

Vascular Dynamics Interim Data on MobiusHD Presented at TCT Conference Shows Significant Reductions in Ambulatory Systolic Blood Pressure At Six Months
Company Has Initiated Pivotal Trial for the MobiusHD in the US and EU

MOUNTAIN VIEW, Calif.-- (October 30, 2017) --Vascular Dynamics, Inc., a privately held medical device company developing novel solutions for the treatment of hypertension, will present updated interim results of the company's first-in-human trial of its MobiusHD® implant today at the TCT conference in Denver. The data showed an average reduction of ambulatory systolic blood pressure of more than 19 mmHg from baseline at the 6-month endpoint in studies conducted in the US and EU.

These interim results of the CALM-FIM (Controlling and Lowering Blood Pressure with MobiusHD First in Man) trial will be outlined today during a didactic session. The data, which were updated from a previous presentation at the European Society of Cardiology conference in August to include data from the United States arm of the Study, demonstrated 89 percent of the 42-patients combined European and United States cohort at six-months had a greater than 10 mmHg drop in office systolic blood pressure or 5 mmHg or more in 24-hour ambulatory systolic blood pressure. In addition, these patients experienced an average of 16.3 percent reduction in their use of antihypertensive medication. Since that time, Vascular Dynamics has initiated its pivotal, sham-controlled trial, CALM 2, in both the United States and Europe.

“These data provide the backbone for our understanding of the enormous potential of this approach to managing resistant hypertension, which is the term for blood pressure that remains too high despite the use of as many as three or more antihypertensive drugs,” said Mark Bates, MD, professor of medicine and surgery, West Virginia University, Charleston, WV, who will present the data at TCT and is the principal investigator of the US arm of the CALM-FIM study. “The impressive results in an open label setting underscore the value of initiating the pivotal, sham-controlled trial to determine to what extent we can replicate, or even improve upon the outcomes.”

“We are encouraged with the results we've seen to date with the MobiusHD CALM-FIM studies in the US and the EU. Earlier this year the European arm results were published in *The Lancet* and we look forward to the publication of the combined data next year,” said Robert Stern, CEO of Vascular Dynamics.¹ “We believe that this treatment represents a paradigm shift in treating resistant hypertension in the clinic and we look forward to continuing to generate data in the CALM 2 pivotal trial.”

About The MobiusHD® System

The MobiusHD® System, a minimally-invasive 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 increase the body's natural response to lower blood pressure through vasodilation. Results of the European arm of the CALM-FIM trial, the first-in-humans trial of the system were published in the September 1, 2017 issue of The Lancet.

About Resistant Hypertension

Hypertension, or elevated blood pressure, is a common medical condition that currently affects one billion people worldwide.² If left untreated, hypertension can cause life-threatening problems, including heart attack, aneurysm, stroke or kidney failure. Patients with hypertension can often reduce their risk factors by making lifestyle changes such as losing weight, quitting smoking, and increased exercise. In cases with advanced hypertension, medical therapies may be prescribed.

Patients experiencing resistant hypertension are uncontrolled with at least 3 antihypertensive drugs and are at four times greater risk of cardiovascular events compared with hypertensive patients achieving blood pressure targets.³ The American Heart Association (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, and the MobiusHD system has also been accepted to participate in the FDA's Expedited Access Pathway (EAP) program. The device is covered by seven issued and pending U.S. and international patents. The MobiusHD system has received a CE Mark for the treatment of hypertension in the European Union. However, the MobiusHD system is not commercially available in the United States. More information is available at www.vascular-dynamics.com.

CAUTION: In the United States, the MobiusHD Device is limited by law to investigational use only.

¹ Spiering, W, Williams, B, Van der Heyden, J..., and for the CALM-FIM_EUR investigators. Endovascular baroreflex amplification for resistant hypertension: a safety

and proof-of-principle clinical study. *Lancet*; 2017 (published online Sept 1.
[http://dx.doi.org/10.1016/S0140-6736\(17\)32337-1](http://dx.doi.org/10.1016/S0140-6736(17)32337-1))
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2 Kearney PM, et al. Global burden of hypertension: Analysis of worldwide data. *Lancet*. 2005;365(9455):217-23

3 Pierdomenico SD, Lapenna D, Bucci A, et al. Cardiovascular outcome in treated hypertensive patients with responder, masked, false resistant, and true resistant hypertension. *Am J Hypertens*. 2005;18: 1422-8.

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