



Orchestra BioMed Presents New AVIM Therapy Clinical Data at HRX Demonstrating Substantial and Sustained Blood Pressure Reductions that are Reproducible Upon Reactivation Following Washout

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- Results from long-term follow up of patients treated with atrioventricular interval modulation ("AVIM") therapy show blood pressure-lowering effects are sustained for years after activation, reversible with no observed rebound hypertension upon deactivation of treatment, and reproducible upon reactivation following a washout period
- Simultaneous peer-reviewed publication of AVIM therapy mechanistic and clinical results
- Orchestra BioMed and Medtronic (NYSE: MDT) have a strategic collaboration to develop and commercialize AVIM therapy for the treatment of uncontrolled hypertension in patients indicated for a pacemaker, an estimated global population of over 750,000 patients annually
- AVIM therapy has FDA Breakthrough Device Designation for the treatment of uncontrolled hypertension in patients with increased cardiovascular risk, an estimated U.S. population of over 7.7 million patients

NEW HOPE, Pa., Sept. 04, 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 new data from its AVIM therapy program, presented at the HRX Live 2025 Meeting, in Atlanta, GA, demonstrating that the blood pressure-lowering effects of AVIM therapy may be sustained for years after activation, are reversible with no evidence of rebound hypertension or blood pressure exceeding initial baseline values, and can be restored upon reactivation. These data further support AVIM therapy's potential role as a controllable, programmable, and durable device-based therapy for uncontrolled hypertension.

Avi Fischer, MD, Senior Vice President of Medical Affairs and Innovation at Orchestra BioMed presented an overview of mechanistic and clinical data supporting the potential role of AVIM therapy for the treatment of uncontrolled hypertension during the Innovation Summit at HRX Live 2025, as part of the session titled "*Pacing and Implanted Device Therapy*." His presentation coincided with the simultaneous peer-reviewed publication of these results in *Heart Rhythm O₂*, titled, "[Atrioventricular Interval Modulation \(AVIM\) for Management of Hypertension](#)."

Dr. Fischer stated, "These results add to the growing body of promising data supporting AVIM therapy's potential role as a novel and programmable treatment option for patients whose hypertension remains uncontrolled despite existing medical regimens. The sustainability, reversibility and reproducibility of effect demonstrated in these results provides additional confidence in the efficacy and safety profile of AVIM therapy currently under investigation in the BACKBEAT global pivotal study. Importantly, these data highlight the potential for AVIM therapy to halt the progression of hypertensive heart disease, which could have significant clinical benefit to millions of patients globally."

Key Findings:

- **Sustainable blood pressure reduction during chronic treatment with AVIM therapy:** A group of patients (n=16) who originally participated in the MODERATO II trial and underwent long-term follow-up for an average of 3.6 years had sustained 24-hour ambulatory systolic blood pressure ("aSBP") reductions of 8.9 mmHg (p<0.001).
- **Reversible treatment effect following therapy deactivation:**
 - **Return to baseline:** AVIM therapy was turned off for a washout period of seven days. On Day 1, aSBP returned to 133.1 mmHg, consistent with original baseline hypertension (132.2 mmHg; p=NS).
 - **Absence of rebound hypertension:** No residual antihypertensive effects or rebound hypertension were observed.
- **Immediate effect upon therapy reactivation:**
 - **Restored reduction in aSBP:** Following the 7-day washout period, aSBP was immediately and significantly reduced (124.4 mmHg; p<0.002) upon reactivation.
- **Reproducible effect**
 - **No statistically significant difference in the therapeutic effects of AVIM therapy** were observed between 6-month (122.8 mmHg), chronic 3.6-year follow-up (122.8 mmHg) and Day 8 reactivation (124.4 mmHg).

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 enrollment, timing, implementation and design of the BACKBEAT pivotal study, the potential efficacy and safety of the Company's commercial product candidates, the ability of the Company's partnerships to accelerate clinical development, and the Company's late-stage development programs, strategic partnerships. 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 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 on March 31, 2025, as updated by any risk factors disclosed under the heading "Item 1A. Risk Factors" in 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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