Orchestra BioMed™ Announces Clinical Data Demonstrating a Significant and Sustained Reduction in Blood Pressure in MODERATO II Control Patients After Crossover to BackBeat Cardiac Neuromodulation Therapy™

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Clinically meaningful and statistically significant reduction in systolic blood pressure is consistent with the decrease previously observed in the study treatment group during the same time period.

Ambulatory Systolic Blood Pressure (aSBP) decreased by an average of 10.3 mmHg (p<0.01) at 6 months.

Office Systolic Blood Pressure (oSBP) decreased by an average of 13.1 and 20.9 mmHg at 6 and 12 months, respectively.

New Hope, PA, July 30, 2021 – Orchestra BioMed™, Inc., ("Orchestra BioMed" or the "Company"), a biomedical innovation company focused on developing transformative therapeutic products for large unmet medical needs in procedure-based medicine, today announced that long-term follow-up data on hypertensive patients from the control group of the MODERATO II study who received crossover treatment with BackBeat Cardiac Neuromodulation Therapy™ (CNT™) were featured in a presentation at the Heart Rhythm Society meeting in Boston, MA on July 29th. The data demonstrated a clinically meaningful and statistically significant reduction in blood pressure in these patients, which was consistent with the decrease previously observed in the study's treatment group during the same period.

"I continue to be impressed and encouraged by the observed reduction in blood pressure in patients treated with BackBeat CNT. Reductions in ambulatory and office systolic blood pressure were clinically significant and persistent in control patients who went on to receive crossover therapy," stated Professor Zbigniew F. Kalarus, M.D., Ph.D., chairman of the department of cardiology at Silesian Center for Heart Diseases (SCHD), Zabrze, Poland. "Of additional importance is that the rate of adverse cardiac events in these patients was lower during the crossover period as compared to the control period, when patients were not receiving treatment with BackBeat CNT."

MODERATO II is a European, prospective, multi-center, double-blind, randomized study of BackBeat CNT (n=26) vs. control (n=21) in patients with persistent hypertension (ASBP ≥130 mmHg and oSBP ≥ 140 mmHg) despite one or more anti-hypertensive medications and a pacemaker indication. Of the 21 control patients (treated with antihypertensive medications only, BackBeat not activated), 14 were eligible for crossover to BackBeat CNT, and 13 completed 12 months of follow-up to-date (one patient died of cancer). Key interim study data:

- Immediately upon activation of BackBeat CNT, aSBP dropped by 16.7±12.9 mmHg (p<0.01) and remained low after 6 months (-10.3±9.3 mmHg, p<0.01); consistent with the decrease observed in the treatment group during the same time period.
- After crossover to BackBeat treatment, oSBP decreased by 13.1±26.6 and 20.9±15.1 mmHg at 6 and 12 months, respectively (p=0.05).
- A lower rate of adverse cardiac events was observed in the control patients during the crossover period as compared to the study control period when patients were not receiving BackBeat CNT.

About BackBeat CNT™

BackBeat CNT, a flagship therapy of Orchestra BioMed, is a bioelectronic treatment designed to immediately, substantially, and persistently lower 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 is designed to mimic the effects of multi-drug hypertension therapy by targeting preload, afterload and sympathetic tone. The initial target treatment population for BackBeat CNT is patients with uncontrolled hypertension who are also indicated for a pacemaker.

About Orchestra BioMed™

Orchestra BioMed is a biomedical innovation company focused on developing transformative therapeutic products for large unmet needs in procedure-based medicine. The Company is led by a highly accomplished, multidisciplinary management team and board of directors with extensive experience in all phases of medical device development. Orchestra BioMed's partnership-enabled business model focuses on forging strategic collaborations with leading medical device companies to drive successful global commercialization of products it develops. Orchestra BioMed was formed in 2018 by assembling a pipeline of multiple late-stage clinical product candidates originally developed by the Company's founding team. The Company's flagship product candidates are Virtue® Sirolimus AngioInfusion™ Balloon (SAB) for the treatment of artery disease, the leading cause of mortality, and BackBeat Cardiac Neuromodulation Therapy™ for the treatment of hypertension, the leading risk factor for death worldwide. Orchestra BioMed has a global strategic partnership with Terumo Corporation, one of the world's largest medical device companies, for development and commercialization of Virtue SAB. Together, the companies plan to initiate a U.S. pivotal trial for the use of Virtue SAB in the treatment of coronary in-stent restenosis in 2021 which will be the first in a series of pivotal trials aimed at achieving regulatory approvals in multiple indications worldwide. The Company has additional product candidates in its pipeline and plans to thoughtfully expand its product pipeline in the future through acquisitions, strategic collaborations, licensing, and organic 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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