FDA Allows Ablative Solutions to Initiate its Phase 2 TARGET-BP I Trial of Combination Drug/Device Therapy for Hypertension under its IND

Pivotal Phase 2 Trial will begin to evaluate Targeted Chemical Denervation

Kalamazoo, MI – September 13, 2016 – Ablative Solutions, Inc. (ASI), a privately held, venture-backed company headquartered in Kalamazoo, MI, with offices in Palo Alto, CA, announced today that the U.S. Food and Drug Administration (FDA) has allowed the Company's Investigational New Drug (IND) application for the Peregrine System™ Kit for catheter-based renal denervation, with targeted delivery of alcohol, for the treatment of uncontrolled hypertension to proceed. Under the IND, Ablative Solutions plans to conduct a multi-center, double-blind, randomized, sham-controlled trial to evaluate its drug-device combination therapy for the treatment of persistent hypertension despite optimal medical treatment, in conjunction with antihypertensive medical therapy.

The trial, called TARGET-BP I, will begin in the United States and will enroll approximately 100 patients in approximately 20 centers globally. The investigational Peregrine System Kit for the treatment of uncontrolled hypertension incorporates a specific formulation of dehydrated alcohol that is infused into the targeted area surrounding the renal artery using the Peregrine System Infusion Catheter, which has a general 510(k) clearance in the U.S. for delivery of therapeutic and diagnostic agents to the perivascular space surrounding peripheral arteries.

The principal investigators (PIs) of the study are experienced thought leaders in the treatment of hypertension who have had leadership roles investigating renal denervation as a therapy for hypertension. The Co-PIs for the U.S. are Michael Weber, MD, Professor of Medicine & Associate Dean of Research, SUNY Downstate College of Medicine, Brooklyn, New York, and David Kandzari, MD, Director and Chief Scientific Officer, Piedmont Heart Institute in Atlanta, Georgia. The European Co-PIs are Felix Mahfoud, MD, Director of Special Hypertension Clinic, University Hospital of Saarland, Germany, and Atul Pathak, MD, Professor of Cardiology/Pharmacology, Clinique Pasteur, Toulouse, France.

"The mechanism for the use of targeted chemical denervation makes sense to me because I believe it has the potential to effectively reduce the over-signaling of the renal nerves that can contribute to hypertension," commented Michael Weber, MD. "The Company has received approval from the FDA to conduct a trial that studies the safety and efficacy of an intervention designed to address challenges that physicians face in managing patients with hypertension. The carefully considered trial protocol and the innovative catheter-based therapeutic delivery being studied in TARGET-BP I will attract considerable attention among the experts and practitioners who work in the field of hypertension."

Co-PI David Kandzari, MD, observed, "The field has learned a lot through early experiences using first-generation products for renal denervation. There is agreement that improving our control of blood pressure is paramount, and we think that interrupting the sympathetic nerves through renal denervation may indeed prove to be clinically beneficial. I'm excited about chemical denervation because I believe it builds upon the learning that has taken place, addressing issues with its approach of using alcohol as a neurolytic agent to directly target these nerves."

In the trial, the Peregrine System Infusion Catheter will be delivered with the use of a minimally invasive technique through a small access site in the femoral artery. In the renal artery, a proprietary deployment system will center the device and, using microneedles, will access the area outside the renal artery and deliver the dehydrated alcohol

directly to the nerve tissue. The alcohol is intended to act as a neurolytic agent, which is expected to interrupt the over-signaling that drives essential hypertension in many patients.

Vartan Ghazarossian, PhD, President and Chief Operating Officer of ASI, said, "We are privileged and honored to be working with thought leaders in the field of hypertension management and renal denervation. We believe that a combination drug-device approach to deliver targeted chemical denervation may indeed provide a therapy that can help those patients whose hypertension is poorly controlled with medication alone. We hope to demonstrate through our clinical trials that perivascular chemical renal denervation using dehydrated alcohol gives physicians and the patients a minimally invasive approach that consistently delivers the desired therapeutic effect."

In the U.S., the Peregrine System Infusion Catheter has been 510(k) cleared by the FDA for a general indication of infusion of diagnostic and therapeutic agents into the perivascular area of the peripheral vasculature. The Peregrine System Infusion Catheter also has CE-mark clearance in Europe for the infusion of a neurolytic agent to achieve a reduction in systemic blood pressure in hypertensive patients. The Peregrine System Kit, which includes both the Peregrine System Infusion Catheter and the dehydrated alcohol, can now be used for investigational use for the treatment of persistent hypertension in conjunction with medical therapy. Additional investigational sites are to be initiated in Europe. In the trials, the Peregrine System Kit will be used by trained investigators familiar with the risks as detailed in the instructions for investigational use.

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 and COO
(650) 321-6884
http://www.ablativesolutions.com