



Orchestra BioMed Receives CE Mark for BackBeat Cardiac Neuromodulation Therapy™ (CNT) for Hypertension

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Late-breaking BackBeat CNT™ randomized, double-blind clinical results selected by Cardiovascular Research Foundation for presentation at TCT 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, announced today that it has received CE Mark approval for its Moderato® implantable pulse generator system that delivers BackBeat Cardiac Neuromodulation Therapy™ (CNT) for treatment of hypertension while also providing standard pacemaker functions.

Additionally, the Cardiovascular Research Foundation (CRF) selected Orchestra BioMed’s MODERATO II clinical study of BackBeat CNT for a late-breaking science presentation at the Transcatheter Cardiovascular Therapeutics (TCT) 2019 annual conference on September 28, 2019 at 12:45 pm PST in the main arena at The Moscone Center in San Francisco. The presentation titled, “MODERATO II: A Double-Blind Randomized Trial of Cardiac Neuromodulation Therapy in Patients with Hypertension,” will be presented by Karl-Heinz Kuck, MD., Ph.D., director of cardiology at the Lans Medicum, Hamburg, Germany and principal investigator for the MODERATO Studies. The MODERATO II results will also be highlighted at a press conference to be held at TCT during the morning of September 28, 2019. Every year, TCT late-breaking presentations feature major medical research breakthroughs and highlight the latest data on the most innovative treatments that will impact patient care and how physicians treat heart disease. The studies selected examine the safety and efficacy of minimally invasive techniques, pharmaceuticals, therapies and devices that demonstrate potential to treat or prevent cardiovascular disease.

“BackBeat CNT is an exciting new approach to device-based blood pressure management and has potential to be a primary treatment modality for the more than two-thirds of pacemaker patients at risk from hypertension,” said Dr. Karl-Heinz Kuck. “In the MODERATO I clinical trial, BackBeat CNT demonstrated excellent efficacy and safety results, particularly given that 78% of the study patients had isolated systolic hypertension and that patients’ average baseline ambulatory systolic blood pressure (137 mmHg) was lower compared to patients in other device-based hypertension studies. I look forward to presenting the six-month primary endpoint results from the MODERATO II study of BackBeat CNT as a late-breaker at TCT later this month.”

“CE Mark approval and selection for late-breaking science presentation at TCT validate the potential for BackBeat CNT to benefit targeted high-risk hypertensive patients, such as those already indicated for a pacemaker,” said David Hochman, Chairman and CEO of Orchestra BioMed. “Effective treatment of these patients, the majority of whom have isolated systolic disease and persistent high blood pressure despite conventional pharmaceutical therapies, represents a significant market opportunity that could have substantial growth, value and market share implications for the field of cardiac rhythm management.”

About BackBeat CNT™

BackBeat CNT, a flagship therapy of Orchestra BioMed, is a bioelectronic treatment that immediately, substantially and chronically lowers blood pressure (BP) while simultaneously modulating the Autonomic Nervous System (ANS). Orchestra BioMed’s CE Mark approved Moderato™ implantable pulse generator system delivers BackBeat CNT while also providing standard pacemaker functions. BackBeat CNT mimics the effects of multi-drug hypertension therapy by targeting preload, afterload and sympathetic tone. BackBeat CNT may be applicable to a wide range of hypertensive patients, including patients with isolated systolic disease and patients with uncontrolled hypertension despite multi-drug medical management.

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.

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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