Orchestra BioMed Announces Virtue SAB Presentation at TCT 2026

October 29, 2026

- *Presentation will highlight Virtue SAB's fundamentally different approach of infusing a large liquid volume of proprietary extended-release SirolimusEFR™ directly into and throughout the vessel wall.*
- *Virtue SAB's mechanism is designed to achieve sustained, transmural sirolimus tissue levels substantially exceeding those achieved by drug-eluting stents and drug-coated balloons.*
- *The Virtue Trial, a pivotal, head-to-head, randomized controlled IDE trial of Virtue SAB versus a commercially available drug-coated balloon in coronary in-stent restenosis, is currently enrolling.*

NEW HOPE, Pa., Oct. 29, 2026 (GLOBE NEWSWIRE) -- Orchestra BioMed Holdings, Inc. (Nasdaq: OBIO) ("Orchestra BioMed" or the "Company"), a biomedical innovation company accelerating high-impact technologies to patients through strategic collaborations with market-leading global medical device companies, today announced that its Virtue® Sirolimus AngioInfusion™ Balloon ("Virtue SAB") will be featured in a presentation at Transcatheter Cardiovascular Therapeutics ("TCT") 2026. TCT, the Cardiovascular Research Foundation's annual scientific symposium and the world's premier educational meeting in interventional cardiovascular medicine, will take place October 31–November 3, 2026, at the San Diego Convention Center in San Diego, California.

The presentation will be delivered by Allen Jeremias, MD, Co-Principal Investigator of the Virtue Trial and Director of Interventional Cardiology Research and Director of the Cardiac Catheterization Laboratory at St. Francis Hospital & Heart Center. Dr. Jeremias will review the differentiated mechanism of action of Virtue SAB, the preclinical and clinical evidence supporting it, and the design of the Virtue Trial, the Company's actively enrolling U.S. Investigational Device Exemption ("IDE") pivotal trial comparing Virtue SAB head-to-head with the AGENT™ paclitaxel-coated balloon for the treatment of coronary in-stent restenosis ("ISR") (NCT07045194).

Presentation Details

The Virtue Sirolimus AngioInfusion Balloon (SAB): Differential Mechanism, Clinical Benefit, and Pivotal IDE Trial Design (Sunday, November 1, 2026, 9:03–9:10 a.m. PT)

- **Session:** TCT Innovation 2: Innovations in Intravascular Imaging and Coronary Technologies
- **Location:** Innovation Theater, Sails Pavilion, Upper Level, San Diego Convention Center
- **Presenter:** Allen Jeremias, MD

The presentation will focus on three key points related to Virtue SAB:

- **A fundamentally different approach to sirolimus delivery, uptake, and extended release:** Sirolimus is the proven antiproliferative drug with well-established safety and effectiveness, but its optimal benefit depends on achieving and sustaining sufficient drug concentrations in tissue through the healing period. Coating-based drug delivery is limited by dose, drug loss in transit, and uneven transfer and diffusion from the surface. Virtue SAB is designed to infuse a large liquid volume of submicron, particle-encapsulated SirolimusEFR directly into the vessel wall through a non-coated, microporous AngioInfusion Balloon to inhibit proliferation and modulate inflammation, the key drivers of restenosis.
- **Promising preclinical and clinical evidence:** Published preclinical data showed that Virtue SAB achieved sirolimus tissue concentrations exceeding those of published drug-eluting stents and drug-coated balloons benchmarks through the critical healing period. In the SABRE study in coronary ISR, Virtue SAB achieved a low three-year target lesion failure rate of 14.3% in all treated patients (intent-to-treat analysis), with no additional target lesion revascularizations between years one and three.
- **The head-to-head, randomized design of the Virtue Trial:** The Virtue Trial is a prospective, multicenter, randomized, single-blind, non-inferiority trial with a planned enrollment of approximately 740 patients comparing Virtue SAB with the commercially available AGENT™ paclitaxel-coated balloon.

Dr. Jeremias commented, "Patients with coronary in-stent restenosis frequently face renewed narrowing of a previously treated artery that requires another intervention. We need more durable treatment options that better address this recurring problem without adding another permanent layer of metal inside the artery. Virtue SAB offers the potential to achieve better vessel healing following intervention through optimized sirolimus drug delivery via balloon-based infusion. The Virtue Trial is an opportunity to

determine whether this novel approach can translate into meaningful clinical benefit for patients. I look forward to sharing this innovative technology and the pivotal IDE trial design with the TCT community."

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 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 (NYSE: MDT), 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 two FDA Breakthrough Device Designations. The BACKBEAT Global Pivotal Trial evaluating AVIM Therapy in this population has completed enrollment.

Virtue SAB is a first-of-its-kind, non-coated drug delivery AngioInfusion balloon system designed to infuse a large liquid dose of a proprietary extended-release formulation of sirolimus, SirolimusEFR™, for the treatment of atherosclerotic artery disease, the leading cause of mortality worldwide. Virtue SAB exceeded the published tissue concentrations of leading limus drug-eluting stents and demonstrated positive three-year clinical data in coronary ISR in the SABRE study, a multicenter, prospective, independent core laboratory–adjudicated pilot clinical study of 50 patients conducted in Europe. 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, in each case, within specified parameters. The Virtue Trial evaluating Virtue SAB for the treatment of coronary in-stent restenosis is currently enrolling patients.

CAUTION: Investigational device. Limited by United States law to investigational use.

For further information about Orchestra BioMed, please visit www.orchestrabiomed.com, and follow us on LinkedIn.

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 enrollment, timing, implementation and design of the Virtue Trial and the Company's other ongoing pivotal trials, the ability of data from the Virtue Trial to support regulatory approval in the U.S., 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 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 filed with the U.S. Securities and Exchange Commission on March 12, 2026, and in its subsequent 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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