# Orchestra BioMed Announces AVIM Therapy Program Presentations at ICI Meeting

December 9, 2024

NEW HOPE, Pa., Dec. 09, 2024 (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 two presentations at the 2024 Innovation in Cardiology Intervention (“ICI”) meeting in Tel Aviv, Israel. The presentations will provide insights on the ongoing BACKBEAT global pivotal study, as well as an overview of the novel mechanism of action of AVIM therapy and supporting clinical evidence for the treatment of uncontrolled hypertension in patients indicated for a dual-chamber pacemaker. The presentations will be part of a broad scientific program of important developments in cardiology, in a session focused on “*Device-Based Hypertension Treatment.*”

**Insights into the BACKBEAT IDE Study**, *presented by Avi Fischer, M.D., Senior Vice President of Medical Affairs and Innovation, Orchestra Biomed* (December 9, 2024; 14:12 JST / 07:12 AM EST)

- Dr. Fischer's presentation will focus on the unmet medical need in patients who are indicated for a pacemaker and also have uncontrolled hypertension despite the use of antihypertensive medication. This group of patients is the target population for the BACKBEAT global pivotal study, which reflects the increased risks associated with elevated systolic blood pressure in older comorbid patients.

**AVIM Mechanism of Action & Supporting Clinical Evidence**, *presented by Andrea Russo, M.D., FACC, FHRS, FAHA, Professor of Medicine, Cooper Medical School of Rowan University, Academic Chief, Division of Cardiology, Director, Electrophysiology and Arrhythmia Services, Cooper University Hospital, and Co-Principal Investigator of the BACKBEAT study* (December 9, 2024; 15:00 JST / 08:00 AM EST)

- Dr. Russo's session will delve into the unique mechanism of action of the AVIM therapy and robust body of supporting clinical data. Dr. Russo will detail how AVIM therapy is designed to modulate the autonomic nervous system to immediately, substantially and persistently reduce blood pressure, as demonstrated in the MODERATO I and II pilot studies.

**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, a significant 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, also known as BackBeat CNT™, 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. The BACKBEAT (BradycArdia paCemaKer with atrioventricular interval modulation for Blood prEssure treAtmenT) global pivotal study will further evaluate the safety and efficacy of AVIM therapy in lowering blood pressure in a similar target population of patients who have been indicated for, and recently implanted with, a dual-chamber cardiac pacemaker.

**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 of the Company's ongoing BACKBEAT global pivotal study, 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, 2023, which was filed with the Securities and Exchange Commission ("SEC") on March 27, 2024 , and under the heading "Item1A. Risk Factors" in Part II of the Company's quarterly report on Form 10-Q for the quarter ended September 30, 2024, filed with the SEC on November 12, 2024.*

*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.*

**Contact**:
Kelsey Kirk-Ellis
Orchestra BioMed
484-682-4892
Kkirkellis@orchestrabiomed.com