Theravance Biopharma, Inc. to Host Virtual Key Opinion Leader (KOL) Event to Discuss Ampreloxetine's Potential for the Treatment of Symptomatic Neurogenic Orthostatic Hypotension (nOH) in Patients with Multiple System Atrophy (MSA) on May 23, 2024

April 10, 2024

DUBLIN, April 10, 2024 /PRNewswire/ -- Theravance Biopharma, Inc. (the "Company") (NASDAQ: TBPH) today announced it will host a virtual KOL event on Thursday, May 23, 2024 from 10:00 AM to 11:30 AM ET, featuring Horacio Kaufmann, MD, FAAN (Felicia B. Axelrod Professor of Neurology and Professor of Medicine at New York University Grossman School of Medicine) and Italo Biaggioni, MD (Professor of Medicine and Pharmacology Director, Vanderbilt Autonomic Dysfunction Center), who will discuss the unmet need and current treatment landscape for MSA patients with symptomatic nOH. To register, click here.

The event will also feature presentations from the Company's CEO, Rick Winningham, Senior VP of Development, Aine Miller, and Chief Business Officer, Rhonda Farnum and will focus on the Company's clinical development program for ampreloxetine, an investigational, once-daily norepinephrine reuptake inhibitor with the potential to be a first-in-class therapy effective in treating a constellation of cardinal symptoms of nOH in MSA patients.

A live question and answer session will follow the formal presentations.

About Horacio Kaufmann, MD, FAAN

Dr. Kaufmann is the Axelrod Professor of Neurology, Professor of Medicine and Professor of Pediatrics and Chief of the Division of Autonomic Disorders, all at New York University Grossman School of Medicine. He is also the Director of the Dysautonomia Center at NYU Langone Health.

Dr. Kaufmann's clinical and research careers have been focused on genetic and neurodegenerative disorders affecting autonomic neurons, with particular emphasis on the synucleinopathies, including Pure Autonomic Failure, Parkinson disease and multiple system atrophy (MSA). He was the PI of the *Natural History Study of the Synucleinopathies (NHSS)*, a multicenter prospective study running for ten years funded by the NINDS. Dr. Kaufmann has established an international collaboration of 22 centers in America, Europe and Asia that shares data and research projects and supports the careers of young clinical scientists. He was co-chair of the task force of the Movement Disorders Society to update the diagnostic criteria of MSA. He is currently the PI of the NINDS funded Clinical Trial Readiness in MSA, an international, multicenter, prospective, observational study to develop a novel clinical outcome assessment and biomarkers for MSA. He has published extensively in top tier academic journals as well as numerous book chapters and consensus criteria.

Dr. Kaufmann has experience designing and conducting phase 1 and large international phase 3 clinical trials for rare diseases. He supervises an active clinical service and teaches autonomic neuroscience to residents and fellows. He is the Editor in Chief of *Clinical Autonomic Research*, the preeminent subspecialty journal published by Springer-Nature.

About Italo Biaggioni, MD

Dr. Biaggioni has over 35 years of experience investigating the interaction between neural (autonomic) metabolic (renin-angiotensin, insulin, incretins) and local (adenosine, nitric oxide) mechanisms involved in cardiovascular regulation. In particular, he is interested in how these interactions participate in the pathophysiology of autonomic disorders. He directs the Vanderbilt Autonomic Dysfunction Center, a multidisciplinary program dedicated to the evaluation and treatment of patients with autonomic disorders that includes neurologists, cardiologists, geriatricians, and clinical pharmacologists. He leads an active research program, with continued NIH funding for over 30 years that has resulted in over 350 peer-reviewed publications. The focus of this research program is to apply clinical research to the development of novel treatment strategies for autonomic disorders. His group has participated in the discovery of new autonomic diseases, and in the development of novel devices, medications, and repurposing of approved drugs for the treatment of patients with autonomic disorders.

About Ampreloxetine

Ampreloxetine is an investigational, once-daily norepinephrine reuptake inhibitor in development for the treatment of symptomatic nOH in patients with 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 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 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).[1] There are approximately 50,000 MSA patients in the US[2] and 70-90% of MSA patients experience nOH symptoms.[3] Despite available therapies, many MSA patients remain symptomatic with nOH.

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 condition, 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, the Company 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 system atrophy patients. The Company is committed to creating/driving shareholder value.

For more information, please visit www.theravance.com.

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

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

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

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