



## **Orchestra BioMed™ Announces AHA 2018 Presentation on BackBeat® Cardiac Neuromodulation Therapy (CNT)**

November 8, 2018

*Novel Treatment Delivers Immediate, Substantial, and Sustained Reduction in Blood Pressure*

*Potential to Become a Broadly Applicable Therapy for Device-Based Hypertension Management*

New Hope, PA – Orchestra BioMed, Inc., (“Orchestra BioMed” or the “Company”), a biomedical innovation company developing advanced therapeutic solutions to address major unmet medical needs, announced today that Professor Petr Neuzil, M.D., Head of the Department of Cardiology of Na Homolce Hospital in Prague, Czech Republic, was invited to present on BackBeat CNT and its impact on device-based hypertension management during a Scientific Session at American Heart Association meeting to take place on November 10th in Chicago, IL. Dr. Neuzil’s presentation will highlight 2-year clinical results from the European Moderato I study of BackBeat CNT which demonstrate strong safety profile of the therapy as well as its ability to immediately, substantially and chronically lower blood pressure in patients with persistent hypertension (office BP > 150mmHg) 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 3 months as well as a substantial and sustained 23.4 mmHg reduction in office cuff systolic blood pressure out to 2 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. “We are looking forward to Moderato II randomized, controlled trial results next year as well as to the long-term potential of this exciting therapy to benefit high-risk patients with uncontrolled high blood pressure.”

To further investigate the efficacy and safety of BackBeat CNT for the treatment of hypertension, Orchestra BioMed is currently enrolling patients into Moderato II, a prospective, 1:1 randomized double-blind active treatment (BackBeat® CNT) versus standard medical therapy trial in pacemaker-indicated patients with uncontrolled blood pressure and treated with at least one anti-hypertension medication. The primary efficacy and safety endpoints will be assessed at 6 months. The Company is expecting results on the first cohort of patients in 2019.

### **About BackBeat® CNT**

BackBeat’s 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). Mimicking the effects of multiple medications by reducing pre-load, after-load and sympathetic tone, it 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, inclusive of Isolated Systolic Hypertension, who are also indicated for a pacemaker and patients with uncontrolled hypertension despite multi-drug medical management. Orchestra BioMed is currently working to obtain regulatory approval for BackBeat CNT in Europe. In addition, the Company is nearing completion of its first cohort of patients in a prospective, randomized, double-blind study, Moderato II, to further evaluate the clinical benefits of the therapy.

### **About Orchestra BioMed™**

*Orchestra BioMed, Inc. is a biomedical innovation company focused on developing high impact, high value, evidence-based therapeutic solutions for procedures that address major medical conditions. The Company’s core innovation and product development expertise are in the areas of drug delivery, interventional devices, bioelectronics and neuromodulation with a primary focus on cardiovascular disease. 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, with potential for long-term, high margin cash flow from royalties, revenue sharing, and licensing and development payments. The Company’s lead product candidates include Virtue® Sirolimus-Eluting Balloon® (SEB), a novel, first-in-class drug-eluting angioplasty balloon that delivers delayed-release bioabsorbable particle encapsulated Sirolimus, and BackBeat® Cardiac Neuromodulation Therapy (CNT), a patented implantable cardiac neuromodulation treatment for hypertension. Orchestra BioMed also has significant strategic ownership in other therapeutic device companies that were originally founded, financed and developed with the assistance from the principals of Orchestra BioMed. These include one wholly-owned subsidiary ([FreeHold Surgical®](#)) and two large minority interests in other therapeutic device companies ([Motus GI®](#), [Vivasure® Medical](#)).*

### **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.*

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