Theravance Biopharma Announces Ampreloxetine (TD-9855) Phase 2 Study Results Selected for Oral Presentation at 32nd European Neurology Congress

March 25, 2019

Presentation to highlight data for novel, once-daily norepinephrine reuptake inhibitor in patients with neurogenic orthostatic hypotension

20-week data support previously-announced clinical observations after four weeks of treatment

DUBLIN, March 25, 2019 /PRNewswire/ -- Theravance Biopharma, Inc. (NASDAQ: TBPH) ("Theravance Biopharma" or the "Company") today announced that data from the Company's Phase 2 clinical trial of ampreloxetine (TD-9855) have been selected for an oral presentation at the 32nd European Neurology Congress. Ampreloxetine is an investigational, once-daily norepinephrine reuptake inhibitor (NRI) in development for the treatment of patients with symptomatic neurogenic orthostatic hypotension (nOH). The oral presentation will highlight the efficacy, safety and tolerability from the completed Phase 2 clinical trial, including results following 20 weeks of treatment with ampreloxetine, which support previously announced clinical observations after four weeks of treatment. The 32ndEuropean Neurology Congress is being held July 22 - 24, 2019, in London.

Theravance Biopharma previously announced positive four-week results from the Phase 2 clinical trial. Findings demonstrated durable improvements in nOH symptom severity as measured by OHSA #1. Patients treated in the extension phase of the study showed a mean symptom improvement of 2.4 points at four weeks. Importantly, mean symptom improvement was greatest (3.8 points) in nOH patients who reported dizziness symptoms (OHSA #1 $\geq$ 4) at baseline, a pre-defined regulatory and clinical threshold that will be used to enroll patients in Phase 3. Additionally, ampreloxetine increased standing systolic blood pressure at the three-minute assessment at all time points on all weekly clinic visits. There were no drug-related serious adverse events reported, and ampreloxetine was generally well tolerated in the study. Based on these results, the Company initiated the registrational Phase 3 clinical trials of ampreloxetine in symptomatic nOH patients in January 2019.

"Selection of our Phase 2 data as an oral presentation at the European Neurology Congress illustrates ampreloxetine's potential to impact a key unmet medical need. nOH is a severely debilitating condition and current therapeutic options are limited in terms of sustained effect and safety," said Brett Haumann, MD, chief medical officer of Theravance Biopharma. "Five-month data from the exploratory open-label portion of the study further suggest that ampreloxetine produces a durable clinical response, a finding that we are assessing in the placebo-controlled registrational Phase 3 program currently underway."

About the Phase 2 Study in nOH

The Phase 2 study of ampreloxetine consisted of three parts. Part A was a single ascending dose (from 1 mg up to 20 mg based on patient response) designed to evaluate impact on blood pressure and standing time for ampreloxetine as compared to placebo. Part B was a double-blind, single dose study designed to evaluate impact on blood pressure and standing time for ampreloxetine as compared to placebo. Part B was discontinued when the trial was amended to include Part C, following the enrollment of ten patients in Part B (five on ampreloxetine; five on placebo). Part C was an open label extension to Part A designed to evaluate improvement in patients' symptoms and impact on blood pressure. Responders in Part A were eligible to enroll in Part C at up to their highest tolerated Part A dose, which included 5 mg, 10 mg and 20 mg. The primary endpoint of the study was measured after four weeks, although patients were able to continue to receive medication for up to five months.

About nOH

Neurogenic orthostatic hypotension (nOH) is a rare disorder defined as a sustained orthostatic fall in systolic blood pressure (SBP) of ≥ 20 mm Hg or diastolic blood pressure (DBP) of ≥ 10 mm Hg within three 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 condition, nOH results in a range of symptoms including dizziness, lightheadedness, fainting, fatigue, blurry vision, weakness, trouble concentration and head and neck pain. nOH is caused by autonomic nervous system (ANS) malfunction and is associated with several underlying medical conditions including multiple system atrophy (MSA), pure autonomic failure (PAF) and Parkinson's disease (PD).

OHSA #1 is an endpoint which is part of the Orthostatic Hypotension Questionnaire, a validated scale assessing the presence of a range of hypotension-related symptoms including dizziness, weakness, problems with vision, fatigue, trouble concentrating and head/neck discomfort. It is based on a scale from 0 (no symptoms) to 10 (worst possible severity of a symptom), with reductions in OHSA points indicating symptom improvement and increases in OHSA score indicating symptom worsening. OHSA #1 specifically measures patients' dizziness, lightheadedness, feeling faint, or feeling like they might black out. OHSA #1 has been accepted as a suitable endpoint in the investigation of neurogenic orthostatic hypotension by FDA.

About Ampreloxetine (TD-9855)

Ampreloxetine is an investigational, once-daily norepinephrine reuptake inhibitor (NRI) being developed for the treatment of patients with symptomatic neurogenic orthostatic hypotension (nOH). The compound has high affinity for binding to norepinephrine transporters. By blocking the action of these transporters, ampreloxetine causes an increase in extracellular concentrations of norepinephrine.

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'sForm 10-K filed with the Securities and Exchange Commission (SEC) on February 28, 2019and 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.

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