Orchestra BioMed Announces Rollout of FDA-Approved BACKBEAT Global Pivotal Study Protocol Update Significantly Expanding Patient Eligibility

August 8, 2025

- *FDA-approved protocol update significantly expands patient eligibility criteria for the BACKBEAT global pivotal study ("BACKBEAT study"), resulting in an estimated more than 24-fold increase in the potentially eligible patient pool as compared to original study protocol*
- *Expanded eligibility criteria now include screening of any hypertensive patients who have received or are scheduled to receive a Medtronic Azure™ or Astra™ pacemaker, including device replacements*

NEW HOPE, Pa., Aug. 08, 2025 (GLOBE NEWSWIRE) -- Orchestra BioMed Holdings, Inc. (Nasdaq: OBIO, "Orchestra BioMed" or the "Company"), a biomedical company accelerating high-impact technologies to patients through risk-reward sharing partnerships, today announced the roll out of a protocol update, approved by the U.S. Food and Drug Administration ("FDA"), that significantly expands patient eligibility criteria for enrollment of the BACKBEAT study evaluating AVIM therapy in pacemaker-indicated patients with uncontrolled hypertension despite the use of antihypertensive medications.

Key updates to eligibility criteria now include patients with:

- Medtronic Astra or Azure dual-chamber pacemakers with sufficient battery life implanted for any reason;
- Medtronic Astra or Azure dual-chamber pacemakers that are first device implants or implanted to replace an existing pacemaker; and
- New York Heart Association ("NYHA") class I or class II symptomatic heart failure.

Orchestra BioMed estimates that the BACKBEAT study protocol update increases the eligible potential patient pool at participating study centers by more than 24-fold as compared to the original protocol and supports the Company's mid-2026 target for completion of enrollment. The Company initiated rollout of the updated protocol in the third quarter of 2025 with full implementation expected in the fourth quarter.

"These expanded eligibility criteria significantly increase the pool of potentially eligible patients available for enrollment in the BACKBEAT study at participating study centers. They also better align the study patient population with the key characteristics of the FDA Breakthrough Device Designation for AVIM therapy, which we estimate represents a patient population of millions of U.S. patients who need better therapeutic options to manage elevated systolic blood pressure and the corresponding higher risk of heart attack, stroke, heart failure and other morbid and mortal events," said David Hochman, Chairman and CEO of Orchestra BioMed. "We believe these updates reinforce the relevance and potential impact of the BACKBEAT study as well as better position us to complete the BACKBEAT study in a timely manner."

"Unlike traditional antihypertensive therapies, AVIM therapy has been designed specifically to address the needs of the older, higher risk hypertensive patients who often also need a pacemaker," commented Andrea Russo, M.D., Academic Chief, Division of Cardiology, Director of Cardiac Electrophysiology and Arrhythmia Services, Cooper University Hospital, and Co-Principal Investigator of the BACKBEAT study. "The ability to activate AVIM therapy during the 10 to 12-year typical device lifecycle of a pacemaker reflects the practical and transformative potential of this therapy for this group of patients. With expanded patient eligibility criteria, the BACKBEAT study population will now better encompass a real-world population of older, pacemaker-indicated patients with uncontrolled hypertension and increased cardiovascular risk."

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 AVIM therapy for the treatment of uncontrolled hypertension, the leading risk factor for death worldwide. Orchestra BioMed is also developing Virtue 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 uncontrolled 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. The Company has received four Breakthrough Device Designations from the U.S. FDA across these two core programs, reflecting the significant potential of its technologies to address high unmet needs in cardiovascular care. 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 uncontrolled 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 by using cardiac physiologic pacing for the treatment of uncontrolled hypertension in patients who have preserved left ventricular systolic function and are at 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 effect of study protocol on the potentially eligible patient pool, the timing of completion of enrollment for the BACKBEAT study, the timing of full implementation of updated study protocol, , the potential benefits of Breakthrough Device Designation, the potential of the Company's technologies to address high unmet needs in cardiovascular care, 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.

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