



Ablative Solutions Announces First Two Patients Treated in the European Peregrine Post-Market Study for Renal Denervation

Kalamazoo, MI, and Tychy, Poland – February 16, 2016 – Ablative Solutions, Inc. (ASI), a privately held company headquartered in Kalamazoo, MI, with offices in Palo Alto, CA, announced today that Professors Wojtek Wojakowski and Mariusz Hochul have treated the first two patients in the European Peregrine Post-Market Study. Patients enrolled in the study receive targeted therapy using the CE-Marked Peregrine System™ Infusion Catheter with a neurolytic agent to treat sympathetic nerves located in the outer layer of the renal arteries.

The Peregrine Post-Market Study is a multi-center clinical trial being launched in centers across Europe. The study is an open-label study designed to collect and evaluate additional safety and performance data using the CE-Marked Peregrine System for the treatment of patients with systemic hypertension.

Prof. Wojtek Wojakowski, the site Principal Investigator, observed that both procedures went smoothly. “We were able to use the Peregrine System to efficiently deliver targeted therapy in these patients with systemic hypertension. In both cases the procedure was essentially painless for the patients, without the use of sedation.”

Professor Pawel Buszman, head of The American Heart of Poland Group (AHP) that directs the hospital at which the patients were treated, said, “We are excited to be working with Ablative Solutions in the clinical evaluation using their innovative therapy to address the treatment of severe hypertension. This is a vital area of interest for us, since many patients in Poland and throughout Europe face serious health complications from challenges in adequately managing their hypertension with medications.”

In Europe, the Peregrine System is CE-Marked to deliver neurolytic agents directly to the sympathetic nerves that reside in the peri-adventitial area of the renal artery, thereby interrupting the oversignaling of the nerves that drive essential hypertension in many patients. Vartan Ghazarossian, President of ASI, said, “The initiation of the Peregrine Post-Market Study is a significant milestone for the company. We believe that our technology provides a reproducible, easy-to-use and targeted denervation technology. This approach allows us to treat patients with minimal or no procedural pain, and with greater efficiency in interrupting overactive sympathetic nerves compared to earlier-generation, energy-based catheter approaches. We hope to demonstrate that perivascular renal denervation using a neurolytic agent (i.e. dehydrated alcohol) will provide a minimally invasive approach that consistently delivers the desired therapeutic effect.”

In the U.S., the Peregrine System has been 510(k) cleared by the U.S. Food and Drug Administration (FDA) for the infusion of diagnostic and therapeutic agents into the perivascular area; however, it is

not currently cleared or approved for the treatment of hypertension. The Peregrine System is intended for use by trained physicians familiar with the risks as detailed in the instructions for use. The Peregrine Post-Market Study includes multiple European clinical sites to enable additional cardiologists and hypertensionists to evaluate Targeted Perivascular Renal Denervation using the Peregrine System in their patients suffering from hypertension.

This press release does not constitute an offer to sell or the solicitation of an offer to buy any securities in an ASI stock offering. There will not be any sale of these securities in any state or jurisdiction in which such offering, sale or solicitation would be unlawful prior to registration or qualification under the securities laws of any such state or jurisdiction.

Forward-Looking Statements

Statements made in this press release that look forward in time or that express beliefs, expectations or hopes regarding future occurrences or anticipated outcomes or benefits are forward-looking statements. A number of risks and uncertainties, such as risks related to product development and commercialization efforts, results of clinical trials, ultimate clinical outcomes and benefit of ASI's products to patients, market and physician acceptance of ASI's products, intellectual property protection and competitive product offerings, could cause actual events to differ from the expectations indicated in these forward-looking statements. You are cautioned not to put any undue reliance on any forward-looking statement. This press release is neither an offer to sell nor a solicitation of an offer to purchase any particular securities. Any such offer or solicitation will be made only pursuant to definitive legal agreements prepared specifically for such purpose. ASI does not assume any obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

For more information:
Vartan Ghazarossian, PhD
President
(650) 321-6884
<http://www.ablative-solutions.com>