



Orchestra BioMed Announces Publication of AVIM Therapy Clinical Data in JACC: Advances Demonstrating Potential to Improve Cardiac Function in Patients with Hypertension and Diastolic Dysfunction

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- *Echocardiographic data analysis demonstrated favorable impact of atrioventricular interval modulation (“AVIM”) therapy on MODERATO II study patients with diastolic dysfunction, a key component in the development of heart failure with preserved ejection fraction (“HFpEF”)*
- *Hypertension is the leading cause of diastolic dysfunction and the most common comorbidity in older patients indicated for a pacemaker*

NEW HOPE, Pa., Aug. 14, 2025 (GLOBE NEWSWIRE) -- Orchestra BioMed Holdings, Inc. (Nasdaq: OBIO, “Orchestra BioMed” or the “Company”), a biomedical innovation company accelerating high-impact technologies to patients through risk-reward sharing partnerships, today announced the publication of clinical data in *JACC: Advances* demonstrating that AVIM therapy significantly improved cardiac function in patients with hypertension and diastolic dysfunction (“DD”), key contributors to the development of HFpEF.

The publication, titled “*Effects of AtrioVentricular Interval Modulation (AVIM) Therapy in Subjects with Hypertension and Diastolic Dysfunction*,” reports findings from a retrospective treatment-blinded analysis of MODERATO II patients. The analysis demonstrated that AVIM therapy significantly reduced systolic blood pressure (SBP) and improved echocardiographic markers of DD, a key contributor to HFpEF – a common comorbidity in patients with isolated systolic hypertension (ISH). These results were previously presented in a late-breaking session at the 2025 Technology and Heart Failure Therapeutics Meeting and are now published in *JACC: Advances*.

Key findings:

- AVIM therapy significantly reduced both office and ambulatory SBP in patients with DD over 6 months, with office SBP reduced by 12.1 ± 12.8 mmHg and ambulatory SBP by 8.3 ± 9.7 mmHg (both $p < 0.01$ vs baseline).
- Patients treated with AVIM showed significant improvements in key measures of diastolic function, including increases in e' (5.9 ± 2.0 to 8.8 ± 3.4 cm/sec) and E/A ratio (0.86 ± 0.39 to 1.60 ± 0.84), consistent with improved myocardial relaxation and improved diastolic compliance.

Marat Fudim, M.D., M.H.S., Advanced Heart Failure Cardiologist, Duke Health and primary author of the publication, commented, “There is a clear clinical link between long-standing hypertension, diastolic dysfunction, and the eventual development of HFpEF, yet few interventions are available that effectively target this pathway. The data from MODERATO II suggest that AVIM therapy may address this unmet medical need by offering sustained reductions in blood pressure while improving ventricular compliance. These effects point to the potential for disease modification and reverse remodeling, particularly important in managing hypertensive heart disease in patients with increased cardiovascular risk. With the BACKBEAT study underway, we look forward to developing additional evidence to validate AVIM therapy as an impactful treatment option that goes beyond blood pressure control.”

Avi Fischer, M.D., Senior Vice President of Medical Affairs and Innovation at Orchestra BioMed, stated, “The progression from uncontrolled hypertension to heart failure with preserved ejection fraction is a costly and growing healthcare burden with limited treatment options, particularly in the population of pacemaker-indicated patients where hypertension is highly prevalent. AVIM therapy is positioned to offer a differentiated, device-based approach designed for earlier intervention in the disease progression by addressing both elevated systolic blood pressure and impaired diastolic function. The findings published in *JACC: Advances* highlight AVIM therapy’s potential to deliver sustained reductions in blood pressure, improve cardiac efficiency and enhance myocardial relaxation, and reinforce our belief that AVIM therapy represents a novel intervention with the potential to both treat hypertension and target diastolic dysfunction, a known risk factor for serious cardiovascular events, including HFpEF.”

AVIM therapy is currently being evaluated in the BACKBEAT global pivotal study, conducted in collaboration with Medtronic, to support potential U.S. regulatory approval for use in pacemaker-indicated patients with uncontrolled hypertension.

The full article is available online in [JACC: Advances](#).

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, the leading risk factor for death worldwide. Orchestra BioMed is also developing the 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 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. 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 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 initiation, enrollment, timing, implementation and design of the Company's planned and ongoing pivotal trials, realizing the clinical and commercial value of AVIM therapy and Virtue SAB, and the potential safety and efficacy of the Company's product candidates. 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 Securities and Exchange Commission ("SEC") on March 31, 2025, and under the heading "Item 1A. Risk Factors" in Part II of the Company's subsequently filed quarterly reports on Form 10-Q.

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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