



Ablative Solutions Announces Publication of Data from the Peregrine Post-Market Study in the *Journal of the American College of Cardiology: Cardiovascular Interventions*
Data Provide Preliminary Evidence of Efficacy of the Investigational Peregrine System Kit

SAN JOSE, Calif. – February 20, 2020 – Ablative Solutions, Inc., a company pioneering new approaches for the treatment of hypertension, today announced that positive six-month results from the Peregrine Post-Market Study demonstrating the safety and efficacy of the company’s CE-marked Peregrine System™ Infusion Catheter were published in the [Journal of the American College of Cardiology: Cardiovascular Interventions](#).

The Peregrine Post-Market Study is a European multicenter open-label trial that evaluated additional safety and performance of the Peregrine System Infusion Catheter using a neurolytic agent (dehydrated alcohol) delivered into the space outside of the renal (kidney) arteries in 45 patients with systemic hypertension. Patients included in the study were taking at least three anti-hypertensive medications.

At six months, mean 24-h ambulatory SBP was reduced by 11 mm Hg, and diastolic blood pressure was reduced by 7 mm Hg. Medication adherence was monitored and remained stable throughout the study. The primary safety endpoint, defined as absence of periprocedural major vascular complications, major bleeding, acute kidney injury, or death within one month, was met in 96% of patients (95% CI: 85% to 99%).

“Publication of the Peregrine Post-Market Study results in a respected peer-reviewed journal is a significant milestone for Ablative Solutions. These results further support our goal to maximize the potential of the Peregrine System as an important adjunctive therapy for managing uncontrolled blood pressure in this large patient population,” said Kate Rumrill, president and chief executive officer at Ablative Solutions. “We continue in our commitment to robust clinical research through our ongoing Target BP clinical trials program to further substantiate the procedural, clinical, and health-economic benefits of the Peregrine Catheter for the treatment of hypertension.”

In an [accompanying editorial](#), Deepak L. Bhatt, M.D., MPH and Arjun Majithia, M.D., MPH (Brigham and Women’s Hospital, Heart & Vascular Center, Harvard Medical School, Boston, Mass.) noted that “although the Peregrine system will clearly need to be tested in a randomized, blinded, sham-controlled clinical trial environment, the study investigators should be complimented for using rigorous, contemporary methods including objective adherence measurements (urine toxicology analysis) and appropriate, clinically relevant endpoints (ambulatory blood pressure).”

Twelve-month results from the study [presented last fall](#) at the 2019 European Society of Cardiology (ESC) Congress in Paris showed that the statistically significant reduction of 24-hour mean systolic ambulatory blood pressure measurement (ABPM) at six months was sustained at 12 months, providing evidence of consistent blood pressure-lowering effect. Twelve (12) month results also showed a reduction of mean systolic 24-hour ambulatory blood pressure of 10 mmHg (\pm 17 mmHg, $p=0.001$) and a reduction in systolic office blood pressure of 20 mmHg (\pm 23 mmHg, $p=0.001$). No patients had major adverse events.

“Results from this trial show that the renal denervation procedure using the Peregrine Catheter and alcohol as a neurolytic agent may be safe and effective for lowering blood pressure in patients with poorly controlled hypertension on medications,” said Prof. Felix Mahfoud, Saarland University Hospital, Germany. “The publication of these data further proves the potential value of the system for both physicians and patients. We look forward to further studying the investigational product in the randomized, sham-controlled TARGET BP clinical program.”

Worldwide, hypertension affects more than one billion people.¹ Management of hypertension often requires multiple medications. More than half of those treated with antihypertensive medications do not achieve their target blood pressure. High blood pressure can eventually lead to serious health problems such as heart attack, stroke and loss of vision. Approximately half of people with uncontrolled hypertension die of heart disease related to poor blood flow, and another third die of stroke.

The investigational Peregrine Kit, which includes the Peregrine System Infusion Catheter (Peregrine Catheter) and Ablative Solutions dehydrated alcohol, is currently being investigated in the TARGET BP clinical program which comprises two clinical trials. Data from the TARGET BP I and TARGET BP OFF-MED trials will be used to continue to advance the understanding of renal denervation.

About the TARGET BP I Trial

The global TARGET BP I trial is a pivotal, blinded, randomized sham-controlled study that is evaluating the safety and efficacy of the Peregrine System Kit in the treatment of patients with uncontrolled hypertension who are taking two to five anti-hypertensive medications.

About the TARGET BP OFF-MED Trial

The TARGET BP OFF-MED trial in Europe is a proof-of-concept blinded, randomized sham-controlled study evaluating the safety and effectiveness of Ablative Solutions' Peregrine Kit for the treatment of patients with uncontrolled hypertension who are not taking anti-hypertensive medications. This study was initiated earlier this year and is actively recruiting.

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 also being studied in a proof-of-concept trial in Europe to evaluate the safety

and efficacy of the product when used to treat patients not taking antihypertensive medications. It is an investigational product not currently approved in the United States or in Europe. Its use is limited to investigational use in clinical trials. More information about the TARGET BP OFF-MED Trial can be found at www.targetbptrial.com. More information about the TARGET BP I Trial can be found at www.targetbpglobalstudy.com.

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 (e.g. alcohol) to achieve a reduction in systemic blood pressure in hypertensive patients. The Peregrine Catheter is not commercially available in the United States or Europe.

About Ablative Solutions

Ablative Solutions, Inc., based in 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. The Peregrine System Kit is currently being investigated as a treatment for hypertension in conjunction with antihypertensive medications. For more information visit www.ablative-solutions.com.

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ⁱ Bloch, Michael J, Worldwide prevalence of hypertension exceeds 1.3 billion, Journal of the American Society of Hypertension 10(10) (2016) 753-754.

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