Orchestra BioMed to Host In-Person R&D Day in New York on AVIM Therapy Program in Hypertensive Pacemaker Patients on June 11, 2024

April 30, 2024

NEW HOPE, Pa., April 30, 2024 (GLOBE NEWSWIRE) -- Orchestra BioMed Holdings, Inc. (Nasdaq: OBIO, “Orchestra BioMed” or the “Company”), a biomedical company accelerating high-impact technologies to patients through risk-reward sharing partnerships, today announced it will host an in-person R&D day at the Lotte New York Palace Hotel on Tuesday, June 11, 2024 at 10:00 AM ET. To register, click here.

The event will feature presentations by company management and key opinion leaders related to the Company’s lead program, atrioventricular interval modulation (AVIM) therapy, including:

- David Kandzari, M.D., FACC, FSCAI, Chief, Piedmont Heart Institute and Cardiovascular Services, Chief Scientific Officer, Piedmont Healthcare, Director, Interventional Cardiology, Piedmont Heart Institute, and Co-principal investigator for the BACKBEAT global pivotal study
- Vivek Reddy, M.D., Director of Cardiac Arrhythmia Services at Mount Sinai Hospital, Director of Electrophysiology at Mount Sinai Health System, Professor of Medicine at the Icahn School of Medicine at Mount Sinai, and Clinical Steering Committee Advisor for the BACKBEAT global pivotal study

The R&D day program will focus on a review of:

- High unmet need and current treatment landscape for pacemaker-indicated patients with uncontrolled hypertension;
- AVIM therapy mechanism of action and supporting clinical and non-clinical mechanistic data;
- Existing body of clinical evidence from the MODERATO I and II studies;
- Design of the BACKBEAT global pivotal study.

A live question and answer session will follow formal presentations.

About Orchestra BioMed

Orchestra BioMed (Nasdaq: OBIO) is a biomedical innovation company accelerating high-impact technologies to patients through risk-reward sharing partnerships with leading medical device companies. Orchestra BioMed’s partnership-enabled business model focuses on forging strategic collaborations with leading medical device companies to drive successful global commercialization of products it develops. Orchestra BioMed’s lead product candidate is atrioventricular interval modulation (AVIM) therapy (also known as BackBeat Cardiac Neuromodulation Therapy (CNT™)) for the treatment of hypertension, a significant risk factor for death worldwide. Orchestra BioMed is also developing Virtue® Sirolimus AngioInfusion™ Balloon (SAB) for the treatment of atherosclerotic artery disease, the leading cause of mortality worldwide. Orchestra BioMed has a strategic collaboration with Medtronic, one of the largest medical device companies in the world, for the development and commercialization of AVIM therapy for the treatment of hypertension in pacemaker-indicated patients, and a strategic partnership with Terumo, a global leader in medical technology, for the development and commercialization of Virtue SAB for the treatment of artery disease. Orchestra BioMed has additional product candidates and plans to potentially expand its product pipeline through acquisitions, strategic collaborations, licensing and organic development. For further information about Orchestra BioMed, please visit www.orchestrabiomed.com, and follow us on LinkedIn.

References to Websites and Social Media Platforms

References to information included on, or accessible through, websites and social media platforms do not constitute incorporation by reference of the information contained at or available through such websites or social media platforms, and you should not consider such information to be part of this press release.

About Hypertension and the Risk of High Blood Pressure in the Pacemaker Population

Hypertension (“HTN”) is characterized by elevated blood pressure, which increases the force of blood pushing against blood vessels, requiring the heart to work harder and consume more oxygen. HTN accelerates the progression of atherosclerosis and leads to increased risk of major cardiac events like heart attack, heart failure, kidney disease and other end organ damage. HTN is the leading global risk factor for death, affecting an estimated 1.28 billion adults worldwide. In the United States, 122 million adults, or approximately 47% of all adults, are estimated to have HTN. While many patients do not notice high blood pressure, cardiovascular risk doubles for every 10-mmHg increase in systolic blood pressure and the mortality rate doubles with an increase of 20 mmHg in systolic blood pressure.[1]

It is estimated that more than 70% of the approximately 1.1 million people globally who are implanted with cardiac pacemakers each year are also diagnosed with HTN. Based on updated American College of Cardiology/American Heart Association guidelines, we estimate that an even higher percentage (approximately 80%) of U.S. patients who are indicated for a pacemaker implant have HTN. Pacemaker patients tend to be elderly and are more likely to suffer from co-morbidities, such as atherosclerosis, hyperlipidemia, diabetes mellitus and chronic kidney disease, and harder to treat effectively with medical therapy for many reasons, including co-morbidities and a high prevalence of isolated systolic HTN.

About AVIM Therapy (BackBeat CNT™)

AVIM therapy, also known as BackBeat CNT™, is an investigational therapy compatible with standard dual-chamber pacemakers designed to substantially and persistently lower blood pressure. It has been evaluated in pilot studies in patients with hypertension who are also indicated for a pacemaker. MODERATO II, a double-blind, randomized, pilot study, showed that patients treated with AVIM therapy experienced net reductions of 8.1 mmHg in 24-hour ambulatory systolic blood pressure (aSBP) and 12.3 mmHg in office systolic blood pressure (oSBP) at six months when compared to control patients. The global IDE pivotal BACKBEAT (BradycArdia paCemaKer with atrioventricular interval modulation for Blood prEssure treAtmenT) study will further evaluate the safety and efficacy of AVIM therapy in lowering blood pressure in a similar target population of patients who have been indicated for, and recently implanted with, a dual-chamber cardiac pacemaker.

Forward-Looking Statements

Certain statements included in this press release that are not historical facts are forward-looking statements for purposes of the safe harbor provisions under the United States Private Securities Litigation Reform Act of 1995. Forward-looking statements generally are accompanied by words such as "believe," "may," "will," "estimate," "continue," "anticipate," "intend," "expect," "should," "would," "plan," "predict," "potential," "seem," "seek," "future," "outlook" and similar expressions that predict or indicate future events or trends or that are not statements of historical matters. These forward-looking statements include, but are not limited to, statements relating to: the initiation, enrollment, timing, implementation and design of the Company's planned and ongoing pivotal trials and reporting of top-line results; the potential safety and efficacy of the Company's product candidates, the ability of the Company's partnerships to accelerate clinical development; the Company's late-stage development programs; strategic partnerships and plans to expand its product pipeline. These statements are based on various assumptions, whether or not identified in this press release, and on the current expectations of the Company's management and are not predictions of actual performance. These forward-looking statements are provided for illustrative purposes only and are not intended to serve as and must not be relied on as a guarantee, an assurance, a prediction, or a definitive statement of fact or probability. Actual events and circumstances are difficult or impossible to predict and may differ from assumptions. Many actual events and circumstances are beyond the control of the Company. These forward-looking statements are subject to a number of risks and uncertainties, including changes in domestic and foreign business, market, financial, political, and legal conditions; risks related to regulatory approval of the Company's commercial product candidates and ongoing regulation of the Company's product candidates, if approved; the timing of, and the Company's ability to achieve expected regulatory and business milestones; the impact of competitive products and product candidates; and the risk factors discussed under the heading "Item 1A. Risk Factors" in the Company's annual report on Form 10-K for the year ended December 31, 2023, which was filed with the SEC on March 27, 2024 and under the heading "Risk Factors" in Amendment No. 2 to the Company's Form S-3 filed on April 25, 2024.

The Company operates in a very competitive and rapidly changing environment. New risks emerge from time to time. Given these risks and uncertainties, the Company cautions against placing undue reliance on these forward-looking statements, which only speak as of the date of this press release. The Company does not plan and undertakes no obligation to update any of the forward-looking statements made herein, except as required by law.

References:

1. Benjamin EJ, Blaha MJ, Chiuve SE, et al., Heart Disease and Stroke Statistics – 2017 Update: A Report from the American Heart Association. Circulation. 2017; 135: e146.

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