Orchestra BioMed to Showcase Transformative Potential of AVIM Therapy in Keynote Presentation on Hypertensive Heart Disease at Georgia Innovation Summit

October 9, 2025

- *Presentation to provide comprehensive overview of AVIM Therapy clinical evidence demonstrating the potential to halt the progression of hypertensive heart disease*
- *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 received 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., Oct. 09, 2025 (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 a data summary supporting the transformative potential of Atrioventricular Interval Modulation ("AVIM") Therapy in the management of hypertensive heart disease will be presented in a keynote talk at the Georgia Innovation Summit in Tbilisi, Georgia on October 10, 2025. The presentation, to be delivered by Avi Fischer, MD, Senior Vice President of Medical Affairs and Innovation at Orchestra BioMed, will showcase AVIM Therapy as a novel, device-based therapeutic approach targeting hypertensive heart disease progression and its potential to redefine standards of care.

Dr. Fischer commented, "This keynote presentation reflects the growing global recognition of AVIM Therapy as a novel, device-based therapy, poised to reshape the future of hypertension care. Hypertension is the principal driver of diastolic dysfunction, which accelerates the development of heart failure. Despite widespread use of antihypertensive therapies, many patients continue to progress along the disease pathway, underscoring the importance of novel therapeutic approaches. The collective body of AVIM Therapy clinical data demonstrates its potential to directly modulate the progression of hypertensive heart disease, offering the potential to intervene earlier in the course of the disease to improve long-term outcomes, transform patient care, and ultimately create lasting value for all stakeholders."

The keynote presentation will provide a comprehensive overview of clinical and mechanistic AVIM Therapy results from pilot and long-term follow-up studies, highlighting the therapy's consistent favorable clinical impact on blood pressure and cardiac function:

- **Immediate, substantial, and sustained blood pressure reduction**
  - **MODERATO I pilot study:** 24-hour ambulatory systolic blood pressure ("aSBP") reduced by 11.6 mmHg at 1 day and 10.1 mmHg at 3 months
  - **MODERATO II pilot study:** 24-hour aSBP reduced by 15.6 mmHg at 1 day and 11.1 mmHg at 6 months, as well as an office systolic blood pressure reduction of 17.5 mmHg at 24 months
- **Favorable impact on cardiac hemodynamics after 24 months of treatment (MODERATO I)**
  - Significant reductions in heart rate and end-diastolic volume
  - No significant changes in end-systolic volume or ejection fraction, supporting safety
- **Improvement in echocardiographic measures of diastolic function (MODERATO II)**
  - Significant increases in e' and E/A ratio, indicating improved myocardial relaxation and diastolic compliance
- **Potential to halt hypertensive heart disease progression**
  - Long-term follow-up demonstrates sustained blood pressure reduction with reversibility of effect and absence of rebound hypertension upon deactivation
  - Favorable effects were reproducible after a 7-day washout period followed by reactivation, underscoring durability and reliability

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 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 and 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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