

Terumo secures exclusive global rights to Orchestra BioMed's SEB

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First and only non-coated drug-eluting angioplasty balloon that delivers a proprietary bioabsorbable, sustained-release formulation of sirolimus



Japan headquartered Terumo Corporation, a leading global medical device manufacturer has announced that it has secured exclusive global development and commercialization rights to Virtue® Sirolimus-Eluting Balloon (SEB) for percutaneous coronary interventions by entering into a strategic partnership with Orchestra BioMed, Inc., a biomedical innovation company providing high-impact solutions for large unmet needs in procedure-based medicine.

Under the terms of the agreement, Terumo will make a one-time, up-front payment of USD 30 million and an equity commitment of USD 5 million to Orchestra BioMed. Terumo will also make substantial future clinical and regulatory milestone payments to Orchestra BioMed.

Terumo will also make a 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.

Upon commercialization, Orchestra BioMed will share meaningfully in future commercial revenues of Virtue SEB through royalties and per unit payments as the exclusive supplier of its proprietary sustained-release formulation of sirolimus 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.

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 may expedite its development and 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.

James Rushworth, CEO of Terumo Medical Corporation (North America) and Chief Commercial Officer of the Interventional Systems Division of Terumo said, "We are excited to partner with Orchestra BioMed and secure global rights to Virtue SEB,

which we intend to make a flagship therapeutic product that 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 field of interventional vascular therapy while fitting seamlessly within current clinical practice and workflow. The highly differentiated, non-coated 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."

David Hochman, Chairman and Chief Executive Officer of Orchestra BioMed said, "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. This strategic partnership is a major milestone for Orchestra BioMed that 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."

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.