



Clinical Data Presented at ESC Congress Show BackBeat Medical's Cardiac Pacing-Based Treatment for Hypertension Produces Significant, Sustained Reductions in Blood Pressure

Results of Multicenter Clinical Study Demonstrate BackBeat's Patented Technology Creates a Potential Breakthrough in Device-Based Treatment of Hypertension

ROME, Aug. 28, 2016 – BackBeat Medical Inc. today announced the presentation of data demonstrating a significant and sustained reduction in blood pressure in patients with hypertension using the company's patented cardiac pacing-based treatment. The focus of an oral late-breaking clinical trial presentation by study investigator Petr Neuzil, M.D., at the European Society of Cardiology's annual scientific meeting, ESC Congress, in Rome, the data consisted of detailed results from a multicenter clinical trial of BackBeat's Programmable Hypertension Control (PHC) therapy.

In the study that enrolled 35 hypertensive patients indicated for implantation of a permanent dual-chamber pacemaker at 10 sites worldwide, participants received a pacemaker developed by BackBeat, called the Moderato™, that incorporates the company's proprietary PHC algorithm. During the first month of treatment, only the standard pacing functions were activated to allow estimation of the expected effect of participation in a study on blood pressure. After the first month, 27 patients met the strict study inclusion criteria at the end of the run-in period. However, PHC therapy was successfully activated in all patients with therapeutic benefit. In this study group that met all of the study inclusion criteria, 24-hour ambulatory systolic pressure significantly decreased by 11 mmHg immediately after PHC activation and was maintained low during the study period. After three months, ambulatory pressure had decreased by 10 mmHg from pre-activation ($p=0.004$; 14 mmHg from baseline, $p<0.001$). Office cuff pressure data were also collected on these patients and showed an average reduction of 16mmHg from pre-activation levels ($p<0.001$, 24 mmHg from baseline) after three months of therapy. This effect was maintained in patients who have so far reached later follow-up time points, with a significant reduction of 20 mmHg ($p<0.001$) from the pre-activation pressure after 12 months of therapy and 21 mmHg ($p=0.02$) after 24 months.

“By reducing ventricle filling and modulating the baroreflex response in hypertensive patients with a unique algorithm in a standard pacemaker, we were able to quickly reduce systolic blood pressure and sustain the response throughout the three-month study period,” said Dr. Neuzil, one of the study's investigators and the head of the department of cardiology at Na Homolce Hospital in Prague, Czech Republic. “Additionally, these results have been maintained in patients beyond two years following the activation of the therapy. This is a highly differentiated approach to treating hypertension that provides a significant reduction in blood pressure with relatively no additional risk because the pacemaker implants are already required for these patients. BackBeat's PHC therapy has the potential to offer

significant clinical benefits and help address the known side effects and compliance challenges associated with hypertension medications.”

BackBeat’s PHC algorithm reduces ventricular filling to lower blood pressure while modulating the response of the baroreflex to prevent activation of the autonomic nervous system. This technology can be readily incorporated into marketed pacemakers using standard leads and standard lead placement. It also could be added to already implanted pacemakers as a software download performed in the clinic. Hypertension affects over 70% of pacemaker patients and is uncontrolled in approximately 38% of the total pacemaker population. These patients could benefit substantially from a potent hypertension therapy such as PHC that could be included in their already necessary pacemaker.

Yuval Mika, Ph.D., CEO and co-founder of BackBeat Medical, said, “PHC therapy potentially represents an entirely new field of hypertension treatment that will leverage the use of pacemakers for a significant new market just as biventricular pacing has been used to treat heart failure. Incorporating BackBeat’s PHC pacing algorithm into standard pacemakers would provide significant differentiation to increase the commercial value of a combination pacemaker. Furthermore, it could drive market share gains in the large population of the patients who could benefit substantially from a hypertension therapy that could be included in their pacemaker. With the data from our study, we believe that this device-based treatment of hypertension is now a reality, and we are actively pursuing plans to make this therapy broadly available first for patients already requiring pacemakers and, in the future, for other hypertensive patients struggling to keep blood pressure under control despite medication.”

BackBeat is currently working to obtain regulatory approval in Europe for PHC therapy using data generated to date with BackBeat’s Moderato™ device. In addition, the first patients have been enrolled in another European BackBeat-sponsored 170-patient, randomized, double-blind study designed to further investigate the benefit of PHC therapy in hypertensive pacemaker patients. This study, which will involve up to 30 clinical sites, will be used to drive adoption and gain reimbursement in Europe as well as support future regulatory approval of PHC therapy in the U.S. and other countries.

About Hypertension

Hypertension (HTN), or high blood pressure, affects an estimated 75 million American adults (1 in 3) according to the CDC and over 1 billion adults globally according to the WHO. HTN is one of the most important factors contributing to cardiovascular morbidity and mortality, accounting for over 9.4 million global deaths annually. Unacceptably high blood pressure is defined as systolic pressure >140 mmHg in the absence of other cardiovascular risk factors, or >130 mmHg in the presence of other risk factors. Cardiovascular risk doubles for every 10 mmHg increase in systolic blood pressure, and mortality rate is doubled with an increase of 20 mmHg in systolic blood pressure. Hypertension increases dramatically with age from 7.3% for ages 18-39 to 65% for ages 60+. The estimated direct and indirect yearly cost of hypertension in the U.S. is \$46.6 billion. Medications are frequently effective in controlling blood pressure but require daily strict compliance by patients and can cause side effects that make them

difficult for patients to tolerate. Only 54% of U.S. HTN patients have their high blood pressure under control (CDC). Further, data from the NIH's landmark Systolic Blood Pressure Intervention Trial (SPRINT) published in 2015 show that more aggressive treatment to achieve a target systolic pressure of 120 millimeters of mercury (mm Hg), reduced rates of cardiovascular events, such as heart attack and heart failure, as well as stroke, by almost a third and the risk of death by almost a quarter, as compared to the target systolic pressure of 140 mm Hg.

About Pacemakers

Pacemakers are permanent implants that directly stimulate, or "pace," the heart. Indications for permanent pacing include the following: symptomatic sick sinus syndrome, including symptomatic sinus bradycardia, tachycardia-bradycardia syndrome, atrial fibrillation with sinus node dysfunction, chronotropic incompetence (inability to increase the heart rate to match a level of exercise) and various degrees of conductance block between the atrium and the ventricle. The annual value of the global pacemaker market is approximately \$4.2B with more than 1 million pacemaker procedures performed worldwide every year. While pacemaker prices have generally been in decline with the exception of new MRI-compatible devices, the introduction of new features, like MRI-compatible pacemakers, resulted in significant increases in device selling price. Furthermore, the introduction of new therapeutic capabilities in pacemakers, like biventricular pacing for the treatment of heart failure, resulted in a significant increase in device price. The addition of features and additional therapeutic capabilities can also affect market share by providing competitive advantages and product differentiation to first movers. It is estimated that more than 70% of the patients that are indicated for the implant of a pacemaker have hypertension. The main reason may be attributed to the average age of the pacemaker patient population being 73 years old and the dramatic increase in the prevalence of hypertension in people over 60 years old. Hypertension is uncontrolled in approximately 55% of these people (approximately 38% of the total pacemaker population). These patients could benefit substantially from a hypertension therapy like PHC that could be included in their already necessary pacemaker.

About BackBeat Medical

BackBeat Medical Inc. is a medical technology company founded in 2010 to develop novel cardiac stimulation-based therapies for hypertension and heart failure. BackBeat has developed a patented cardiac pacing-based treatment for hypertension (HTN) called programmable hypertension control (PHC) therapy. PHC is comprised of proprietary pacing algorithms that can be readily incorporated into standard pacemakers using standard leads and standard lead placement and thus has broad applicability. PHC offers a new potent device-based HTN therapeutic alternative potentially opening up a large market to treat HTN patients, particularly HTN patients who already have or require a pacemaker. Clinical results generated to date using BackBeat's own Moderato™ pacemaker incorporating PHC algorithms demonstrate that this therapy has a substantial and sustained therapeutic effect on blood pressure as determined by both in-office cuff measurements (average reduction of 24 mmHg from baseline) and 24-hour ambulatory measurements (average reduction of 14 mmHg from baseline) with clinical follow up extending up to two years.

Media Contacts:

David Schull or Todd Davenport, Ph.D.

Russo Partners, LLC

(212) 845-4271

(212) 845-4235

david.schull@russopartnersllc.com

todd.davenport@russopartnersllc.com