Orchestra BioMed Showcases AVIM Therapy as Purpose-Built Solution for Hypertensive Heart Disease at CSI Frankfurt 2025

June 18, 2025

- *Presentation underscores unique potential for atrioventricular interval modulation ("AVIM") therapy to manage blood pressure in older, high-risk patients who have indicators of diastolic dysfunction and progression to heart failure with preserved ejection fraction ("HFpEF")*
- *Hypertensive heart disease represents over 7.7 million U.S. patients, the same population with hypertension and elevated cardiovascular risk cited in the recent FDA Breakthrough Device Designation ("BDD") for AVIM therapy*

NEW HOPE, Pa., June 18, 2025 (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 the presentation of key clinical insights into the role of AVIM therapy for the treatment of high-risk hypertension at the Congenital, Structural, and Valvular Heart Disease Interventions ("CSI") 2025 Meeting. The data highlight AVIM therapy's unique potential to address hypertensive heart disease, a significant and under-recognized cardiovascular syndrome that affects a growing segment of the aging hypertension population.

The talk, *"Atrioventricular Interval Modulation (AVIM) Therapy for Hypertension and HFpEF,"* will be delivered by Daniel Burkhoff, M.D., Ph.D., Director of Heart Failure, Hemodynamics and Mechanical Circulatory Support Research at Cardiovascular Research Foundation and clinical advisor to Orchestra BioMed. Dr. Burkhoff will spotlight the clinical utility of AVIM therapy as a novel, device-based approach to blood pressure management designed **specifically for patients with hypertensive heart disease**. This population has increased risk for major adverse cardiac events and currently lacks sufficient therapeutic options. The presentation will take place on June 18, 2025, at 3:33pm CEST / 9:33am ET as part of the "*Interventions for Chronic Heart Failure*" session.

Dr. Burkhoff commented, "Hypertensive heart disease is not a singular diagnosis, but a high-risk cardiovascular syndrome driven by longstanding, uncontrolled high blood pressure which significantly increases the likelihood of adverse clinical outcomes such as stroke, myocardial infarction, diastolic dysfunction and progression to heart failure. The data I will review at CSI explore how AVIM therapy may offer a unique treatment specifically catered to this group of patients leveraging a mechanism of action designed to reduce cardiac preload and modulate autonomic nervous system responses to reduce blood pressure and improve cardiovascular function. This represents a potential paradigm shift in how we approach blood pressure management using tailored interventions designed to directly impact the complex pathophysiology of high-risk hypertension."

The presentation will cover:

- The **clinical burden and therapeutic gaps** in managing patients with high-risk hypertension and increased risk of heart failure;
- The growing **body of clinical and mechanistic evidence** demonstrating AVIM therapy's potential to lower blood pressure and improve cardiac function; and
- Details on the **BACKBEAT global pivotal study**, currently enrolling patients with uncontrolled hypertension who are indicated for a dual-chamber pacemaker. The study is being conducted in collaboration with **Medtronic**, the global leader in cardiac pacing therapy.

"AVIM therapy was purpose-built to address the complex and underserved needs of patients with hypertensive heart disease, a subgroup often overlooked by conventional therapy," said Avi Fischer, M.D., Senior Vice President of Medical Affairs and Innovation at Orchestra BioMed. "As a programmable, pacemaker-integrated solution, AVIM therapy has the potential to fit seamlessly into existing electrophysiology practices while opening the door to better outcomes in a large, underserved population. Dr. Burkhoff's presentation at CSI Frankfurt further reinforces the growing clinical interest in AVIM therapy and highlights the significant opportunity to transform care of hypertensive heart disease, especially given our recently granted BDD status, which applies directly to this patient profile."

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 AVIM therapy for the treatment of hypertension, the leading

risk factor for death worldwide. Orchestra BioMed is also developing Virtue 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 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 development and commercialization of Virtue SAB for the treatment of artery disease. The Company has received four Breakthrough Device Designations from the U.S. FDA across these two core programs, reflecting the significant potential of its technologies to address high unmet needs in cardiovascular care. 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 AVIM Therapy

AVIM therapy 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. In addition to reducing blood pressure, clinical results using AVIM therapy demonstrate improvements in cardiac function and hemodynamics. The 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 patients who have systolic blood pressure above target despite anti-hypertensive medication and who are indicated for or have recently received a dual-chamber cardiac pacemaker. AVIM therapy has been granted Breakthrough Device Designation by the FDA for the treatment of uncontrolled hypertension in patients who have increased cardiovascular risk.

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 enrollment, implementation and design of the Company's planned and ongoing pivotal trials, realizing the clinical and commercial value of the Company's product candidates, the potential safety and efficacy of the Company's product candidates, and the ability of the Company's partnerships to accelerate clinical development. 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, 2024, which was filed with the SEC on March 31, 2025 and the risk factor discussed under the heading "Item 1A. Risk Factors" in the Company's Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2025, which was filed with the SEC on May 12, 2025.

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.

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