Viatris and Theravance Biopharma Announce Positive Top-Line Results from YUPELRI® (revefenacin) Phase III Trial in China for the Treatment of Chronic Obstructive Pulmonary Disease (COPD)

November 13, 2023

Top-line results from Phase III study in China demonstrate the efficacy and safety profile of YUPELRI in patients with COPD

PITTSBURGH and DUBLIN, Nov. 13, 2023 /PRNewswire/ -- Viatris Inc. (NASDAQ: VTRS), a global healthcare company, and Theravance Biopharma, Inc. (NASDAQ: TBPH) today announced positive results from the YUPELRI® (revefenacin) Phase III placebo-controlled clinical trial conducted in China assessing the efficacy and safety of YUPELRI, a once-daily nebulized long-acting muscarinic antagonist (LAMA) for the maintenance treatment of patients with COPD. Top-line results showed that YUPELRI met its primary efficacy endpoint demonstrating a statistically significant increase in trough FEV_1 (forced expiratory volume in one second) versus placebo. The results are comparable to those from studies of the same design used for U.S. registration and provide support for a regulatory filing in China anticipated to occur in mid-2024.

Top Line Results Highlights:

- A total of 258 patients enrolled with 257 included in safety and full analysis sets. Both groups were well balanced for baseline characteristics with 129 treated with YUPELRI and 128 treated with placebo.
- Study population was moderate to very severe COPD patients with mean baseline FEV_1 approximately 50% predicted. Approximately two-thirds of patients remained on long-acting beta-2 agonist/inhaled corticosteroids throughout the study.
- Primary efficacy analysis of change from baseline in trough FEV_1 measured 24 hours after the final dose at week 12 detected a mean (95% confidence intervals) treatment difference of 150.9 (104.1, 197.7) mL compared to placebo.
- Safety and tolerability profile assessed by summary of adverse events consistent with U.S. package insert.

Viatris President Rajiv Malik said, "We are pleased with the positive top-line results of our Phase III clinical results for YUPELRI in China. The strength of the data and the primary endpoint analysis, which is consistent with our U.S. clinical data, firmly supports a comparable efficacy and safety profile of YUPELRI. With this data, we look forward to progressing our regulatory application in China and continue to believe, when approved, a once-daily nebulized revefenacin product will be an important therapeutic option for the millions of patients in the region with COPD."

"Given its novel profile, we and Viatris share a commitment to make YUPELRI available for as many COPD patients as possible, particularly those who stand to benefit from nebulized therapy, and we commend VIATRIS on the execution of this study," said Rick E Winningham, CEO of Theravance Biopharma. "The consistent lung function improvement demonstrated in this study supports the use of LAMA therapy as foundational in a range of patients and we are encouraged that COPD patients in China may soon have the opportunity to benefit from a new, valuable treatment option."

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].

About the Study
The Phase III study was designed to compare the efficacy and safety of revefenacin (175mcg) and double-blind placebo nebulized once-daily in moderate to very severe COPD patients in China over a 12-week treatment period.

About Theravance Biopharma / Viatris Collaboration
Theravance Biopharma and Viatris Inc. and their respective affiliates have established a strategic collaboration to develop and commercialize nebulized revefenacin products for COPD and other respiratory diseases. Theravance Biopharma and Viatris co-promote YUPELRI® (revefenacin) in the U.S., with their combined sales infrastructure targeting healthcare professionals who treat COPD patients suitable for YUPELRI. In 2019, the companies announced the expansion of their development and commercialization agreement for nebulized revefenacin to include China and certain adjacent territories, which include Hong Kong SAR, the Macau SAR and Taiwan.

About Viatris
Viatris Inc. (NASDAQ: VTRS) is a global healthcare company uniquely positioned to bridge the traditional divide between generics and brands, combining the best of both to more holistically address healthcare needs globally. With a mission to empower people worldwide to live healthier at every stage of life, we provide access at scale. In 2022 alone, we supplied high-quality medicines to approximately 1 billion patients around the world. With our exceptionally extensive and diverse portfolio of medicines, a one-of-a-kind global supply chain designed to reach more people when and where they need them, and the scientific expertise to address some of the world's most enduring health challenges, access takes on deep meaning at Viatris. We have the ability to touch all of life's moments, from birth to end of life, acute conditions to chronic diseases. We are headquartered in the U.S., with global centers in Pittsburgh, Shanghai and Hyderabad, India. Learn more at viatris.com and investor.viatris.com, and connect with us on Twitter, LinkedIn, Instagram and YouTube.

Viatris Forward Looking Statements

This press release includes statements that constitute "forward-looking statements." These statements are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Such forward looking statements may include statements regarding positive results from the YUPELRI® (revefenacin) Phase III placebo-controlled clinical trial conducted in China assessing the efficacy and safety of YUPELRI, a once-daily nebulized long-acting muscarinic antagonist (LAMA) for the maintenance treatment of patients with COPD; top-line results showed that YUPELRI met its primary efficacy endpoint demonstrating a statistically significant increase in trough FEV_1 (forced expiratory volume in one second) versus placebo; the results are comparable to those from studies of the same design used for U.S. registration and provide support for a regulatory filing in China anticipated to occur in mid-2024; the strength of the data and the primary endpoint analysis, which is consistent with our U.S. clinical data, firmly supports a comparable efficacy and safety profile of YUPELRI; and with this data, we look forward to progressing our regulatory application in China and continue to believe, when approved, a once-daily nebulized revefenacin product will be an important therapeutic option for the millions of patients in the region with COPD. Because forward-looking 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: actions and decisions of healthcare and pharmaceutical regulators; changes in healthcare and pharmaceutical laws and regulations in the U.S. and abroad; any regulatory, legal or other impediments to Viatris' ability to bring new products to market, including but not limited to "at-risk" launches; Viatris' or its partners' ability to develop, manufacture, and commercialize products; the possibility that Viatris may be unable to realize the intended benefits of, or achieve the intended goals or outlooks with respect to, its strategic initiatives; the possibility that Viatris may be unable to achieve expected benefits, synergies and operating efficiencies in connection with acquisitions, divestitures, or its global restructuring program, within the expected timeframe or at all; impairment charges or other losses related to the divestiture or sale of businesses or assets; Viatris' failure to achieve expected or targeted future financial and operating performance and results; the potential impact of public health outbreaks, epidemics and pandemics, including the ongoing challenges and uncertainties posed by COVID-19; the scope, timing and outcome of any ongoing legal proceedings, and the impact of any such proceedings; any significant breach of data security or data privacy or disruptions to our information technology systems; risks associated with international operations; the ability to protect intellectual property and preserve intellectual property rights; changes in third-party relationships; the effect of any changes in Viatris' or its partners' customer and supplier relationships and customer purchasing patterns; the impacts of competition; changes in the economic and financial conditions of Viatris or its partners; uncertainties and matters beyond the control of management, including general economic conditions, inflation and exchange rates; failure to execute stock repurchases consistent with current expectations; stock price volatility; and the other risks described in Viatris' filings with the Securities and Exchange Commission (SEC). Viatris routinely uses its website as a means of disclosing material information to the public in a broad, non-exclusionary manner for purposes of the SEC's Regulation Fair Disclosure (Reg FD). Viatris undertakes no obligation to update these statements for revisions or changes after the date of this release other than as required by law.

About Theravance Biopharma

Theravance Biopharma, Inc.'s focus is to deliver Medicines that Make a Difference® in people's lives. In pursuit of its purpose, Theravance Biopharma leverages decades of expertise, which has led to the development of FDA-approved YUPELRI® (revefenacin) inhalation solution indicated for the maintenance treatment of patients with chronic obstructive pulmonary disease (COPD). Ampreloxetine, its late-stage investigational norepinephrine reuptake inhibitor in development for symptomatic neurogenic orthostatic hypotension, has the potential to be a first in class therapy effective in treating a constellation of cardinal symptoms in multiple symptom atrophy patients. Theravance Biopharma is committed to creating/driving shareholder value. For more information, please visit www.theravance.com.

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YUPELRI® is a registered trademark of Mylan Specialty L.P., a Viatris company.

Theravance Biopharma Forward Looking Statements

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, as amended, and the Private Securities Litigation Reform Act of 1995. Such forward looking statements may include statements regarding positive results from the YUPELRI® (revefenacin) Phase III placebo-controlled clinical trial conducted in China assessing the efficacy and safety of YUPELRI, a once-daily nebulized long-acting muscarinic antagonist (LAMA) for the maintenance treatment of patients with COPD; top-line results showed that YUPELRI met its primary efficacy endpoint demonstrating a statistically significant increase in trough FEV_1 (forced expiratory volume in one second) versus placebo; the results are comparable to those from studies of the same design used for U.S. registration and provide support for a regulatory filing in China anticipated to occur in mid-2024; the strength of the data and the primary endpoint analysis, which is consistent with U.S. clinical data, firmly supports a comparable efficacy and safety profile of YUPELRI; and with this data, the partners look forward to progressing a regulatory application in China and continue to believe, when approved, a once-daily nebulized revefenacin product will be an important therapeutic option for the millions of patients in the region with COPD. These statements are based on the current estimates and assumptions of management as of the date of this press release and are subject to risks, uncertainties, changes in circumstances, assumptions and other factors that may cause the actual results 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: actions and decisions of healthcare and pharmaceutical regulators; changes in healthcare and pharmaceutical laws and regulations in the U.S. and abroad; any regulatory, legal or other impediments to our or our collaboration partner's ability to bring new products to market, including but not limited to "at-risk" launches; our or our collaboration partner's ability to develop, manufacture, and commercialize products; 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 are unsafe, ineffective or not differentiated; 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; risks associated with establishing and maintaining sales, marketing and distribution capabilities with appropriate technical expertise and supporting infrastructure; ability to retain key personnel; the ability of Theravance Biopharma and its collaboration partner's to protect and to enforce its intellectual property rights; and general economic and market conditions. Other risks affecting Theravance Biopharma are in the Company's Form 10-Q filed with the SEC on November 9, 2023, and other periodic reports filed 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.

[1] C. Wang, J. Xu, L. Yang et al., "Prevalence and risk factors of chronic obstructive pulmonary disease in China (the China Pulmonary Health [CPH] study): a national cross-sectional study," The Lancet, vol. 391, no. 10131, pp. 1706–1717, 2018.

[2] Fang L, Gao P, Bao H, et al., "Chronic obstructive pulmonary disease in China: a nationwide prevalence study," Lancet Respir Med 2018; 6: 421–430.

[3] Yin P, Wang H, Vos T, et al., "A subnational analysis of mortality and prevalence of COPD in China From 1990 to 2013: Findings from the global burden of disease study 2013," Chest. 2016;150:1269–1280.

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