Kona Medical Announces Initiation of WAVE I Study of Renal Denervation Therapy for Hypertension

The Associated Press

BELLEVUE, Wash. & MENLO PARK, Calif.--(BUSINESS WIRE)--Oct 23, 2012--Kona Medical, Inc. (www.konamedical.com) today announced the initiation of the first clinical study of its device therapy for drug-resistant hypertension. The Kona Surround SoundTM system utilizes focused ultrasound, delivered from outside the body, to treat the nerves leading to and from the kidney. The therapy of renal denervation has been shown in other studies to lead to significant and lasting reductions in high blood pressure. Kona is sponsoring the WAVE I clinical study to evaluate the safety and efficacy of its novel technology. WAVE I is now enrolling subjects at St. Vincent's Hospital in Melbourne, Australia, under the direction of Primary Investigator Robert Whitbourn, MD. The study design and initial results of WAVE I will be presented on behalf of the investigators by Todd Brinton, MD on Wednesday, October 24 th at the Transcatheter Cardiovascular Therapeutics conference in Miami, Florida.

Unlike other renal denervation methods which rely on a catheter emitting therapeutic energy through the wall of the renal artery to affect the renal nerves, Kona's Surround SoundTM technology uses a novel method of treating the nerves from outside the patient. A transducer positioned outside the body delivers targeted ultrasound energy that "surrounds" the artery and treats the nerves located in the vicinity of the vessel. By creating a focused energy field around the outside of the artery, the Kona system may result in a more complete and effective ablation in a way that does not impact the walls of the artery.

"Renal denervation is becoming one of the fastest-growing interventional therapies," commented Dr. Whitbourn. "The Kona system has the potential to further improve clinical results, and may also lead to improved access to renal denervation therapy. We are pleased to be participating in the evaluation of the Kona system and anticipate reporting complete study results next spring." "Initiation of the WAVE I study is an important milestone in the development of therapies for hypertension," added Michael Gertner, MD, founder and CEO of Kona Medical. "Ultrasound has inherent advantages as an energy source for ablation, and we believe that external delivery of ultrasound energy better addresses the variability of the location of renal nerves and may lead to better outcomes. Importantly, focused external ultrasound also can enable a system which is entirely non-invasive. This could greatly expand access to renal denervation therapy, and would offer a more patient-friendly alternative for the tens of millions of people who suffer from drug-resistant hypertension." About Kona Medical Based in Bellevue, Washington, and Menlo Park, California, Kona Medical is committed to alleviating the suffering and health risks associated with drug-resistant hypertension with a more effective, less invasive approach to renal artery denervation. The company

was founded in 2009 and in May of this year, the company announced a $30M Series C financing led by a large-cap medical technology company and previous investors, including Essex Woodlands, Domain Associates, Morgenthaler Ventures and BioStar Ventures.

About Hypertension Hypertension (or high blood pressure) is a leading cause of death worldwide. It is a significant, growing global healthcare problem affecting over one billion people and is associated with an increased risk of heart attack, stroke, heart failure, kidney disease and death. According to the American Heart Association, over 75 million people in the USA alone have high blood pressure, and the economic costs exceed $50 billion annually. Despite public awareness and the availability of numerous pharmaceutical therapies, only about half of all treated hypertensive patients achieve adequate blood-pressure control. Moreover, between 5 and 10% of the hypertensive population is drug resistant, resulting in millions of patients worldwide who could benefit from an effective therapy.

For additional information, please visit www.konamedical.com.

Note: Kona Medical’s technology is investigational and is not yet for sale or approved by the US Food and Drug Administration.

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