Orchestra BioMed to Present AVIM Therapy Clinical and Mechanistic Data at HRS 2026

April 23, 2026

- *Pre-randomization Atrioventricular Interval Modulation Therapy ("AVIM Therapy") set-up data from the MODERATO II randomized, prospective, multi-center, double-blind, controlled trial show an **immediate average reduction of 13.2 mmHg** in office systolic blood pressure ("oSBP")*
- ***97% of patients experienced an immediate blood pressure reduction** of >5 mmHg reduction in oSBP prior to randomization*
- *AVIM Therapy demonstrated the potential to deliver **immediate, substantial, and sustained reductions** in blood pressure, with evidence of improved diastolic function and reverse cardiac remodeling*
- *The BACKBEAT Global Pivotal Trial, which Orchestra BioMed is actively enrolling as part of a strategic collaboration with Medtronic (NYSE: MDT), targets a similar patient population as MODERATO II using a similar approach to blood pressure assessment and AVIM Therapy activation*

NEW HOPE, Pa., April 23, 2026 (GLOBE NEWSWIRE) -- Orchestra BioMed Holdings, Inc. (Nasdaq: OBIO) ("Orchestra BioMed" or the "Company"), a biomedical company accelerating high-impact technologies to patients through strategic partnerships with market-leading global medical device companies, today announced two AVIM Therapy presentations at the Heart Rhythm Society (HRS) 2026 Annual Meeting.

HRS 2026 Presentations and Data Highlights
Atrioventricular Interval Modulation (AVIM) Therapy as a Treatment for Hypertensive Heart Disease (Saturday, April 25, 10:06-10:18am, Room S102 McCormick Place)

Prof. Karl-Heinz Kuck, M.D., Medical Director, LANS Cardio Hamburg will present new data from the MODERATO II randomized, prospective, multi-center, double-blind, controlled trial which demonstrate AVIM Therapy's potential to deliver immediate, substantial, and sustained blood pressure reduction without reliance on additional medications or patient adherence. Key findings include:

- **An Immediate and Substantial oSBP Reduction:** Upon activation, AVIM Therapy demonstrated a mean reduction in oSBP of **13.2 mmHg**.
- **A High Responder Rate: 97% of patients achieved a 5 mmHg** or greater reduction in oSBP.
- **High Rates of Sustained Blood Pressure Control:** At 6 months, mean ambulatory systolic blood pressure ("aSBP") was **125.2 mmHg, with 89% of patients achieving aSBP <140 mmHg**, the current oSBP treatment goal according to European Society of Cardiology guidelines, **and 58% of patients achieving aSBP <130 mmHg**, the more stringent U.S. oSBP treatment goal according to American Heart Association and American College of Cardiology guidelines.
- **Durable Long-Term Effect:** Sustained reductions in aSBP were observed through 3.6 years of follow-up in a sub-cohort of patients.

Prof. Kuck, who also served as Principal Investigator for the MODERATO II pilot trial, commented, "The observed response rate and mean blood pressure reduction in the MODERATO II trial provide a clear and consistent baseline signal of AVIM Therapy's effect. The magnitude of ambulatory blood pressure reduction brought the majority of patients well within contemporary guideline-recommended targets for optimal blood pressure control. We look forward to further results from the BACKBEAT Global Pivotal Trial as AVIM Therapy, in combination with a modest medical regimen, may offer a differentiated path to sustained blood pressure control in this older, higher-risk patient population."

Pressure-Volume Analysis Demonstrates Hemodynamic Effects of Atrioventricular Interval Modulation (AVIM) Therapy in Hypertension
(Friday, April 24, 10:00am-12:00pm, Abstract Pavilion – Exhibit Hall, McCormick Place)

Prof. Milan Chovanec, M.D., Na Hamolce Hospital will present results from a clinical pressure-volume loop trial of AVIM Therapy in pacemaker-indicated patients with uncontrolled hypertension despite the use of anti-hypertensive medication. These data, which were published in *JACC: Clinical Electrophysiology*, demonstrate the favorable impact of AVIM Therapy compared to standard pacing on systolic blood pressure ("SBP") and overall cardiac function when delivered using both conduction system pacing ("CSP") and standard right ventricular ("RV") pacing lead locations.

AVIM Therapy acutely reduced SBP by decreasing cardiac preload and effective arterial elastance (afterload) independent of lead location without affecting left ventricular contractility. When compared to AV pacing, AVIM Therapy drove statistically significant ($p<0.05$) reductions in:

- Systolic blood pressure, end diastolic volume, end diastolic pressure, and end systolic volume using both CSP and RV pacing lead locations
- Stroke work without significantly reducing stroke volume
- Total peripheral resistance (measured by Ea) and no change in contractility

About Orchestra BioMed

Orchestra BioMed is a biomedical innovation company accelerating high-impact technologies to patients through strategic collaborations with market-leading global medical device companies. The Company's two flagship product candidates - Atrioventricular Interval Modulation (AVIM) Therapy and Virtue® Sirolimus AngioInfusion™ Balloon (Virtue SAB) - are currently undergoing pivotal clinical trials for their lead indications, each representing multi-billion-dollar annual global market opportunities. AVIM Therapy is a bioelectronic treatment for hypertension, the leading risk factor for death worldwide, and is designed to be delivered by a pacemaker and achieve immediate, substantial and sustained reductions in blood pressure in patients with hypertensive heart disease. The Company has a strategic collaboration with Medtronic, one of the largest medical device companies in the world and the global leader in cardiac pacing therapies, for the development and commercialization of AVIM Therapy for the treatment of uncontrolled hypertension in pacemaker-indicated patients. AVIM Therapy has FDA Breakthrough Device Designation for these patients, as well as an estimated 7.7 million total patients in the U.S. with uncontrolled hypertension despite medical therapy and increased cardiovascular risk. Virtue SAB is a highly differentiated, first-of-its-kind non-coated drug delivery angioplasty balloon system designed to deliver a large liquid dose of proprietary extended-release formulation of sirolimus, SirolimusEFR™, for the treatment of atherosclerotic artery disease, the leading cause of mortality worldwide. Virtue SAB has been granted Breakthrough Device Designation by the FDA for the treatment of coronary in-stent restenosis, coronary small vessel disease and below-the-knee peripheral artery disease. For further information about Orchestra BioMed, please visit www.orchestrabiomed.com, and follow us on LinkedIn.

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 trial, 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 trial 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 ongoing pivotal trials, realizing the clinical and commercial value of AVIM Therapy and Virtue SAB, the potential safety and efficacy of the Company's product candidates, including the ability of AVIM Therapy to deliver sustained reductions in blood pressure and cardiac hemodynamic benefits, 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, 2025, which was filed with the SEC on March 12, 2026.

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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