Ablative Solutions Announces Results from Treatment of Patients with Hypertension in the European Peregrine Post-Market Study

Data from Post-Market Multi-Center Trial Presented in Late-Breaker at CRT 2019

Kalamazoo, Mich. and Washington, D.C. – March 7, 2019 – Ablative Solutions, Inc., a company pioneering new approaches for the treatment of hypertension, today announced new data from the Peregrine Post-Market Clinical Trial, which were presented this week during a late-breaking session at the 2019 Cardiovascular Research Technologies (CRT) meeting in Washington, D.C.

The Peregrine Post-Market Study is a European multicenter open-label trial that evaluated the safety and performance of the CE marked Peregrine System™ Infusion Catheter using alcohol as a neurolytic agent in 45 patients with systemic hypertension. The efficacy endpoint of the study was met, with a reduction in mean systolic 24-hour ambulatory blood pressure of 11mmHg (±14 mm Hg, $p<0.001$) at six-month follow-up. Additionally, the average reduction in systolic office blood pressure was 18 mmHg (± 21 mmHg, $p<0.001$). Antihypertensive medications were unchanged in 73% and reduced in 23% of patients at six months. The study demonstrated 100% procedural success, and the safety endpoint was met in 96% of patients. Two patients had major adverse events of peri-procedural access site pseudoaneurysms, with major bleeding in one patient. There were no deaths or instances of myocardial infarction (MI), stroke, or transient ischemic attack (TIA).

“The Peregrine Post-Market Study showed efficient nerve ablation with the CE marked Peregrine Catheter, resulting in significantly sustained reduction in both systolic and diastolic blood pressure at six months, with the vast majority of patients not requiring an increase in the number of anti-hypertensive medications during this time,” said Prof. Felix Mahfoud, Saarland University Hospital, Germany.

“These promising results met the study’s safety and efficacy endpoints, confirming a safe and effective reduction in blood pressure by means of alcohol-mediated renal denervation, with 71% of patients responding,” said Nicole Haratani, executive vice president of global clinical, regulatory affairs and quality at Ablative Solutions. “We are excited to now begin investigations of the drug-device combination Peregrine System™ Kit as part of the TARGET BP clinical program.”

The Peregrine System Infusion Catheter has received a Certificate of Conformity and has been CE marked for the infusion of a neurolytic agent (e.g. alcohol) to achieve a reduction in systemic blood pressure in hypertensive patients. Designed to be performed in a short and straightforward procedure with minimal sedation required, the Peregrine Catheter is engineered to target nerves known to influence the body’s regulation of blood pressure. The delivery of a neurolytic agent, dehydrated alcohol in this study, directly to the space outside of the renal artery is intended to block the overactive signaling of the sympathetic nerves.

The investigational Peregrine Kit, which includes the Peregrine System Infusion Catheter (Peregrine Catheter) and Ablative Solutions dehydrated alcohol, will be investigated in the

TARGET BP clinical program which comprises two clinical trials. The global TARGET BP I Trial in centers in the U.S. and EU is a blinded, randomized sham-controlled study which will evaluate the safety and efficacy of the Peregrine Kit in the treatment of patients with uncontrolled hypertension and who are taking two to five anti-hypertensive medications. Patient enrollment in the Target BP I trial is anticipated to begin in 2019. The recently initiated TARGET BP OFF-MED Trial in Europe is a proof-of-concept, blinded, randomized sham-controlled study evaluating the safety and effectiveness of the Peregrine Kit for the treatment of patients with uncontrolled hypertension who are not taking anti-hypertensive medications.

“Based on early clinical results using the CE-marked Peregrine Catheter, we are excited to be embarking upon the pivotal TARGET BP I Clinical Trial of the investigational Peregrine Kit to evaluate safety and efficacy when used in the treatment of patients with uncontrolled hypertension in conjunction with antihypertensive medications,” said David Kandzari, M.D., co-principal investigator of the TARGET BP I trial, and Director of Interventional Cardiology and Chief Scientific Officer at Piedmont Heart Institute in Atlanta, Georgia.

Ablative Solutions recently announced a $77 million financing to complete clinical trials in support of U.S. and European regulatory submissions for the company’s minimally invasive renal denervation technology.

About the Peregrine System Infusion Catheter
The Peregrine System Infusion Catheter has 510(k) clearance for the infusion of diagnostic and therapeutic agents into the perivascular area of the peripheral vasculature. The Peregrine System Infusion Catheter is CE marked for the infusion of a neurolytic agent to achieve a reduction in systemic blood pressure in hypertensive patients. It is not commercially available.

About the Peregrine System Kit
The Peregrine System Kit is currently being studied to evaluate safety and efficacy when used in the treatment of patients with uncontrolled hypertension in conjunction with antihypertensive medications. It is an investigational product not currently approved in the United States and which is not yet CE marked. Its use is limited to investigational use in clinical trials.

About Ablative Solutions
Ablative Solutions, Inc., based in Kalamazoo, Mich., and San Jose, Calif., was founded in 2011 with a vision to address the unmet need of hypertension. Ablative Solutions’ approach targets the overactive sympathetic nervous system, which may play a role in hypertension, heart failure, kidney disease, metabolic syndrome and sleep apnea.[1, 2] The Peregrine System Infusion Catheter provides physicians with a way to infuse diagnostic and therapeutic agents into the area surrounding the renal artery, where sympathetic nerves are located. The Peregrine System Kit is currently being investigated as a treatment for hypertension in conjunction with antihypertensive medications. For more information visit www.ablativesolutions.com.

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