in moderate to very severe COPD patients administered once-daily YUPELRI for up to 52 weeks as compared to placebo and tiotropium (Spiriva® HandiHaler®). While the YUPELRI Phase 3 program was not designed or powered to achieve statistical significance on differences in COPD exacerbation rates, researchers were interested in a post-hoc analysis of data from the studies to identify trends in this area.

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.

Researchers evaluated and presented data on COPD exacerbations that were collected from the three clinical trials comprising the Phase 3 YUPELRI program. Pooled data from the two replicate 12-week pivotal Phase 3 efficacy trials, which included a total of 1,229 patients with moderate to very severe COPD, demonstrated that the mean annualized rate of all COPD exacerbations was 0.47 for YUPELRI dosed at 175 mcg/day and 0.45 for YUPELRI dosed at 88 mcg/day. When compared to the mean annualized rate of exacerbations for placebo of 0.55, these results represent COPD exacerbation rate reductions in the range of 15% to 18%.

Additionally, data from the 12-month Phase 3 safety trial, which included a total of 1,055 with moderate to very severe COPD, demonstrated that the estimated annualized rate of all COPD exacerbations was 0.38 for YUPELRI dosed at 175 mcg/day and 0.57 for YUPELRI dosed at 88 mcg/day, compared to 0.46 for tiotropium (Spiriva® HandiHaler®) dosed at 18 mcg/day. These results for the 175 mcg/day YUPELRI dose represent a 17% reduction in COPD exacerbation rates as compared to tiotropium.

"Following the successful completion of the large Phase 3 clinical program for YUPELRI, we were interested in conducting additional analyses of the data to identify interesting trends that may warrant further research including reductions in COPD exacerbation rates. While this post-hoc analysis was not powered for statistical significance, it did demonstrate an interesting trend highlighted by a reduction in COPD exacerbation rates of more than 15% with the 175 mcg/day YUPELRI dose as compared to both tiotropium and placebo," said James F. Donohue, M.D., professor of medicine, pulmonary and critical care medicine at the University of North Carolina, Chapel Hill, and lead author for the data presented at ERS. "As a clinician, I see firsthand the damaging impact that COPD exacerbations have on patients' overall health, long-term disease status and quality of life. Results of the analysis are encouraging and provide rationale for further evaluating the impact that YUPELRI may have on reducing COPD exacerbation rate."

"We are proud of the successful Phase 3 program conducted for YUPELRI and further encouraged by new observations of reduced rates of COPD exacerbations in patients treated with YUPELRI across these studies," said Rick E Winningham, chairman and chief executive officer of Theravance Biopharma. "While not necessary for potential FDA approval, these COPD exacerbations data provide us with important additional context regarding the potential therapeutic profile of YUPELRI, which we and our partner Mylan believe can serve as an important once-daily treatment option for COPD patients who need or prefer nebulized therapy."

Mylan President Rajiv Malik added, "We continue to be pleased with the progress of our scientific program supporting YUPELRI. The latest observations demonstrate the depth of our work and commitment to clinical execution. We're proud to have these results featured at the ERS International Congress and look forward to continuing our work with Theravance and FDA to advance this important treatment for patients."

Theravance Biopharma and Mylan previously reported that in two replicate pivotal Phase 3 efficacy studies, YUPELRI demonstrated statistically significant and clinically meaningful improvements as compared to placebo in trough forced expiratory volume in one second (FEV1) and in overall treatment effect on trough FEV1 (OTE FEV1) after 12 weeks of dosing.[1] YUPELRI had comparable rates of adverse events (AEs) to placebo, low rates of serious adverse events (SAEs), and no clinically meaningful differences in blood parameters or electrocardiogram (ECG) data, across all

treatment groups (active and placebo). As previously reported, the most commonly reported AEs, across both trials and across all treatment groups, were exacerbations, cough, dyspnea and headache. Additionally, the companies completed a 12-month Phase 3 safety study in which no new safety issues were identified. Rates of AEs and SAEs in the study were low and comparable to those seen in the standard of care treatment arm.

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 YUPELRI as a once-daily, nebulized bronchodilator for the treatment of patients with COPD, to be compatible with any standard jet nebulizer.

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 US 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-US 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 US sales and double-digit royalties on ex-US 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] Nearly 15.7 million Americans (6.4%) report that they have been diagnosed with COPD and more are believed to be undiagnosed.[3] 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.[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.[4] 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.

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'sForm 10-Q filed with the Securities and Exchange Commission (SEC) on May 9, 2018and 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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References

[1] "Clinically meaningful" is defined by industry established Minimal Clinically Important Difference (MCID) for lung function (100 mL improvement in FEV1).

[2] 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.

[3]Center for Disease Control, COPD https://www.cdc.gov/copd/index.html. Accessed on January 3, 2018.

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

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