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Ardian's Catheter-Based Treatment for Hypertension Demonstrates Substantial and Sustained Blood Pressure Reduction in Landmark Randomized Clinical Trial

Breakthrough Findings Simultaneously Reported at American Heart Association Scientific Sessions 2010 and Published in The Lancet

Chicago – Nov. 17, 2010 – Late-breaking data presented today at the American Heart Association Scientific Sessions 2010 and simultaneously published in *The Lancet* demonstrated that the landmark Symplicity HTN-2 trial evaluating Ardian's Symplicity[®] Catheter System™ met its primary endpoint.

The study showed that, after six months, patients treated with Ardian's device experienced an average drop in blood pressure of 32/12 mmHg compared to an increase in blood pressure of 1/0 mmHg in the control group of patients treated with medical therapy alone ($p < 0.0001$).

Research has shown that each incremental 20/10 mmHg increase of blood pressure above normal levels is associated with a doubling of cardiovascular mortality over a 10 year periodⁱ and that reducing systolic blood pressure by as little as 5 mmHg can reduce the risk of stroke by almost 30 percent.ⁱⁱ

"The impressive results of this study show that Ardian's Symplicity System has the potential to become a truly revolutionary treatment," said Murray Esler, M.D., Ph.D., principal investigator of the trial and associate director of the Baker IDI Heart and Diabetes Institute of Melbourne, Australia. "Combined with findings from the earlier Symplicity HTN-1 study, which demonstrated the safety and durability of the therapy out to two years, these results fuel our enthusiasm for the potential of this treatment to significantly impact the standard of care for the large number of patients suffering from this disease."

The Symplicity HTN-2 trial was an international, multi-center, prospective, randomized, controlled study of the safety and effectiveness of renal denervation in patients with uncontrolled hypertension. One hundred-six patients were enrolled from 24 investigational sites. At baseline

the randomized treatment and control patients had similar high blood pressures: 178/97 mmHg and 178/98 mmHg, respectively, despite both receiving an average daily regimen of five antihypertensive medications. After six months, the average blood pressure of the renal denervation group was reduced to 146/85 mmHg, compared to an average blood pressure of 179/98 mmHg for the control group.

The study also found that the therapy was safe, with no serious device or procedure-related events, no cardiovascular complications and no kidney-related complications.

“Hypertension is often described as a ‘silent killer’ as it frequently has no symptoms yet significantly increases a patient’s risk of heart attack, stroke or death,” said Andrew Cleeland, president and CEO of Ardian, Inc. “Positive data from the Symplicity HTN-2 trial reinforces our belief that this treatment has the potential to significantly improve the quality of life for the millions of people around the world with uncontrolled hypertension. We look forward to beginning a U.S. pivotal study of the device to gather data needed to bring this promising therapy to patients and physicians in the United States.”

About the Symplicity® Catheter System™

The Symplicity Catheter System is used to perform a procedure termed renal denervation (RDN). In a straight-forward endovascular procedure, similar to an angioplasty, the physician inserts the small, flexible Symplicity Catheter into the femoral artery in the upper thigh and threads it into the renal artery. Once in place within the renal artery, the device delivers low-power RF energy to deactivate the surrounding renal sympathetic nerves. This, in turn, reduces hyper-activation of the sympathetic nervous system, which is often the cause of chronic hypertension. The one-time procedure aims to permanently reduce blood pressure. RDN may also allow patients to reduce or eliminate the need for lifelong antihypertensive medications.

In addition to hypertension, the therapy may hold promise for treating heart failure, diabetes and chronic kidney disease, conditions also characterized by elevated sympathetic nerve activity. The Symplicity Catheter System has received CE Mark approval in the European Union and is investigational in the United States. Visit <http://www.ardian.com/patients/symplicity.shtml> to view an animation of the device and the procedure.

About Hypertension

Though it has no symptoms, hypertension (high blood pressure) is the number one risk factor for premature death worldwide, affecting about one in three adults.ⁱⁱⁱ Nearly half of Europeans suffer from hypertension^{iv} and in the United States, approximately 75 million people are affected, only two-thirds of whom are treated.^v Of those receiving treatment, approximately half are not achieving target blood pressure levels. The medications often prescribed for hypertension must be taken daily for the duration of a patient’s life, can be costly, and often result in side effects that can negatively impact quality of life. Globally, the estimated annual healthcare expenditure directly related to hypertension is approximately \$500 billion.^{vi}

About Ardian

Privately held Ardian Inc., based in Mountain View, Calif., develops catheter-based therapies to treat hypertension and related conditions. Ardian is the eighth company created by The Foundry, a leading medical device incubator based in Menlo Park, Calif. Ardian's investors include Morgenthaler Ventures, Advanced Technology Ventures, Split Rock Partners, Medtronic and Emergent Medical Partners. For more information, please visit www.ardian.com.

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ⁱⁱ Mohr, J.P., *Churchill Livingstone*, 2004.

ⁱⁱⁱ Mathers, C., et al. *World Health Organization*; 2009.

^{iv} Wolf-Maier, K., et al. *JAMA* 2003;289:2363-9.

^v Lloyd-Jones, D., et al. *Circulation* 2010;121:e46-e215.

^{vi} Lawes, CM., et al. *Lancet*. 2008;371:1513-1518.