Ablative Solutions Announces Positive 12-Month Results from Study Evaluating Company's Novel Therapy for Uncontrolled Hypertension

Data Provide Preliminary Evidence of Efficacy of the Investigational Peregrine System Kit

SAN JOSE, Calif. and PARIS – September 3, 2019 – Ablative Solutions, Inc., a company pioneering new approaches for the treatment of hypertension, today announced 12-month results from the Peregrine Post-Market Clinical Trial, which were presented today during a symposium at the 2019 European Society of Cardiology (ESC) Congress in Paris.

The Peregrine Post-Market Study is a European multicenter open-label trial that evaluated additional safety and performance of the CE-marked 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.

A statistically significant reduction of 24-hour mean systolic ambulatory blood pressure measurement (ABPM) at six months, the study's primary efficacy outcome, 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 (± 17 mmHg, p=0.001) and a reduction in systolic office blood pressure of 20 mmHg (± 23 mmHg, p=0.001). No patients had major adverse events.

"The results from this feasibility trial are highly promising, showing that the safe and effective reduction in blood pressure by means of alcohol-mediated renal denervation that was seen at one, three, and six months was sustained at 12 months in patients with poorly controlled blood pressure," said Prof. Felix Mahfoud, Saarland University Hospital, Germany. "We look forward to further studying the investigational product in the randomized, sham-controlled TARGET BP clinical program."

"The 12-month safety and performance in the Post Market study provides preliminary evidence 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. Horst Sievert, CardioVascular Center in Frankfurt, Germany. "Alcohol-mediated renal denervation with the Peregrine System may be a compelling way to treat hypertension."

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.

“We are pleased by these promising results, which reaffirm the promise of the Ablative Solutions approach to blood pressure reduction. We are committed to robust clinical research to further substantiate the procedural, clinical, and health-economic benefits of the Peregrine Catheter for the treatment of hypertension,” said Kate Rumrill, President and CEO of Ablative Solutions. “Worldwide, hypertension affects more than one billion people.[i] We remain committed to investigating and collecting further evidence to bring novel therapeutic options to the large population suffering from uncontrolled 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 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.ablativesolutions.com.

This press release shall not constitute an offer to sell or the solicitation of an offer to buy, nor shall there be any sale of these securities in any state or jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such state or jurisdiction.

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

# # #