



Orchestra BioMed™ Announces Presentation of Positive 2-Year Clinical Results and Program Update for BackBeat® Cardiac Neuromodulation Therapy at TCT 2018

September 25, 2018

Immediate, Substantial, and Sustained Reduction in Blood Pressure Demonstrates Potential to Offer Highly Differentiated, Breakthrough Treatment for Hypertension

San Diego, CA – Orchestra BioMed, Inc. ("Orchestra BioMed" or the "Company"), a biomedical innovation company developing transformational therapeutic devices targeting major medical conditions, presented positive 2-year clinical results from its multicenter clinical trial for BackBeat® Cardiac Neuromodulation Therapy (CNT) at the Transcatheter Cardiovascular Therapeutics (TCT) 2018 in San Diego, CA. Daniel Burkhoff, M.D., Ph.D., Director, Heart Failure, Hemodynamics and Mechanical Circulatory Support Research for the Cardiovascular Research Foundation, presented clinical outcomes of the Moderato I Study, which demonstrated immediate, substantial and sustained reduction in blood pressure when BackBeat CNT was used in patients with persistent hypertension (office BP > 150mmHg) despite two or more anti-hypertensive medications and an indication for a pacemaker.

"The clinical efficacy and safety data observed with BackBeat CNT in a patient population with a significant portion of isolated systolic disease is very promising. Hypertension affects over 70% of pacemaker patients. These patients could benefit substantially from a potent hypertension therapy such as BackBeat CNT that could be included in their already necessary pacemaker," said Professor Petr Neuzil, M.D., Head of the Department of Cardiology of Na Homolce Hospital in Prague, Czech Republic and one of the Principal Investigators of the study.

The 27 patients that met the study inclusion criteria were implanted with BackBeat's proprietary Moderato™ dual-chamber pacemaker that incorporates the BackBeat CNT algorithms. The primary safety and efficacy endpoint results of the study were as follows:

- Efficacy Outcomes: Immediate, substantial and sustained reduction in blood pressure.
 - 14.2 mmHg decrease from baseline ($p < 0.001$) in 24 hours Ambulatory Systolic Blood Pressure (AMB BP) at 3 months
 - 23.4 mmHg decrease from baseline ($p < 0.001$) in systolic blood pressure (SBP) sustained out to 2 years
- High responder rate in a population where 78% of patients had isolated systolic hypertension.
 - 85% AMB BP reduced >5mmHG
 - 74% AMB BP reduced >10 mmHg
- Safety Outcomes: The study met the safety endpoint.
 - Observed reduction in end systolic and diastolic volumes with no change to ejection fraction suggests improvement of cardiac function
 - Observed reduction in heart rate out to 2 years indicative of reduced sympathetic activity

"These statistically significant results demonstrate the potential for BackBeat CNT to be a broadly applicable therapy that substantially lowers blood pressure immediately and maintains reduced pressures for years," commented Dr. Burkhoff. "It is rare to see a new therapy show such dramatic and sustained effects in such a small number of patients."

To further investigate the efficacy and safety of BackBeat CNT for the treatment of hypertension, Orchestra BioMed is enrolling patients into a prospective, 1:1 randomized double-blind active treatment (BackBeat® CNT) versus standard medical therapy trial, Moderato II, in patients with uncontrolled blood pressure (office Systolic > 140, Day and AMB BP > 130 mmHg) treated with at least one anti-hypertension medication that are indicated for a dual-chamber pacemaker. The primary efficacy endpoint of the first cohort of the study is the comparison of the mean reduction in 24-hour systolic ambulatory blood pressure following 6 months of therapy between the treatment and the control. Primary safety endpoint is the rate of major adverse cardiac event (MACE) at 6 months between the treatment and control. 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 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, hypertensive patients who are also indicated for a pacemaker and uncontrolled hypertensive patients. 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 (~50 patients) in a prospective, randomized, double-blind study, Moderato II, to further substantiate the clinical benefits of therapy.

About Orchestra BioMed™

Orchestra BioMed, Inc. is a biomedical innovation company focused on developing transformational therapies for major medical conditions, such as

cardiovascular, gastrointestinal and metabolic disease, that affect a significant portion of the population and drive a majority of healthcare costs. 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. Orchestra BioMed expects to generate long-term, high margin cash flow from royalties, revenue sharing, and licensing and development payments from strategic partners that secure commercial rights to Orchestra BioMed-developed products. Orchestra BioMed's core innovation and development expertise is in the areas of drug delivery, bioelectronics and neuromodulation, as well as interventional, robotic and other minimally-invasive therapeutic devices.

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.

Investor and Media Contact:

Jenene Thomas Communications, LLC
Jenene Thomas
(833) 475-8247
obio@jtccir.com

Source: Orchestra BioMed, Inc.