Theravance Biopharma and Mylan Expand YUPELRI® (revefenacin) Development and Commercialization Agreement to Include China and Adjacent Territories

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First and only once-daily, nebulized bronchodilator has potential to address unmet needs of China's nearly 100 million chronic obstructive pulmonary disease (COPD) patients

DUBLIN and HERTFORDSHIRE, England and PITTSBURGH, June 14, 2019 /PRNewswire/ -- Theravance Biopharma Ireland Limited, a subsidiary of Theravance Biopharma, Inc. (NASDAQ: TBPH) ("Theravance Biopharma") and Mylan N.V. (NASDAQ: MYL) ("Mylan") today announced the expansion of the companies' current development and commercialization agreement for nebulized revefenacin to include China and certain adjacent territories. Revefenacin, marketed as YUPELRI® in the U.S., is a long-acting muscarinic antagonist (LAMA), which is the first and only once-daily, nebulized bronchodilator approved for the treatment of chronic obstructive pulmonary disease (COPD) in the U.S.

It is estimated that COPD affects nearly 100 million individuals in China[1] with approximately 43 percent of those patients suffering from moderate to very severe forms of the disease[2]. COPD is one of the top three causes of mortality in China, accounting for approximately 910,000 deaths annually[3]. COPD presents a significant financial burden to the healthcare system in China, contributing up to $266 billion in costs annually[2].

In 2015, Theravance Biopharma and Mylan, and their affiliates, established a strategic collaboration to develop and commercialize nebulized revefenacin products for COPD and other respiratory diseases in all global markets with the exception of China and adjacent territories. Under terms of the new agreement, Theravance Biopharma has granted Mylan exclusive development and commercialization rights to nebulized revefenacin in China and adjacent territories, which include Hong Kong SAR, the Macau SAR and Taiwan. In exchange, Theravance Biopharma will receive an upfront payment of $18.5 million and will be eligible to receive additional potential development and sales milestones totaling $54 million together with tiered royalties on net sales of nebulized revefenacin, if approved. Mylan will be responsible for all aspects of development and commercialization in the partnered regions, including pre- and post-launch activities and product registration and all associated costs.

"We are pleased to expand our ongoing revefenacin development and commercialization collaboration with Mylan to include China, as we believe that this novel compound has the therapeutic profile to provide key benefits to the country's large and underserved COPD patient population. Our companies share the belief that revefenacin can play a critical role in COPD treatment, particularly for those patients who require or prefer nebulized therapy," said Rick E Winningham, chairman and chief executive officer of Theravance Biopharma, Inc. "Mylan is a global leader in nebulized respiratory therapies and has been a valued and trusted partner since we entered our original collaboration in 2015. Based on its deep experience with nebulized revefenacin, Mylan is well positioned to efficiently guide the compound through the development and regulatory approval process in China, as well as maximize its commercial potential in the partnered regions."

Mylan President Rajiv Malik said: "Mylan has had a long-term, strategic focus on its growing presence in China, one of the world's largest pharmaceutical markets. Our expanded partnership on revefenacin represents a natural next step, and together with Theravance Biopharma we look forward to making a meaningful difference for the millions of patients living with COPD in China. Through our continued investment in a comprehensive portfolio of products across the value chain, our deep understanding of the evolving Chinese healthcare landscape, our scientific excellence and innovation, and our industry-leading pipeline, we look forward to continue meeting unmet needs for patients in China and the world over."

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. Theravance Biopharma is eligible to receive up to $259 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).

About Revefenacin

Revefenacin inhalation solution, marketed as YUPELRI in the US, is a novel once-daily nebulized LAMA that is approved for the maintenance treatment of COPD in the US. LAMAs are a cornerstone of maintenance therapy for COPD and revefenacin is positioned as a first-in-class once-daily single-agent bronchodilator product for COPD patients who require, or prefer, nebulized therapy. Revefenacin'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.

In two replicate pivotal Phase 3 efficacy studies conducted in the US, revefenacin demonstrated statistically significant and clinically meaningful improvements as compared to 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.[4] Revefenacin 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 adverse events, across both trials and across all treatment groups, were cough, nasopharyngitis, upper respiratory tract infection, headache, and back pain. Additionally, a 12-month Phase 3 open-label safety study versus tiotropium did not identify any new safety issues. Rates of AEs and SAEs in the study were low and comparable to those seen in the tiotropium treatment arm.

YUPELRI is a registered trademark of Mylan N.V.

About Theravance Biopharma
Theravance Biopharma, Inc. ("Theravance Biopharma") is a diversified biopharmaceutical company primarily focused on the discovery, development and commercialization of organ-selective medicines. Our purpose is to create transformational medicines to improve the lives of patients suffering from serious illnesses. Our research is focused in the areas of inflammation and immunology.

In pursuit of our purpose, we apply insights and innovation at each stage of our business and utilize our internal capabilities and those of partners around the world. We apply organ-selective expertise to biologically compelling targets to discover and develop medicines designed to treat underserved localized diseases and to limit systemic exposure, in order to maximize patient benefit and minimize risk. These efforts leverage years of experience in developing lung-selective medicines to treat respiratory disease, including FDA-approved YUPELRI® (revefenacin) inhalation solution indicated for the maintenance treatment of patients with chronic obstructive pulmonary disease (COPD). Our pipeline of internally discovered programs is targeted to address significant patient needs.

We have an economic interest in potential future payments from 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 characteristics, benefits and mechanisms of action of the Company's product and product candidates, and the Company's expectations for product candidates through development and potential regulatory approval and commercialization (including their potential as components of combination therapies and their differentiation from other products or potential products). 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, 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 May 10, 2019 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 trials. These statements are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Because forward-looking statements inherently involve risks and uncertainties, actual future results may differ materially from those expressed or implied by such statements. Factors that could cause or contribute to such differences include, but are not limited to any changes in, interruptions to, or difficulties with Mylan's or its partners' ability to develop, manufacture, and commercialize products; the effect of any changes in Mylan's or its partners' customer and supplier relationships and customer purchasing patterns; other changes in third-party relationships; the impact of competition; changes in the economic and financial conditions of the businesses of Mylan or its partners; the scope, timing, and outcome of any ongoing legal proceedings and the impact of any such proceedings on Mylan's or its partners' business; any regulatory, legal, or other impediments to Mylan's or its partners' ability to bring products to market; actions and decisions of healthcare and pharmaceutical regulators, and changes in healthcare and pharmaceutical laws and regulations, in the United States and abroad; Mylan's and its partners' ability to protect intellectual property and preserve intellectual property rights; risks associated with international operations; other 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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[4] "Clinically meaningful" is defined by industry established Minimal Clinically Important Difference (MCID) for lung function (100 mL improvement in FEV_1).

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