Orchestra BioMed Announces Presentations Highlighting AVIM Therapy Potential Impact on Hypertensive Heart Disease and Heart Failure at THT and CRT

March 3, 2026

NEW HOPE, Pa., March 03, 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 presentations that will be given at the Technology Heart Failure and Therapeutics ("THT") and Cardiovascular Research Technologies ("CRT") 2026 Meetings highlighting the potential for the Company's Atrioventricular Interval Modulation Therapy ("AVIM Therapy") program in hypertensive heart disease and heart failure patients.

Presentation at THT 2026
Atrioventricular Interval Modulation Therapy: A Device-Based Therapy for Hypertension and Diastolic Heart Failure *(Tuesday, March 3, 2026, at 10:20am ET)*

- **Presenter:** David E. Kandzari, MD, FACC, MSCAI, Chief, Piedmont Heart Institute and Cardiovascular Services, Co-Principal Investigator for the BACKBEAT global pivotal study ("BACKBEAT Study")
- Dr. Kandzari will present mechanistic and clinical data highlighting the potential application of AVIM Therapy to treat diastolic dysfunction, a precursor of heart failure with preserved ejection fraction ("HFpEF"). The presentation will highlight pilot study data demonstrating sustained systolic blood pressure reductions associated with delivery of AVIM Therapy alongside improvements in cardiac hemodynamics, ventricular remodeling, and echocardiographic measures of diastolic function.

Dr. Kandzari commented, "AVIM Therapy has the potential to offer a new treatment paradigm that leverages active implantable devices with a long, established clinical history. The BACKBEAT Study, which continues to accelerate and build momentum, is focused on evaluating the potentially compelling benefit of this novel, always-on therapy for hypertension in pacemaker-indicated patients. In parallel, pilot study clinical and mechanistic results demonstrate that modulation of the atrioventricular interval drives hemodynamic and autonomic nervous system function impact that could help patients with HFpEF, a population with limited therapeutic options. Together, the presentations at the THT and CRT meetings underscore that AVIM Therapy has the future potential to benefit both hypertensive heart disease and heart failure patients."

Presentation at CRT 2026
Update on AVIM Therapy: A Pacemaker-Based Treatment for Hypertension *(Sunday, March 8, 2026, at 9:18am ET)*

- **Presenter:** Dan Burkhoff, MD, PhD, Director, Heart Failure, Hemodynamics and MCS Research, Cardiovascular Research Foundation
- Dr. Burkhoff will summarize the robust body of pilot study clinical evidence demonstrating sustained and reproducible systolic blood pressure reductions associated with delivery of AVIM Therapy, along with improvements in hemodynamics, ventricular remodeling, and stable long-term outcomes in pacemaker-indicated patients with hypertension.

Dr. Burkhoff added, "In pilot studies, AVIM Therapy demonstrated an immediate reduction in systolic blood pressure that starts upon treatment activation and persists through nearly four years of follow-up. Long-term washout pilot study data demonstrating reproducible blood pressure reduction without evidence of disease progression further highlight the unique potential clinical utility of this therapy. Sustained blood pressure control in higher risk, older, comorbid patients that does not require additional patient adherence to daily medications can have important clinical impact in a population where blood pressure management is essential to reducing the risk of stroke, myocardial infarction, and heart failure."

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 as a firmware upgrade to 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, 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 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 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, 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.

Investor Contact:
Silas Newcomb
Orchestra BioMed
Snewcomb@orchestrabiomed.com

Media Contact:
Kelsey Kirk-Ellis
Orchestra BioMed
kkirkellis@orchestrabiomed.com