



Ablative Solutions Announces Enrollment and Randomization of First Patient in Global Clinical Trial Evaluating Company's Novel Therapy for Uncontrolled Hypertension

TARGET BP Clinical Program studies renal denervation using the investigational Peregrine System Kit

SAN JOSE, Calif. – July 23, – Ablative Solutions, Inc., a company pioneering new approaches to the treatment of hypertension, today announced the enrollment and randomization of the first patient in the TARGET BP I global clinical trial. Piedmont Heart Institute in Atlanta is the first hospital center worldwide to enroll and randomize a patient in the TARGET BP I clinical trial.

"It is exciting to initiate this important trial to evaluate the Peregrine System™ Kit for the treatment of patients with uncontrolled hypertension. More than half of those treated with antihypertensive medications do not achieve their target blood pressure, so there is a great need for improved therapeutic options," stated David Kandzari, M.D., co-principal investigator of the TARGET BP I trial, director of interventional cardiology and chief scientific officer at Piedmont Heart Institute.

"The enrollment and randomization of the first patient in the TARGET BP I trial is a significant milestone for Ablative Solutions and an exciting new phase in the clinical development of the Peregrine Kit," said Kate Rumrill, president and chief executive officer at Ablative Solutions. "We are committed to the management of hypertension and providing a higher level of clinical evidence for medical interventions that can aid in controlling this disease. We believe the Peregrine System Kit has the potential to become an important adjunctive therapy for managing uncontrolled blood pressure in this large patient population."

Both the global TARGET BP I trial and the ongoing European TARGET-BP OFF-MED trial are part of the TARGET BP clinical trials program and are designed to evaluate the safety and efficacy of the Peregrine System Kit when used to treat patients with uncontrolled hypertension. The Peregrine System Kit, which is comprised of a patented infusion catheter and dehydrated alcohol, is used in a minimally invasive procedure with the goal of deactivating the nerves surrounding the renal (kidney) arteries and thereby reducing blood pressure.

"A European Post-Market Study assessing a similar combination, which used the CE-marked Peregrine Catheter with alcohol as a neurolytic agent, provided promising early data that supported moving into the pivotal clinical studies. That study showed a reduction in mean systolic 24-hour ambulatory blood pressure of 11 mmHg (± 14 mmHg, $p < 0.001$) at six-month follow-up, and demonstrated a strong signal of safety," said Tim Fischell, M.D., chief medical officer at Ablative Solutions.

The 12-month results from the study will be presented at the European Society of Cardiology meeting on September 3.

Worldwide, high blood pressure affects more than one billion people, and only about half of these people have their high blood pressure under control. 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.

Data from the TARGET BP I trial will be used to support regulatory approval in the United States for the product's use for the treatment of hypertension, in conjunction with medical therapy. Data will also support the European approval of the medicinal product for the treatment of hypertension.

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 I trial can be found at www.targetbpglobalstudy.com. More information about the TARGET BP OFF-MED trial can be found at www.targetbptrial.com.

About the Peregrine System Infusion Catheter

The Peregrine System Infusion Catheter has FDA 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., with offices 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. For more information, visit www.ablative-solutions.com.

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