Orchestra BioMed Announces AVIM Therapy to Be Featured in Two Sessions at HRX Live 2026

September 16, 2026

Sessions will highlight Orchestra BioMed's collaboration with Medtronic and explore the potential for AVIM Therapy to treat hypertensive heart disease in pacemaker-indicated patients and beyond

NEW HOPE, Pa., Sept. 16, 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 that its investigational Atrioventricular Interval Modulation Therapy ("AVIM Therapy") will be featured in two sessions at HRX Live 2026 -- the Heart Rhythm Society's annual innovation-focused meeting taking place September 18-20, 2026, in Atlanta, Georgia.

A sponsored roundtable will focus on Orchestra BioMed's strategic collaboration with Medtronic to accelerate the development and commercialization of AVIM Therapy for the treatment of uncontrolled hypertension in patients indicated for a cardiac pacemaker. A second panel will explore the expanding role of permanent pacing beyond bradycardia, including AVIM Therapy as an emerging cardiac pacing-based approach to treat uncontrolled hypertension and hypertensive heart disease.

Roundtable on AVIM Therapy & Medtronic Collaboration

Accelerating AVIM Therapy for Hypertensive Heart Disease: The Medtronic / Orchestra BioMed Innovation Partnership (Saturday, September 19, 2026, 9:40-10:25 a.m. ET)

- **Moderator:** Vivek Reddy, MD, Director of Cardiac Arrhythmia Services, The Mount Sinai Fuster Heart Hospital; Director of Electrophysiology, Mount Sinai Health System
- **Panelists:** Robert C. Kowal, MD, PhD, Vice President and General Manager of Cardiac Pacing Therapies, Medtronic Electrophysiology Therapies; Andrea Russo, MD, Academic Chief, Division of Cardiology, and Director of Cardiac Electrophysiology and Arrhythmia Services, Cooper University Hospital; Charles Love, MD, Professor of Medicine and Director of Cardiac Rhythm Device Services, Johns Hopkins Hospital; and David Hochman, Chairman, Chief Executive Officer and Founder of Orchestra BioMed

The panel will explore AVIM Therapy's mechanism of action and potential as a cardiac pacing-based treatment for hypertension, the most common comorbidity among pacemaker-indicated patients. Panelists will review clinical evidence showing immediate, substantial and sustained reductions in systolic blood pressure, as well as improvements in hemodynamics and cardiac function. They will also provide an update on the BACKBEAT Global Pivotal Trial ("BACKBEAT Trial") and examine the Orchestra BioMed and Medtronic collaboration as a differentiated model for accelerating medical device innovation. Dr. Reddy serves as Executive Chairman of the BACKBEAT Trial Steering Committee, Dr. Russo serves as Co-Principal Investigator of the trial, and Dr. Love serves as a member of the Steering Committee.

Dr. Reddy commented, "AVIM Therapy exemplifies the kind of innovation HRX was created to showcase. It builds on the long-established pacemaker platform, expanding cardiac pacing into hypertension therapy, a critically important area of clinical need, the leading risk factor for death worldwide, and the most common comorbidity in pacemaker patients. The BACKBEAT Trial is nearing enrollment completion, and the collaboration between Orchestra BioMed and Medtronic offers a compelling model for accelerating the development of a potentially transformative therapy for the large population of patients living with uncontrolled hypertension."

Panel Session Featuring AVIM Therapy

Permanent Pacing but not for Bradycardia (Friday, September 18, 2026, 4:45-5:30 p.m. ET)

- **Moderator:** Robert C. Kowal, MD, PhD, Vice President and General Manager of Cardiac Pacing Therapies, Medtronic Electrophysiology Therapies
- **Panelists:** Prof. Karl-Heinz Kuck, MD, University Heart Center Lübeck; Andrea Russo, MD, Cooper University Hospital; Margaret Infeld, MD, Tufts Medical Center; Daniel Friedman, MD, Duke University School of Medicine; and Daniel Lustgarten, MD, PhD, University of Vermont Medical Center

This panel will explore the expanding role of permanent cardiac pacing beyond the treatment of bradycardia. AVIM Therapy will be

among several emerging pacing-based applications featured in the discussion.

David Hochman, Chairman, Chief Executive Officer and Founder of Orchestra BioMed, added, "The inclusion of AVIM Therapy in two HRX Live 2026 sessions reflects growing recognition within the electrophysiology community that AVIM Therapy can play a significant role in expanding the therapeutic value of cardiac pacing. We look forward to engaging with the clinicians, innovators and industry leaders shaping the future of cardiovascular care. These discussions will focus on AVIM Therapy's potential to address the significant unmet need among patients with uncontrolled hypertension and hypertensive heart disease."

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 Designations 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 trial is evaluating 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 two Breakthrough Device Designations 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 filed with the U.S. Securities and Exchange Commission on March 12, 2026 as updated by any risk factors disclosed under the heading "Item 1A. Risk Factors" in Part II of the Company's subsequently filed quarterly reports on Form 10-Q.

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