



Orchestra BioMed Announces Further Details on In-Person R&D Day in New York Featuring Key Opinion Leaders to Discuss AVIM Therapy Program in Hypertensive Pacemaker Patients on June 11, 2024

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NEW HOPE, Pa., June 04, 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 further details on its 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 R&D day will feature in-depth presentations focused on the Company's lead program, atrioventricular interval modulation (AVIM) therapy, including:

- The high unmet need for treatment of uncontrolled hypertension in pacemaker-indicated patients and other older high-risk patients
- The AVIM therapy mechanism of action and supporting clinical and non-clinical mechanistic data
- The robust existing body of clinical evidence from the MODERATO I and II studies
- Design of and rationale for the BACKBEAT global pivotal study

In addition to Orchestra BioMed management presentations, the event will include esteemed key opinion leading physicians:

David Kandzari, M.D., FACC, FSCAI, Chief of the Piedmont Heart Institute and Cardiovascular Service Line; Director, Interventional Cardiology of the Piedmont Heart Institute; Chief Scientific Officer for Piedmont Healthcare in Atlanta, Georgia; and co-principal investigator on the BACKBEAT global pivotal study

- Dr. Kandzari specializes in cardiovascular disease, peripheral arterial disease and interventional cardiology. Board certified by the American Board of Internal Medicine and its subspecialty Board of Cardiovascular Disease and Board of Interventional Cardiology, Dr. Kandzari has held national and international leadership roles in clinical trials in cardiovascular disease and has participated in national and international program committees in cardiology. He has authored and coauthored more than 400 studies, book chapters and scientific reviews, and has delivered more than 800 lectures, both nationally and internationally, on a variety of issues related to both interventional and general cardiology. Dr. Kandzari has been consecutively voted as one of Atlanta's Top Doctors by Atlanta Magazine from 2011 to 2024 and is peer-nominated in the top 1% of cardiologists by U.S News and World Report.

Vivek Reddy, M.D., Director of Cardiac Arrhythmia Services for The Mount Sinai Hospital and the Mount Sinai Health System; Leona M. and Harry B. Helmsley Charitable Trust Professor of Medicine in Cardiac Electrophysiology at Icahn School of Medicine at Mount Sinai; and Clinical Steering Committee Advisor for the BACKBEAT global pivotal study

- Dr. Reddy is one of the nation's premier cardiac electrophysiologists, leading a team of physician-scientists who are developing and testing advanced therapies for cardiac arrhythmias – including atrial fibrillation and ventricular tachycardias, the most common cause of sudden cardiac death. Dr. Reddy's pioneering clinical research is changing the way cardiac patients are treated and cured. Under his leadership, Mount Sinai is the lead site on several multinational clinical trials exploring new arrhythmia procedures and technologies. In 2014, Dr. Reddy implanted the world's first miniature leadless pacemaker in a patient's heart in the United States at The Mount Sinai Hospital.

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 Angiolfusion™ 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. 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 IDE approved BACKBEAT (BradyCardia paCemaKer with atrioventricular interval modulation for Blood prEssure treAtment) global pivotal 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.

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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