Orchestra BioMed™ Receives FDA Breakthrough Device Designation for Virtue® Sirolimus-Eluting Balloon (SEB)

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First and only non-coated sirolimus-eluting angioplasty balloon system to show promising clinical results

Potential to offer significant advantages for treatment of coronary in-stent restenosis (ISR), a condition that represents over 10% of total interventional procedures

New Hope, PA – Orchestra BioMed, Inc. ("Orchestra BioMed" or the "Company"), a biomedical innovation company developing advanced therapeutic solutions to address major unmet healthcare needs, announced today that it has secured Breakthrough Device designation by the U.S. Food and Drug Administration (FDA) for its Virtue® Sirolimus-Eluting Balloon for the treatment of coronary in-stent restenosis (ISR).

Breakthrough Designation is granted to certain medical devices and device-led combination products that provide for a more effective treatment of life-threatening or irreversibly debilitating diseases. It enables manufacturers to provide patients and health care providers with timely access to medical devices by expediting their development, assessment, and review. Benefits of this designation include frequent interactions and feedback from FDA during the premarket review phase. Through this program, Orchestra BioMed can expect prioritized review of its submission for Virtue SEB.

"In Virtue SEB, we finally have a therapeutic innovation that truly warrants breakthrough designation for the treatment of coronary ISR, a particularly challenging condition for which available treatment options are limited," commented Dean Kereiakes, M.D., FACC, FSCAI, medical director of The Christ Hospital Heart and Vascular Center and professor of Clinical Medicine at The Ohio State University. "The unique design of Virtue SEB provides a reliable way to apply the proven anti-proliferative, anti-restenotic benefits of sirolimus during balloon angioplasty without the potential hazards of a permanent metal implant or a balloon coating that may produce downstream particulates and micro-emboli. Clinical results at three-year follow-up with Virtue SEB in ISR are very promising and I am very much looking forward to utilizing this exciting new technology in clinical trials in the U.S."

"We believe Virtue SEB addresses an important unmet clinical need and provides an improved treatment alternative for a patient population with limited options. It is the first and only non-coated angioplasty balloon that provides arterial delivery of sirolimus, the proven gold standard drug used on drug-eluting stents for preventing restenosis of treated arteries." commented Darren R. Sherman, president, chief operating officer and founder of Orchestra BioMed. "We plan to fully leverage the benefits of FDA Breakthrough Device designation as we seek to accelerate the U.S. clinical and regulatory development of Virtue SEB with the goal of providing physicians and patients with the benefits of our novel therapeutic device."

About Virtue® SEB and Coronary ISR

Virtue SEB is a novel, first-in-class non-coated drug-eluting balloon system that delivers sustained-release bioabsorbable nanoparticle-encapsulated Sirolimus, the proven gold-standard drug for preventing restenosis, to the artery during balloon angioplasty without the need for a coating. Virtue SEB's ability to reliably deliver sirolimus via bioabsorbable particles directly to the artery with an elution profile comparable to commercially available drug-eluting stents has been demonstrated in extensive non-clinical studies published in a peer-reviewed journal. Virtue SEB is the first and only non-coated sirolimus-eluting angioplasty balloon system to show promising clinical results in patients with coronary ISR.

Coronary ISR, the reclogging of an artery following the implant of a drug-eluting or bare metal stent, represents over 10% of total interventional cardiology procedures according the American College of Cardiology's National Cardiovascular Data Registry (NCDR) [2]. FDA approved treatment options, such as plain balloon angioplasty and brachytherapy, are limited and offer subpar clinical outcomes. Juan Granada, M.D., associate professor of Medicine at the Columbia University College of Physicians and Surgeons and president and CEO of Cardiovascular Research Foundation, presented three-year clinical results with Virtue SEB from the Sirolimus Angioplasty Balloon for In-Stent Restenosis (SABRE) Trial at the Transcatheter Cardiovascular Therapeutics (TCT) 2018 in San Diego, CA. In the SABRE trial, Virtue SEB demonstrated excellent efficacy and safety performance in a very challenging ISR patient population with predominantly long, diffuse lesions within stents that had been implanted, on average, nearly four years prior to the study enrollment. The per protocol primary safety and efficacy endpoint results of the study were as follows:

- 0.0% Major Adverse Cardiac Events (MACE) in hospital and at 30-day follow-up
- 0.12 mm Late Lumen Loss (LLL) at 6-month angiographic assessment
- 5.6% Target Lesion Failure (TLF) at 3 years

About Orchestra BioMed™

Orchestra BioMed, Inc. is a biomedical innovation company focused on developing high impact therapeutic solutions to address significant unmet needs in healthcare. The Company advances promising therapies through clinical development and aims to leverage strategic partnerships with established global leaders to optimize commercialization. This strategy positions Orchestra BioMed to generate long-term, high-margin cash flow from revenue sharing, royalty, licensing and product development agreements.

With a primary focus on the treatment of cardiovascular health issues that affect tens of millions of people worldwide, the Orchestra BioMed pipeline includes BackBeat Cardiac Neuromodulation Therapy, a patented implantable cardiac stimulation-based treatment for hypertension, and Virtue® Sirolimus-Eluting Balloon, a novel, first-in-class drug/device combination product that delivers programmed-release bioabsorbable

nanoparticle encapsulated Sirolimus to the artery during balloon angioplasty for treatment of atherosclerosis. Orchestra BioMed also has significant strategic ownership in other therapeutic device companies, including FreeHold Surgical (a wholly-owned subsidiary), Motus GI and Vivasure Medical.

Forward Looking Statements

Some of the statements made herein constitute forward-looking statements. These statements relate to future financial and other performance or anticipated plans and are identified by words such as "may," "will," "should," "expect," "could," "scheduled," "plan," "intend," "anticipate," "believe," "estimate," "potential," "propose" and "continue" or negative variants of such terms. These and similar forward-looking statements discuss the Company's future expectations and plans. 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. These statements are only estimates of future performance. Actual performance or events may not meet such expectations or estimates and may, in fact, differ materially.

Although the Company believes that the expectations reflected in the forward-looking statements made herein are reasonable, the Company cannot and does not guarantee future results, levels of activity, performance or achievements. Moreover, the Company does not assume any responsibility for the accuracy and completeness of such forward-looking statements in the future. The Company does not plan and, subject to applicable law, undertakes no obligation to update any of the forward-looking statements made herein after the date hereof in order to conform such statements to actual results.

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