

Theravance Biopharma Announces Approval of YUPELRI® (revefenacin) by China's NMPA

June 26, 2025

- *YUPELRI approved by China's NMPA as the first once-daily nebulized LAMA for maintenance treatment of COPD*
- *Approval triggers \$7.5 million milestone payment from Viatriis, with eligibility to receive further sales milestones and tiered royalties on net sales in China*
- *Theravance Biopharma incurs no commercial costs in China; Viatriis is responsible for the launch and commercialization*

DUBLIN, June 26, 2025 /PRNewswire/ -- Theravance Biopharma, Inc. ("Theravance Biopharma" or the "Company") (NASDAQ: TBPH) today announced that Viatriis Inc. ("Viatriis"), has secured regulatory approval from China's National Medical Products Administration (NMPA) for YUPELRI® (revefenacin) inhalation solution, the first once-daily nebulized long-acting muscarinic antagonist (LAMA) approved for maintenance treatment of chronic obstructive pulmonary disease (COPD) in China.

This approval triggers a one-time \$7.5 million milestone from Viatriis to Theravance Biopharma, which is expected to be received in Q3 2025. Theravance Biopharma is also eligible for further sales-based milestones of up to \$37.5 million and tiered royalties of 14% to 20% on net sales in China. Viatriis is responsible for all aspects of development and commercialization of YUPELRI in China.

Today's announcement offers further support for Theravance Biopharma's diversified and improving financial position, which includes \$131 million in cash as of March 31, 2025, an additional \$225 million from the recent sale of TRELEGY royalties to GSK, 35% of U.S. YUPELRI profits, and up to \$150 million in near-term potential TRELEGY milestone payments from Royalty Pharma. It also comes as the Company nears completion of enrollment in the open label portion of CYPRESS, its registrational study of ampreloxetine in symptomatic neurogenic orthostatic hypotension associated with multiple system atrophy. Ampreloxetine is a wholly-owned asset with the potential to address a significant unmet need in this rare neurological disorder.

About Ampreloxetine

Ampreloxetine, an investigational, once-daily, selective norepinephrine reuptake inhibitor in development for the treatment of symptomatic neurogenic orthostatic hypotension (nOH) in patients with multiple system atrophy (MSA). The unique benefits of ampreloxetine treatment reported in MSA patients from Study 0170 included an increase in norepinephrine levels, a favorable impact on blood pressure, clinically meaningful and durable symptom improvement, and no signal for worsening of supine hypertension. In the US, the Company has been granted an Orphan Drug Designation for ampreloxetine for the treatment of symptomatic nOH in patients with MSA and, if results from the ongoing Phase 3 CYPRESS study are supportive, plans to file an NDA for full approval in this indication.

About CYPRESS (Study 0197), a Phase 3 Study

Study 0197 ([NCT05696717](https://clinicaltrials.gov/ct2/show/study/NCT05696717)) is currently enrolling. This is a registrational Phase 3, multi-center, randomized withdrawal study to evaluate the efficacy and durability of ampreloxetine in participants with MSA and symptomatic nOH after 20 weeks of treatment; the primary endpoint of the study is change in the Orthostatic Hypotension Symptom Assessment (OHSA) composite score. The Study includes four periods: screening, open label (12-week period, participants will receive a single daily 10 mg dose of ampreloxetine), randomized withdrawal (eight-week period, double-blind, placebo-controlled, participants will receive a single daily 10 mg dose of placebo or ampreloxetine), and a long-term treatment extension. Secondary outcome measures include change from baseline in Orthostatic Hypotension Daily Activity Scale (OHDAS) item 1 (activities that require standing for a short time) and item 3 (activities that require walking for a short time).

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 once-daily norepinephrine reuptake inhibitor in development for symptomatic neurogenic orthostatic hypotension (nOH) in patients with Multiple System Atrophy (MSA), has the potential to be a first in class therapy effective in treating a constellation of cardinal symptoms in MSA patients. The Company 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 Viatriis Specialty LLC. Trademarks, trade names or service marks of other companies appearing on this press release are the property of their respective owners.

Forward-Looking Statements

This press release 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, 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. Examples of such statements include statements relating to: the Company's expectations regarding its future profitability, expenses and uses of cash, the Company's goals, designs, strategies, plans and objectives, future growth of YUPELRI sales, future milestone payments, the ability to provide value to shareholders, the Company's regulatory strategies and timing of clinical studies, possible safety, efficacy or differentiation of our investigational therapy, the status of patent infringement litigation initiated by the Company and its partner against certain generic companies in federal district courts; contingent payments due to the Company from the sale of the Company's TRELEGY ELLIPTA royalty interests to Royalty Pharma, and expectations around the use of OHSa scores as endpoints for clinical trials. These statements are based on the current estimates and assumptions of the management of Theravance Biopharma 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 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: factors that could increase the Company's cash requirements or expenses beyond its expectations and any factors that could adversely affect its profitability, whether the milestone thresholds can be achieved, 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 or product are unsafe, ineffective or not differentiated, risks of decisions from regulatory authorities that are unfavorable to the Company, 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, the ability of the Company to protect and to enforce its intellectual property rights, volatility and fluctuations in the trading price and volume of the Company's shares, and general economic and market conditions. Other risks affecting the Company are in the Company's Form 10-Q filed with the SEC on May 12, 2025, 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.

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