Orchestra BioMed™ Announces Clinical Data Showing Significant and Sustained Reduction in Systolic Blood Pressure Out to Two Years with BackBeat Cardiac Neuromodulation Therapy™

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Clinically meaningful and statistically significant reduction of 16.6 mmHg in systolic blood pressure out to two years

88% of the treated patients had isolated systolic hypertension (ISH)

70.6% of all treated patients and 80% of treated ISH patients had their blood pressure under control at 24 months

New Hope, PA, May 17, 2021 – Orchestra BioMed™, Inc., ("Orchestra BioMed" or the "Company"), a biomedical innovation company focused on developing transformative therapeutic products for large unmet clinical needs in procedure-based medicine, presented interim two-year data on its MODERATO II patients treated with BackBeat Cardiac Neuromodulation Therapy™ on May 15th, 2021 at the virtual American College of Cardiology (ACC) Meeting. The data demonstrated a clinically meaningful and statistically significant reduction of 16.6 mmHg in office Systolic Blood Pressure (oSBP) that was sustained out to two years.

"These data provide evidence of significant long-term reductions in systolic blood pressure with a lower-than-expected rate of major cardiac events when BackBeat CNT is activated for a period of up to two years," stated Daniel Burkhoff, M.D., Ph.D., Director of Heart Failure, Hemodynamics and MCS Research at the Cardiovascular Research Foundation. "Of clinical significance is the fact that the majority of the patients in the MODERATO II study had ISH. In these patients, a significant reduction in systolic blood pressure with minimal effect on diastolic blood pressure is ideal and is difficult to achieve with antihypertensive medications. Furthermore, 80% of the ISH patients in MODERATO II had their blood pressure under control at 24 months, which could translate to meaningful reductions in cardiovascular events."

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 26 treatment patients, 25 completed 18 months of follow-up (one patient died of cancer) and 17 reached 24 months of therapy to date. Key interim study data:

- Patients demonstrated a sustained reduction in oSBP during all visits after activation of BackBeat CNT with a reduction of 12.4±11.7 mmHg, 9.2±15.1 mmHg, 17.8±18.2 mmHg and 16.6±20.4 mmHg at 6, 12, 18 and 24 months post-activation, respectively ($p < 0.01$ at all time points vs. pre-activation).
- Blood pressure was under control in a high percentage of patients with 56.0%, 68.0%, and 70.6% of patients achieving blood pressure bellow 140mmHg at 12, 18, and 24 months of follow-up, respectively.
- The number of major cardiac events was below the expected rate for this high-risk patient population.
- Of the 17 patients that finished 24 months of therapy, 15 patients (88% of group) had ISH, a condition where systolic blood pressure is elevated but diastolic blood pressure is normal. ISH patients treated with BackBeat CNT demonstrated a significant reduction in oSBP of 10.6±11.1 mmHg and 14.2±20.5 mmHg ($p<0.02$) after 6 and 24 months of treatment, respectively.

About BackBeat CNT™

BackBeat CNT, a flagship therapy of Orchestra BioMed, is a bioelectronic treatment that immediately, substantially and persistently 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. 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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