Orchestra BioMed's AVIM Therapy Global Intellectual Property Estate Reaches 137 Issued Patents for the Treatment of Hypertension and Heart Failure

May 7, 2025

- *Secured ten new fully-issued patents related to hypertension treatment during last 12 months, bringing global issued patent estate total for this condition to 120 patents*
- *Patent estate covering atrioventricular interval modulation ("AVIM") therapy now includes 46 issued U.S. patents and 91 patents outside the U.S. that collectively comprise over 2100 claims related to the treatment of hypertension as well as heart failure*
- *Heart failure pipeline program now protected by an additional 17 issued global patents*
- *FDA recently granted Breakthrough Device Designation to AVIM therapy for use in patients with uncontrolled hypertension at increased cardiovascular risk, including those at risk of heart failure*

NEW HOPE, Pa., May 07, 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 continued expansion of its global intellectual property (IP) estate supporting its proprietary AVIM therapy pipeline (formerly known as Cardiac Neuromodulation Therapy or "CNT"). Over the past 12 months, the Company has secured 10 new patents related to treatment of hypertension. The Company has also secured a total of 17 patents covering application of the technology for treatment of heart failure, significantly expanding the reach of its IP platform.

"We are very proud of the continued expansion of our intellectual property portfolio supporting AVIM therapy, which we are actively evaluating for the treatment of hypertension in the BACKBEAT global pivotal study in collaboration with Medtronic," commented David Hochman, Chairman and Chief Executive Officer of Orchestra BioMed. "Over the past year, we have strengthened our patent estate with ten newly issued patents covering the treatment of hypertension. Our issued hypertension-specific patent portfolio is now 120 patents strong and we expect it to continue to grow in the future. Equally exciting is our growing heart failure treatment patent estate which is now comprised of seventeen issued patents. This extraordinary array of intellectual property reflects our strategic commitment to protect our proprietary, high-impact device-based therapy which we believe can help physicians better address the needs of patients with hypertension, the leading global risk factor for death, as well as heart failure, which affects more than 64 million people worldwide."

AVIM therapy is currently being evaluated in the BACKBEAT global pivotal study for the treatment of uncontrolled hypertension in patients who have or are indicated to receive a pacemaker. This population reflects the broader population of people living with high blood pressure who are at elevated risk for severe cardiovascular events and comorbidities such as myocardial infarction, stroke and heart failure, underscoring the potential broader impact of AVIM therapy beyond blood pressure management. AVIM therapy was recently granted Breakthrough Device Designation by the U.S. Food and Drug Administration ("FDA") for the treatment of uncontrolled hypertension with increased cardiovascular risk, regardless of an indication for a pacemaker to treat a cardiac rhythm disorder.

The Orchestra BioMed global intellectual property portfolio related to the treatment of hypertension and heart failure with AVIM therapy includes patent protection in key markets, including the United States, Europe, Japan, and China.

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 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. 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 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 further 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.

About the FDA Breakthrough Device Program

The FDA Breakthrough Device Program, established in 2015, is designed to expedite the development, review, and potential market access of medical devices that may offer more effective treatment or diagnosis for life-threatening or irreversibly debilitating conditions. The designation provides manufacturers with prioritized FDA review and early, frequent interactions with agency experts to efficiently address development and regulatory considerations. Breakthrough status may also support streamlined reimbursement pathways, including eligibility for New Technology Add-on Payments (NTAP) and Transitional Pass-Through Payments (TPT), by helping to demonstrate substantial clinical improvement.

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 expected coverage and future growth of the Company's intellectual property portfolio, the potential efficacy, safety and commercial value of the Company's commercial product candidates, including the ability of AVIM therapy to favorably influence ventricular function, implementation of the Company's ongoing BACKBEAT global pivotal study, the potential benefits of receiving a Breakthrough Device Designation, including its ability to expedite FDA reviews and streamline reimbursement pathways, the ability of the Company's partnerships to accelerate clinical development, and the Company's 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 U.S. Securities and Exchange Commission on March 31, 2025, 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.

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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