



Orchestra BioMed™ Presents Clinical Data at EuroPCR 2019 Demonstrating Safety and Efficacy of BackBeat Cardiac Neuromodulation Therapy (CNT)

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Novel implantable bioelectronic treatment delivers immediate, substantial, and sustained reduction in blood pressure

Data showed 14.2 mmHg reduction in 24-hour ambulatory systolic blood pressure at three months and 23.4 mmHg reduction in office cuff systolic blood pressure out to two years

Therapy applicable to a wide range of hypertensive patients including those with isolated systolic hypertension

Paris, France – Orchestra BioMed, Inc., (“Orchestra BioMed” or the “Company”), a biomedical innovation company providing high-impact solutions for large unmet needs in procedure-based medicine, today announced the presentation of two-year clinical data from the European Moderato I study of BackBeat Cardiac Neuromodulation Therapy (“BackBeat CNT”) for hypertension at the EuroPCR Conference in Paris, France. Prof. Petr Neuzil, M.D., Ph.D., CSc., FESC, head of the department of cardiology of Na Homolce Hospital in Prague, Czech Republic, presented data which showed a strong safety profile of BackBeat CNT and its ability to immediately, substantially and chronically lower blood pressure in patients with persistent hypertension (office BP > 150 mmHg) despite two or more anti-hypertensive medications and an indication for a pacemaker.

“In the Moderato I study, BackBeat CNT demonstrated an impressive 14.2 mmHg reduction in 24-hour ambulatory systolic blood pressure at three months as well as a substantial and sustained 23.4 mmHg reduction in office cuff systolic blood pressure out to two years. These statistically significant results are very exciting as they support the potential for BackBeat CNT to become a broadly applicable therapy for device-based hypertension management” said Professor Neuzil, one of the principal investigators of the study.

BackBeat CNT is applicable to a wide range of hypertensive patients, including isolated systolic disease and patients with high blood pressure despite medical therapy. The Moderato I study enrolled patients with uncontrolled hypertension despite multi-drug medical management and who are also indicated for a pacemaker.

“We are encouraged by the data from Moderato I study showing substantial reduction in systolic blood pressure which could potentially reduce the risk of heart attack and stroke,” said Darren R. Sherman, president, chief operating officer and founder of Orchestra BioMed. “We recently completed enrollment of patients in the Moderato II study to further investigate the efficacy and safety of BackBeat CNT for the treatment of hypertension and are on track to present 6-month data later this year.”

The Moderato II study is a prospective, 1:1 randomized double-blind active treatment with BackBeat CNT versus standard medical therapy trial in pacemaker-indicated patients with uncontrolled blood pressure and treated with at least one antihypertensive medication. The primary efficacy and safety endpoints will be assessed at six months.

“We are looking forward to Moderato II six-months results and the long-term potential of this exciting therapy to benefit high-risk patients with uncontrolled high blood pressure,” stated Professor Neuzil.

In 2019, Orchestra BioMed plans to initiate enrollment in a randomized, double-blind study to assess the clinical safety and effectiveness of BackBeat CNT in patients with hypertension in the absence of antihypertensive medications. The primary efficacy endpoint will be the difference in the average 24-hour ambulatory systolic blood pressure in the active group compared to control at three months after randomization.

About BackBeat CNT

BackBeat CNT, a flagship product of Orchestra BioMed, is a bioelectronic therapy that immediately, substantially and chronically lowers blood pressure (BP) while simultaneously modulating the Autonomic Nervous System (ANS). BackBeat CNT replicates the effects of multiple medications by reducing pre-load, after-load and sympathetic tone. The therapy can be delivered using standard rhythm management device hardware, such as dual-chamber pacemakers. BackBeat CNT is 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® 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. 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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