Orchestra BioMed™ Announces FDA Breakthrough Device Designation for Virtue® Sirolimus-Eluting Balloon for Treatment of Below-the-Knee Peripheral Artery Disease

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First and only non-coated sirolimus-eluting angioplasty balloon system to receive Breakthrough Device designation for below-the-knee disease

Follows Breakthrough Device designation for Virtue Sirolimus-Eluting Balloon in coronary in-stent restenosis granted in Q2 2019

New Hope, PA – Orchestra BioMed ™, Inc., ("Orchestra BioMed" or the "Company"), a biomedical innovation company providing high-impact solutions for large unmet needs in procedure-based medicine, in partnership with Terumo Corporation (Terumo, TSE: 4543), one of the world's leading medical device manufacturers, today announced the Company has secured Breakthrough Device Designation by the U.S. Food and Drug Administration (FDA) for its Virtue Sirolimus-Eluting Balloon (SEB) in the treatment of below-the-knee (BTK) peripheral artery disease.

Peripheral artery disease (PAD) affects approximately 8.5 million people in the U.S and is growing dramatically in the elderly population.[1] BTK (infrapopliteal) atherosclerosis is the most common cause of critical limb ischemia (CLI), which is associated with a high rate of amputations and poor survival outcomes.[2] The treatment of BTK atherosclerotic disease is complex as lesions in these small diameter arteries tend to be diffuse, long and often involve calcification. Currently approved therapeutic options are limited and have been shown to be marginally effective, leaving substantial unmet need for more effective treatment options for BTK atherosclerosis.

"Virtue SEB's unique design enables delivery of sustained-release sirolimus during angioplasty without the need for coating or permanent implant. This highly differentiated design makes this product the ideal candidate for Breakthrough Device Designation in BTK peripheral artery disease," said James P. Zidar, MD, FACC, FSCAI, clinical professor of medicine, UNC Health Systems, physician-in-chief, Heart & Vascular Corporate. "Currently, there is a significant unmet need in the BTK stenosis treatment landscape. The presence of underlying comorbidities renders many patients unsuitable for bypass surgery. Angioplasty with plain balloons, which has been the default endovascular therapy for years, has a low success rate. Adding a proven anti-restenotic agent like sirolimus has the potential to enhance this treatment approach and drive better patient outcomes."

Virtue SEB is a novel, first-in-class drug/device combination product that delivers a sustained-release sirolimus formulation directly to the artery during balloon angioplasty without the need for a coating. Breakthrough Device Designation is granted to medical devices and device-led combination products that provide the potential for a more effective treatment option for life-threatening or irreversibly debilitating diseases. Manufacturers are then able to offer patients and healthcare providers quicker access to new medical devices by expediting the development, assessment, and review process.

"Our team is grateful that the FDA has recognized the potential value Virtue SEB can provide patients and physicians by granting this second Breakthrough Device Designation for an important arterial therapeutic indication," said Darren R. Sherman, president, chief operating officer and co-founder of Orchestra BioMed. "This designation will be critical as we continue to work with Terumo to accelerate Virtue SEB's global clinical and regulatory program in both coronary and peripheral indications. In BTK disease, treatment with Virtue SEB has the potential to improve long-term outcomes and reduce periprocedural complications which can extend hospital stay and increase cost of treatment."

About Virtue® SEB

Virtue SEB is a novel, first-in-class drug/device combination product that delivers sustained-release bioabsorbable encapsulated sirolimus, a proven drug for preventing restenosis, directly to the artery during balloon angioplasty without the need for a coating. Virtue SEB's ability to reliably deliver sirolimus via bioabsorbable sub-micron particles with a drug elution profile comparable to commercially available drug-eluting stents has been demonstrated in extensive preclinical studies published in a peer-reviewed journal.[3] Virtue SEB is the first and only non-coated sirolimus-eluting angioplasty balloon system to receive FDA Breakthrough Designation for below-the-knee stenosis as well as for coronary in-stent restenosis (ISR), another challenging indication for which the product has shown promising 3-year core-lab adjudicated efficacy and safety clinical results in the SABRE trial. Orchestra BioMed and Terumo plan to execute a global clinical program to gain regulatory approval for commercial sale of Virtue SEB in multiple markets and indications including coronary ISR and below-the-knee stenosis.

About Orchestra BioMed ™

Orchestra BioMed is a biomedical innovation company providing high-impact solutions for large unmet needs in procedure-based medicine. The Company partners with established market leaders to drive global commercialization of its products, establishing multiple long-term potential revenue streams and supporting further product development. Its current product pipeline was organically developed and features Virtue® Sirolimus-Eluting Balloon (SEB) for the treatment of artery disease, the leading cause of death worldwide, and BackBeat Cardiac Neuromodulation Therapy (CNT) for the treatment of hypertension, the leading contributing risk factor for death worldwide. The company has a global strategic partnership with Terumo Corporation, one of the world's largest medical device companies, for the development and commercialization of Virtue SEB. Orchestra BioMed's business model optimizes capital efficiency and cash flow by developing therapies with a high probability of success that fulfill a specific need, fit within current clinical workflow and deliver health-economic value. Orchestra BioMed is led by a multi-disciplinary team with a long track record of successful product development.

About Terumo ™ Corporation

Tokyo-based Terumo Corporation is one of the world's leading medical device manufacturers, with approximately US$6 billion in sales and operations in more than 160 nations. Founded in 1921, the company develops, manufactures and distributes world-class medical devices, including products for use in cardiothoracic surgery, interventional procedures and transfusion medicine; the company also manufactures a broad array of syringe and hypodermic needle products for hospital and physician-office use. Terumo contributes to society by providing valued products and services to the healthcare market, and by responding to the needs of healthcare providers and the people they serve. Terumo Corporation's shares are listed on the first section of the Tokyo Stock Exchange (No. 4543, Reuters symbol <4543.T>, or Bloomberg 4543: JP) and is a component of the Nikkei 225, Japan's leading stock index.

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.

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[1] CDC. 2016. Peripheral Arterial Disease Fact Sheet [online] Available at: https://www.cdc.gov/dhdsp/data_statistics/fact_sheets/fs_pad.htm[Accessed 7 August 2019]

[2] Fowkes FG, Rudan D, Rudan I, Aboyans V, Denenberg JO, McDermott MM, et al. Comparison of global estimates of prevalence and risk factors for peripheral artery disease in 2000 and 2010: a systematic review and analysis. Lancet 2013;382:1329-40

[3] Stefan V, Mathias V, Indulis K, et al. The SABRE Trial (Sirolimus Angioplasty Balloon for Coronary In-Stent Restenosis): Angiographic Results and 1-Year Clinical Outcomes, JACC Cardiovasc Interv. 2017 Oct 23;10(20):2029-2037. doi: 10.1016/j.jcin.2017.06.021