Theravance Biopharma to Present Data on Ampreloxetine at the 36th International Symposium on The Autonomic Nervous System

October 29, 2025

- Ampreloxetine clinical development program to be featured in four presentations at the upcoming International Symposium on The Autonomic Nervous System
- Topline results from the ongoing Phase 3 CYPRESS study of ampreloxetine anticipated in Q1 2026

DUBLIN, Oct. 29, 2025 /PRNewswire/ -- Theravance Biopharma, Inc. (NASDAQ: TBPH) today announced that it will be participating at the 36th International Symposium on the Autonomic Nervous System, organized by the American Autonomic Society (AAS), taking place November 5-8, 2025, in Clearwater Beach, FL. The Company will have one platform presentation and three poster presentations on its clinical development program for ampreloxetine, a potential first-in-class norepinephrine reuptake inhibitor in development for the treatment of symptomatic neurogenic orthostatic hypotension (nOH) symptoms due to multiple system atrophy (MSA).

"We are excited to have a strong presence at the upcoming International Symposium on the Autonomic Nervous System. Our platform presentation will highlight results from the previous REDWOOD trial, where we observed a durable symptomatic nOH benefit with improvement in activities of daily living in the pre-specified subgroup analysis in patients with MSA treated with ampreloxetine[1]," commented Lucy Norcliffe-Kaufmann, Ph.D., Theravance Biopharma's Executive Director of Clinical Science. "Additionally, we are pleased to share the rigorous methodologies we developed based on our previous trial experience to support enrollment and patient retention. By applying these insights, we were well positioned to successfully address the executional challenges associated with clinical studies in rare and severe neurodegenerative diseases."

Presentations information and key findings:

Platform presentation: Precision therapy with ampreloxetine for neurogenic orthostatic hypotension in multiple system atrophy
Presenter: Lucy Norcliffe-Kaufmann, Ph.D.; Theravance Biopharma's Executive Director of Clinical Science and Associate Professor, New York University Langone Health Dysautonomia Center
Session date and time: Saturday, November 8, 2025, at 8:30 am ET

The following three posters will be presented at Poster Session II, taking place on Thursday, November 6, 2025, at 7:00-8:30 pm ET:

Poster title: The impact of ampreloxetine on supine hypertension: an ambulatory blood pressure monitoring study
Presenter: Lucy Norcliffe-Kaufmann, Ph.D.; Theravance Biopharma's Executive Director of Clinical Science and Associate Professor, New York University Langone Health Dysautonomia Center
Poster number: 9

Poster title: Retention strategies in rare disease clinical trials: a case study of symptomatic treatment for multiple system atrophy
Presenter: Molly Szpyhulsky, MBA, BSN, RN; Theravance Biopharma U.S.
Poster number: 15

Poster title: Enrollment strategies in a phase III trial for MSA-related nOH: insights from global investigators
Presenter: Molly Szpyhulsky, MBA, BSN, RN; Theravance Biopharma U.S.
Poster number: 10

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 the Phase 3 CYPRESS (Study 0197) Study
The CYPRESS Study (NCT05696717) 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 the Phase 3 SEQUOIA (Study 0169) and REDWOOD (Study 0170) Studies
Study 0169 (NCT03750552) was a Phase 3, 4-week, multi-center, randomized, double-blind, placebo-controlled, parallel-group study to evaluate the efficacy and safety of ampreloxetine compared to placebo in patients with symptomatic nOH (n=195). Patients from Study 0169 were eligible to enter into Study 0170 (NCT03829657), a Phase 3, multi-center, 22-week study comprising a 16-week open-label period and a 6-week double-blind,

placebo-controlled, randomized withdrawal period to evaluate the sustained benefit in efficacy and safety of ampreloxetine in patients with symptomatic nOH. The primary endpoint for Study 0170 of treatment failure at week 6 was defined as a worsening of both Orthostatic Hypotension Symptom Assessment Scale (OHSA) question #1 and Patient Global Impression of Severity (PGI-S) scores by 1.0 point. After Study 0169 did not meet its primary endpoint, the Company took actions to close out the ongoing clinical program including Study 0170. The study was more than 80% enrolled (n=128/154 planned) despite stopping early. The primary endpoint was not statistically significant for the overall population of patients, which included patients with Parkinson's disease, pure autonomic failure and MSA (odds ratio=0.6; p-value=0.196). The pre-specified subgroup analysis by disease type suggests the benefit seen in patients receiving ampreloxetine was largely driven by MSA patients (n=40). An odds ratio of 0.28 (95% CI: 0.05, 1.22) was observed in MSA patients indicating a 72% reduction in the odds of treatment failure with ampreloxetine compared to placebo. The benefit to MSA patients was observed in multiple endpoints including OHSA composite, Orthostatic Hypotension Daily Activities Scale (OHDAS) composite, Orthostatic Hypotension Questionnaire (OHQ) composite and OHSA #1.[1]

About Multiple System Atrophy (MSA) and Symptomatic Neurogenic Orthostatic Hypotension (nOH)
MSA is a progressive brain disorder that affects movement and balance and disrupts the function of the autonomic nervous system. The autonomic nervous system controls body functions that are mostly involuntary. One of the most frequent autonomic symptoms associated with MSA is a sudden drop in blood pressure upon standing (nOH).[2] There are approximately 50,000 MSA patients in the US[3] and 70-90% of MSA patients experience nOH symptoms.[4] Despite available therapies, many MSA patients remain symptomatic with nOH.[5]

Neurogenic orthostatic hypotension (nOH) is a rare disorder defined as a fall in systolic blood pressure of ⩾20 mm Hg or diastolic blood pressure of ⩾10 mm Hg, within 3 minutes of standing. Severely affected patients are unable to stand for more than a few seconds because of their decrease in blood pressure, leading to cerebral hypoperfusion and syncope. A debilitating disorder, nOH results in a range of symptoms including dizziness, lightheadedness, fainting, fatigue, blurry vision, weakness, trouble concentrating, and head and neck pain.

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.
THERAVANCE BIOPHARMA®, THERAVANCE® and the Cross/Star logo are registered trademarks of the Theravance Biopharma group of companies (in the U.S. and certain other countries).

YUPELRI® is a registered trademark of Viatris 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, Inc. (the "Company") 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 royalty 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 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: 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 August 13, 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.

Contact:
investor.relations@theravance.com
650-808-4045

[1] Freeman R, et al. Precision therapy with ampreloxetine for neurogenic orthostatic hypotension in multiple system atrophy. MedRxiv. https://www.medrxiv.org/content/10.1101/2025.08.12.25332833v1.

[2]https://medlineplus.gov/genetics/condition/multiple-system-atrophy/

[3] UCSD Neurological Institute (25K-75K, with ~10K new cases per year); NIH National Institute of Neurological Disorders and Stroke (15K-50K).

[4] Delveinsight MSA Market Forecast (2023); Symptoms associated with orthostatic hypotension in pure autonomic failure and multiple systems atrophy, CJ Mathias (1999).

[5] Data on file. MSA Natural History Statistics, NYU September 2019.

View original content to download multimedia:https://www.prnewswire.com/news-releases/theravance-biopharma-to-present-data-on-ampreloxetine-at-the-36th-international-symposium-on-the-autonomic-nervous-system-302597901.html

SOURCE Theravance Biopharma, Inc.