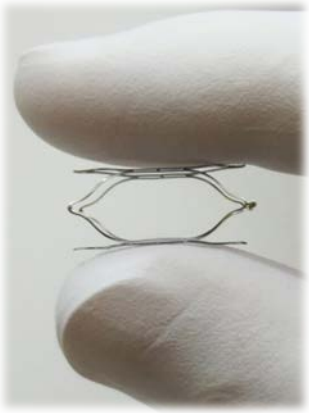
Vascular Dynamics' MobiusHD™ System Receives CE Mark for the Treatment of Resistant Hypertension

System offers novel approach for controlling hypertension using the body's natural hypertension control mechanism

MOUNTAIN VIEW, Calif. (January 6, 2016) – Vascular Dynamics, Inc., a private medical device company developing novel solutions for the treatment of hypertension, today announced receipt of CE Mark approval for its MobiusHD™ System, a minimally invasive system for the treatment of resistant hypertension. Approximately one in 10 people with high blood pressure, or nearly 100 million people worldwide, have drug-resistant hypertension.[1]



"Receiving CE Mark approval for the treatment of resistant hypertension is a major milestone for our company as we validate our novel solution for the millions of people whose hypertension is not adequately controlled by drugs," said Robert Stern, President and CEO of Vascular Dynamics. "Initial results suggest significant improvement in the average blood pressure readings post barostenting procedure in our ongoing CALM first-in-human clinical trials in the U.S. and EU and we are progressing toward the filing of our International Pivotal study to support our U.S. FDA approval."

Drug-resistant hypertension is a major unmet medical need as it significantly increases the risk of heart disease, stroke and kidney disease. The MobiusHD System capitalizes on the ability of the body's baroreceptor mechanism to regulate blood pressure. Baroreceptors are receptors located in the carotid artery that sense blood pressure and relay that information to the brain. The MobiusHD implant is designed to amplify the signals received by the surrounding arterial baroreceptors, and thereby amplify the body's natural response to lower blood pressure through vasodilation.

"Options for patients to reduce their blood pressure are limited once they have failed multi-drug therapy. We have seen very good results in the patients we have treated at our center in the first-in-human clinical trial with the MobiusHD barostenting procedure. We are very excited about the new MobiusHD barostenting procedure and look forward to being able to provide it to our patients who have limited treatment options," said Wilko Spiering, MD, UMC Utrecht, President of the Dutch Society of Vascular Internists and Secretary of the Dutch Society of Hypertension. "Our team looks forward to working with the Vascular Dynamics team to accelerate the clinical process with the next round of studies in the EU."

"I've seen numerous approaches to controlling resistant hypertension over the years," said Gregg W. Stone, MD, Director of Cardiovascular Research and Education at Columbia University Medical Center/New York Presbyterian Hospital and co-chair of the upcoming Vascular Dynamics' MobiusHD International pivotal study. "Most drugs have side effects leading to poor compliance, and more invasive approaches have other drawbacks.

"The MobiusHD is a simple, passive implant that is designed to reduce blood pressure while preserving the body's natural ability to modulate blood pressure. The minimally invasive MobiusHD barostenting procedure could be life changing for this patient population while also reducing the cost of healthcare," added Dr. Stone.

"We now have nine active centers in the U.S. and 12 centers in the EU open for recruitment. We are taking a measured approach with our clinical trials to ensure that we are gathering the appropriate data and maintaining our safety profile," added Mr. Stern. "We have the advantage of insight from a veteran team of medical device professionals and are well funded, having raised about $30 million from 'blue chip' investors including Invus Opportunities, HBM Healthcare Investments, Rainbow Medical and the MedFocus Funds."

About the CALM Clinical Study

Vascular Dynamics is conducting the prospective, open-label, controlled, multicenter CALM study (**C**ontrolling **A**nd **L**owering Blood Pressure With The **M**obiusHD) in the U.S. and Europe with the primary endpoint of safety at six months following the procedure. Patients enrolled in the study have systolic blood pressure of 160 mmHg or greater, and are taking three or more prescription antihypertensives medicines, including a diuretic. Patients are prescreened with Doppler ultrasound and a coronary computed tomography angiogram (CTA) or magnetic resonance angiogram (MRA)**.** The CALM U.S. study is among the first under an FDA Investigational Device Exemption (IDE) following the agency's issuance of draft guidance on IDEs for early feasibility studies. The intent of FDA's guidance is to foster early-stage development of medical devices within the U.S. to address clinical needs and improve patient care, particularly when alternative treatments or assessments are unavailable.

About the MobiusHD Barostenting Procedure

The MobiusHD is a passive implant delivered using standard percutaneous techniques that amplifies the signaling measured by the baroreceptors in the wall of the carotid sinus. Blood pressure is reduced because the increase in baroreceptor signaling results in a commensurate reduction in blood pressure.

About Hypertension

According to the American Heart Association (AHA), of 74 million American adults with high blood pressure, 48% do not have their condition under control. Between 15% and 20% of all hypertensives are considered resistant to medical therapy. High blood pressure was a primary or contributing cause of death for more than 360,000 Americans in 2013. The AHA estimates that high blood pressure costs the U.S. $46 billion each year, including the cost of healthcare services, medications to treat high blood pressure and lost productivity.

About Vascular Dynamics, Inc.

Vascular Dynamics develops catheter-delivered technologies to bring a better quality of life to patients who are resistant to conventional treatments for hypertension. Vascular Dynamics was one of nine companies chosen in 2012 by the FDA to participate in the Early Feasibility Study IDE Pilot Program. The company is conducting open-label, controlled, multicenter, first-in-human clinical trials in the U.S. and Europe to evaluate the safety and performance of the MobiusHD™ device. In December 2015 the MobiusHD™ System was awarded CE Mark certification. The device is covered by 7 issued and pending U.S. and international patents. More information is available at www.vasculardynamics.com.

CAUTION: Investigational device. Limited by Federal (United States) law to investigational use.
MobiusHD is a trademark of Vascular Dynamics, Inc. in the United States and other countries.

[1] Persell, Stephen D. Hypertension 57.6 (2011): 1076-1080.

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