Orchestra BioMed™ Announces Presentation of 3-Year Clinical Results for Virtue® Sirolimus-Eluting Balloon at TCT 2018

September 24, 2018

Excellent Long-Term Safety and Efficacy Profile Demonstrate Potential to Offer Valuable New Treatment for Coronary In-Stent Restenosis

San Diego, CA – Orchestra BioMed, Inc. ("Orchestra BioMed" or the "Company"), a biomedical innovation company developing transformational therapeutic devices targeting major medical conditions, announced the 3-year clinical results from its Sirolimus Angioplasty Balloon for In-Stent Restenosis (SABRE) Trial at the Transcatheter Cardiovascular Therapeutics (TCT) 2018 in San Diego, CA. 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 the outcomes of SABRE trial, which demonstrated excellent efficacy and safety performance of the Virtue® Sirolimus-Eluting Balloon (SEB) in a very challenging patient population with predominantly long, diffuse restenosis lesions within stents that had been implanted an average of nearly 4 years prior to the study enrollment. The primary safety and efficacy per protocol 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
- No Target Lesion Revascularization (TLR) events following 6-month angiographic assessment

"The clear biological efficacy demonstrated by this study, despite complex and challenging cases, was consistent with the effective therapeutic delivery of sirolimus during angioplasty. The results with Virtue SEB compare favorably to proven drug-eluting stents (DES) and Paclitaxel-coated balloons (PCB) and outperform PCBs in some key safety metrics observed in other coronary in-stent restenosis trials," commented Stefan Verheye M.D., Senior Interventional Cardiologist at Antwerp Cardiovascular Center, ZNA Middelheim, Antwerp, Belgium and Principal Investigator in the SABRE study.

"We still do not have a perfect solution for the treatment of late stent failures and the 3- year results of the SABRE trial are very encouraging in the search to find a 'leave nothing behind solution' with a favorable safety profile and biological efficacy comparable to proven drug-eluting stents," said Dr. Granada.

The SABRE trial was a prospective, 50-patient multi-center study conducted in European centers. Twelve-month follow-up data from the SABRE study was published in JACC: Cardiovascular Interventions, October 2017. Clinicians in the study had 100% procedural success rate (per patient) with Virtue® SEB, indicating the ease of use of the system. By enabling the simultaneous delivery of a full therapeutic dose of sirolimus during angioplasty, Virtue® SEB aims to address long-term issues associated with late adverse events following treatment of coronary arteries with stents, which are permanent implants.

Unmet Clinical Needs Associated with Coronary In-Stent Restenosis

Although the original introduction of bare metal stents (BMS) significantly improved short- term outcomes observed with plain balloon angioplasty, extensive data shows late adverse events occur at an annual rate of approximately 2.1% following the year after implantation. Drug-eluting stents (DES), which currently exclusively utilize sirolimus or chemical analogs, were introduced to further advance the treatment of coronary restenosis. While the presence of a drug immediately following the implantation dramatically improved the TLF rates in the first year after implantation over BMS, longer term TLF rates are higher (2-4%/year) even with 2nd generation DES. It is believed that the long-term events are driven by the permanent presence of a metal stent in the artery. Bioabsorbable stents, led by Absorb GT1 Bioabsorbable Vascular Scaffold (Abbott), were designed to overcome the permanent implant issue by dissolving over 24-36 months following implantation and showed promising short-term outcomes. However, at 3 years, Absorb GT1 Bioabsorbable Vascular Scaffold was associated with statistically significant higher rates of late stent-related thrombosis than DES and Abbott has halted commercial sales of the product.

Clinical interest to eliminate the need for a permanent stent is perhaps strongest in cases of coronary in-stent restenosis (ISR) where the off-label placement of an additional stent on top of the original stent has been shown to drive an increase in long-term TLF. While angioplasty balloons coated with the cytotoxic agent paclitaxel have been approved in the US for the treatment of the superficial femoral artery, a large peripheral vessel in the upper leg, and have shown promise outside the US for the treatment of coronary ISR, sirolimus is the gold-standard pharmaceutical agent used in conjunction with coronary stenting to prevent restenosis (reclogging) of an artery following percutaneous coronary intervention (PCI), as extensive clinical data demonstrated clinical superiority to paclitaxel. Further, drug-coated balloons present potential concerns associated with the safety risk of creating large size particulate from the coating that block smaller vessels distal to treated lesions.

About Virtue® SEB

The Virtue® Sirolimus-Eluting Balloon (SEB), a flagship product of Orchestra BioMed, is a balloon angioplasty system that allows for delivery and controlled-release of therapeutic dose of sirolimus without the need for coating. Virtue SEB performs balloon angioplasty using a patented microporous balloon and allows simultaneous, full-dose drug delivery to the lesion without the need for coating thereby eliminating safety concerns of dislodging large emboli and removing concerns associated with drug and coating loss during navigation to the target lesion. Virtue SEB delivers and

controls the release of a full therapeutic dose of sirolimus using a proprietary bioabsorbable particle technology. Drug elution kinetics have been shown to be consistent with the pharmacokinetic profiles for the proven DES (EuroIntervention, August 2016).

About Orchestra BioMed™

Orchestra BioMed, Inc. is a biomedical innovation company focused on developing transformational therapies for major medical conditions, such as cardiovascular, gastrointestinal and metabolic disease, that affect a significant portion of the population and drive a majority of healthcare costs. Orchestra BioMed's business strategy is to leverage partnerships with established global market leaders to optimize the clinical impact and commercial value of its products. Orchestra BioMed expects to generate long- term, high margin cash flow from royalties, revenue sharing, and licensing and development payments from strategic partners that secure commercial rights to Orchestra BioMed-developed products. Orchestra BioMed's core innovation and development expertise is in the areas of drug delivery, bioelectronics and neuromodulation, as well as interventional, robotic and other minimally-invasive therapeutic devices. For more information about Orchestra BioMed, please visit www.orchestrabiomed.com.

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.

Investor and Media Contact:

Jenene Thomas Communications, LLC
Jenene Thomas
(833) 475-8247
OBIO@jtcir.com

Source: Orchestra BioMed, Inc.