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

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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., Ph.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 filing 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.

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