Orchestra BioMed Announces AVIM Therapy and Virtue SAB Program Presentations at ICI Meeting

December 8, 2025

- *Joint presentation by Orchestra BioMed and Medtronic leadership to discuss ongoing strategic collaboration for development and commercialization of AVIM Therapy for treatment of uncontrolled hypertension in patients indicated for a pacemaker*

NEW HOPE, Pa., Dec. 08, 2025 (GLOBE NEWSWIRE) -- Orchestra BioMed Holdings, Inc. (Nasdaq: OBIO, "Orchestra BioMed" or the "Company"), a biomedical innovation company accelerating high-impact technologies to patients through risk-reward sharing partnerships, today announced three presentations at the 2025 Innovation in Cardiology Intervention ("ICI") meeting in Tel Aviv, Israel, including two presentations focused on Atrioventricular Interval Modulation Therapy ("AVIM Therapy") and one focused on Virtue® Sirolimus AngioInfusion™ Balloon ("Virtue SAB").

The AVIM Therapy presentations will highlight the structure and operational strength of the Company's strategic collaboration with Medtronic, plc (NYSE: MDT, "Medtronic"), as well as the therapy's potential clinical utility in hypertensive heart disease.

- **The Power of Partnerships: Orchestra BioMed and Medtronic's Collaboration to Advance AVIM Therapy to Patients**, *presented by David Hochman, Chairman and Chief Executive Officer of Orchestra Biomed and Robert C. Kowal, M.D., Ph.D., Vice President and General Manager of Cardiac Pacing Therapies within the Medtronic Cardiac Rhythm Management operating unit* (December 9, 2025; 14:00 IST / 07:00 AM EST)
- **AVIM Therapy for the Treatment of Hypertensive Heart Disease**, *presented by Avi Fischer, M.D., Senior Vice President of Medical Affairs and Innovation, Orchestra Biomed* (December 8, 2025; 15:12 IST / 08:12 AM EST)

The Virtue SAB presentation will provide insights into the novel design of this first non-coated drug delivery system for coronary artery disease treatment, as well as the Virtue IDE trial focused on coronary in-stent restenosis.

- **Virtue SAB and the Virtue Trial: A Next-Generation, Non-Coated Sirolimus-Eluting AngioInfusion Balloon and IDE Coronary ISR Trial vs. AGENT PCB**, *presented Bill Little, Executive Vice President of Corporate Development and Strategy* (December 8, 2025; 14:00 JST / 07:00 AM EST)

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 drug delivery angioplasty balloon system designed to deliver a 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 ISR, 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 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 Breakthrough Device Designation by the FDA for the treatment of uncontrolled hypertension in patients who have increased cardiovascular risk.

About Virtue SAB

Virtue SAB is a highly differentiated, first-of-its-kind drug delivery angioplasty balloon system designed to deliver a proprietary extended-release formulation of sirolimus, SirolimusEFR™. It uses a non-coated microporous AngioInfusion™ Balloon to protec the drug in transit and consistently deliver a large liquid dose, overcoming certain limitations of drug-coated balloons. SirolimusEFR delivered by Virtue SAB has been shown in published preclinical series involving hundreds of arterial deliveries to achieve sustained tissue levels well above the known required therapeutic tissue concentration for inhibiting restenosis (1 ng/mg tissue) for the entire critical healing period of approximately 30 days. Virtue SAB demonstrated positive three-year clinical data in coronary ISR in the SABRE study, a multi-center, prospective, independent core lab-adjudicated clinical study of 50 patients conducted in Europe. Virtue SAB has been granted Breakthrough Device Designation by the FDA for the treatment of coronary ISR, coronary small vessel disease and peripheral artery disease below-the-knee.

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