Orchestra BioMed™ Announces Global Strategic Partnership with Terumo Corporation for Development and Commercialization of Virtue® Sirolimus-Eluting Balloon

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Virtue® SEB is expected to become a flagship therapeutic product for Terumo and will strengthen its broad US and global portfolio of interventional solutions

Terms of the partnership include substantial up-front and milestone payments, equity investment, a strong commitment to global clinical program, as well as meaningful revenue sharing through royalty and exclusive drug formulation supply payments

Partnership validates Orchestra BioMed's strategy to leverage alliances with established market leaders to drive global commercialization of its high-impact products

New Hope, PA – Orchestra BioMed, Inc. (Orchestra BioMed), a biomedical innovation company providing high-impact solutions for large unmet needs in procedure-based medicine, today announced it has formed a global strategic partnership with Terumo Corporation (Terumo, TSE: 4543), one of the world's leading medical device manufacturers, for development and commercialization of Virtue ® Sirolimus-Eluting Balloon (SEB), one of its lead assets, in the percutaneous coronary and peripheral interventions field.

Virtue SEB is the first and only non-coated drug-eluting angioplasty balloon that delivers a proprietary bioabsorbable, sustained-release formulation of sirolimus, the gold standard drug for preventing restenosis following a percutaneous interventional procedure. In April, the U.S. Food and Drug Administration (FDA) granted Virtue SEB Breakthrough Device Designation for treatment of coronary in-stent restenosis (ISR), which provides prioritized regulatory review for this challenging cardiovascular condition that represents more than 10% of total interventional coronary procedures and for which available treatment options are limited. In a prospective study of very challenging ISR patients, Virtue SEB demonstrated excellent angiographic results at six months as well as outstanding clinical outcomes out to three years. Orchestra BioMed plans to conduct a near-term U.S. registrational trial for ISR.

- Under the terms of the agreement, Terumo will make a one-time, up-front payment of $30 million and an equity commitment of $5 million to Orchestra BioMed. Terumo will also make substantial future clinical and regulatory milestone payments to Orchestra BioMed.
- Terumo will also make a strong commitment to finance and execute a global clinical program in collaboration with Orchestra BioMed to gain regulatory approval for commercial sale of Virtue SEB in multiple markets and indications.
- Orchestra BioMed will share meaningfully in future commercial revenues of Virtue SEB through royalties and per unit payments as the exclusive supplier of the proprietary sustained-release sirolimus formulation used in Virtue SEB.
- Orchestra BioMed retains the rights to develop and license technology used in Virtue SEB for clinical applications outside of coronary and peripheral vascular interventions.

"We are delighted to be aligning with Terumo, which has a rich history of global leadership in medical devices. Terumo has a proven global distribution and operations infrastructure with the sales and marketing expertise necessary to make Virtue SEB broadly accessible to physicians and patients worldwide, pending regulatory approvals." said David Hochman, chairman and chief executive officer of Orchestra BioMed. "This strategic partnership is a major milestone for Orchestra BioMed. It validates our differentiated strategy to focus on the development of high-impact therapies while leveraging alliances with established market leaders, like Terumo, to drive global commercialization of our products."

"We are excited to partner with Orchestra BioMed and secure global rights to Virtue SEB, which we intend to make a flagship therapeutic product. It strongly compliments our broad US and global portfolio of interventional solutions. We believe Virtue SEB is an important innovation that has the potential to address key unmet needs in the interventional vascular space, while fitting seamlessly within current clinical practice and workflow," said James Rushworth, CEO of Terumo Medical Corporation (North America) and chief commercial officer of the Interventional Systems Division of Terumo. "The unique design of Virtue SEB demonstrates Orchestra BioMed's deep knowledge of the needs of interventional cardiologists and its capability to deliver innovative solutions that have the potential to improve patient outcomes."

Virtue SEB strengthens the current cardiovascular product offering of Terumo Interventional Systems, Terumo Corporation's largest division, which includes a complete, solution-based product portfolio used in advanced coronary and peripheral endovascular treatments, with market-leading solutions for vascular access, lesion access and intervention. Orchestra BioMed and Terumo are seeking to make Virtue SEB the first drug-eluting balloon approved for coronary use in the U.S. Orchestra BioMed expects to initiate a U.S. registrational trial for Virtue SEB in ISR under an Investigational Device Exemption (IDE) from the FDA within the next year. Virtue SEB is currently not approved in any market, but Terumo and Orchestra BioMed plan to conduct trials to support global regulatory approvals in indications including ISR, small coronary vessels, peripheral artery disease below-the-knee and other indications. Terumo and Orchestra BioMed's objective is to commercialize Virtue SEB in the U. S., Japan, China, and other markets.

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® 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. 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 after the date hereof in order to conform such statements to actual results.

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