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Ardian's Catheter-Based System for Renal Denervation Now Commercially Available in Australia

Mountain View, Calif. – Nov. 17, 2010 – Ardian, Inc., a pioneer in catheter-based therapies for hypertension, today announced that its Symplicity® Catheter System™ has been included in the Australian Register of Therapeutic Goods, making it available for commercial use in Australia. The Symplicity Catheter System is a first-of-kind device for renal denervation, which has been linked with a reduction of uncontrolled high blood pressure.

“Ardian's Symplicity System could have a significant impact on the standard of care for hypertension, which often has no symptoms yet significantly increases a patient's risk of heart attack, stroke or death,” said Prof. Murray Esler, associate director of the Baker IDI Heart and Diabetes Institute of Melbourne, Australia. “I look forward to presenting results of the international randomized clinical trial of the therapy today.”

Prof. Esler is the principal investigator of the Symplicity HTN-2 trial, a prospective, randomized, controlled study of the safety and effectiveness of renal denervation (RDN) in patients with uncontrolled hypertension compared to standard medical therapy. The study randomized 106 patients from 24 investigational sites in Europe, Australia and New Zealand. Results were presented today at the American Heart Association Scientific Sessions in Chicago, Illinois, USA.

Several Australian institutions have played a key role in the clinical evaluation of the new treatment. Prof. Robert Whitbourn performed the world's first RDN procedure at St. Vincent's Hospital (Melbourne) in 2007. Patients have also been enrolled by Prof. Henry Krum and Dr. Tony Walton at The Alfred Hospital (Melbourne), by Profs. Murray Esler and Markus Schlaich at The Baker IDI Heart and Diabetes Institute (Melbourne), and by Dr. Suku Thambar at John Hunter Hospital (New South Wales).

“Much of the pioneering clinical work with the Symplicity System has been conducted in Australia, so the ability to commercialize there is a particularly gratifying milestone for Ardian,” said Andrew Cleeland, president and CEO of Ardian, Inc. and an Australian. “We are pleased that this important treatment is now available to physicians and patients in Australia.”

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 Symplicity HTN-2 and previous clinical studies have shown is often the cause of chronic hypertension. Initial clinical trials of this procedure have demonstrated a clinically significant reduction in hypertension that is sustained to at least two years.

In addition to being included in the Australian Register of Therapeutic Goods, 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.ⁱ Nearly half of Europeans suffer from hypertensionⁱⁱ and in the United States, approximately 75 million people are affected, only two-thirds of whom are treated.ⁱⁱⁱ 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.^{iv}

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

ⁱⁱ Wolf-Maier, K., et al. *JAMA* 2003;289:2363-9.

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

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