



FDA Grants Orchestra BioMed Additional Breakthrough Device Designation for AVIM Therapy

April 30, 2026

- *Atrioventricular Interval Modulation ("AVIM") Therapy Food and Drug Administration ("FDA") Breakthrough Device Designations span the broader population of patients with uncontrolled hypertension despite medication at increased cardiovascular risk and the specific pacemaker-indicated population being evaluated in the BACKBEAT Trial*
- *The addressable U.S. patient population for AVIM Therapy, based on the indications for use specified in its Breakthrough Device Designations, comprises over 7.7 million adults with hypertension despite medication*
- *Breakthrough Device Designation supports favorable reimbursement pathways, including potential eligibility for New Technology Add-on Payment ("NTAP") and Transitional Pass-Through ("TPT") payment, which can facilitate broader, more timely patient access and provider adoption*

NEW HOPE, Pa., April 30, 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 the FDA has granted a second Breakthrough Device Designation ("BDD") for AVIM Therapy specific to patients with uncontrolled hypertension despite the use of anti-hypertensive medications, and an indication for a pacemaker.

Together, the two BDDs for AVIM Therapy cover indications that encompass both the broader population of patients with uncontrolled hypertension despite medication and increased cardiovascular risk as well as the specific pacemaker-indicated population with uncontrolled hypertension being evaluated in the BACKBEAT Global Pivotal Trial ("BACKBEAT Trial"), which Orchestra BioMed is conducting in collaboration with Medtronic (NYSE: MDT). This additional BDD supports strategic optionality for the clinical, regulatory and commercial reimbursement strategies for AVIM Therapy for both the pacemaker population and potential future expansion populations with uncontrolled hypertension and increased cardiovascular risk.

"We are pleased to receive this additional Breakthrough Device Designation from the FDA. We believe it is directly aligned with the patient population being studied in our ongoing BACKBEAT Trial which we are executing in collaboration with Medtronic," said **David Hochman, Chairman and Chief Executive Officer of Orchestra BioMed**. "Continued alignment from the FDA, alongside our strategic relationship with Medtronic and accelerated enrollment in the BACKBEAT Trial, puts us in a strong position to advance AVIM Therapy to pivotal trial results."

Orchestra BioMed has a strategic collaboration with Medtronic, the global market leader in cardiac pacing therapies, for development and commercialization of AVIM Therapy for the treatment of uncontrolled hypertension in pacemaker-indicated patients. Under the terms of the existing collaboration agreement, Medtronic holds the right of first negotiation to expand its licensing agreement with Orchestra BioMed to obtain global rights to commercialize AVIM Therapy for the treatment of uncontrolled hypertension in patients that do not have an indication for a pacemaker.

The FDA Breakthrough Devices Program, which reflects the FDA's commitment to device innovation and protecting public health, is designed to expedite the development of and provide priority review for innovative medical technologies that have the potential to significantly improve outcomes for patients with serious or life-threatening conditions. To be eligible for this designation, a device must demonstrate the potential to provide more effective treatment or diagnosis of a life-threatening or irreversibly debilitating condition. In addition, the device must meet at least one of the following criteria: it must represent breakthrough technology, have no approved or cleared alternatives, offer significant advantages over existing options, or be determined by the FDA to be in the best interest of patients.

Beyond regulatory acceleration, the BDD may also support favorable reimbursement pathways, including eligibility for incremental inpatient reimbursement through the New Technology Add-on Payment and outpatient Transitional Pass-Through payments under the Centers for Medicare & Medicaid Services programs. These mechanisms may help facilitate more timely access to breakthrough technologies while supporting provider adoption and patient access.

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 AngiInfusion[™] 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](https://www.linkedin.com/company/orchestra-biomed).

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 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 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, the potential benefits of BDD, including its ability to expedite FDA reviews and support favorable reimbursement pathways, 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, 2025, which was filed with the SEC on March 12, 2026.

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.

Investor Contact:

Silas Newcomb
Orchestra BioMed
Snewcomb@orchestrabiomed.com

Media Contact:

Kelsey Kirk
Orchestra BioMed
kkirkellis@orchestrabiomed.com