



# ARDIAN

## Ardian<sup>®</sup> Receives 2010 EuroPCR Innovation Award and Demonstrates Further Durability of Renal Denervation Treatment for Hypertension

Palo Alto, CA June 3, 2010 – Ardian announced today that it has received the 2010 EuroPCR Innovation Award for its Symplicity<sup>®</sup> Catheter System<sup>™</sup>, which may provide a new treatment option for millions of patients living with uncontrolled hypertension. The treatment, called renal denervation (RDN), is the first catheter-based treatment for hypertension and has shown significant blood pressure reductions in early clinical evaluations.

The award, presented at the annual EuroPCR meeting in Paris, France last week, recognizes the one technology each year that shows the greatest potential to change the practice of interventional medicine. Previous winners of this honor include Transcatheter Aortic Valve Implant (TAVI) technology and Bioabsorbable Stent systems.

The honor came just days after the presentation of data in the late breaking trials session at the EuroPCR 2010 annual meeting, reporting sustained, long-term durability of the treatment. These data reported on 117 uncontrolled hypertensive patients from the Symplicity HTN-1 pilot study, showing that those treated with the Symplicity Catheter System maintained a clinically significant reduction in blood pressure at the 18 month follow-up.

The data includes patients enrolled with persistently elevated blood pressure despite treatment with an average of five medications from centers in Europe, Australia and the US. This latest presentation builds on those previously published in *The Lancet* (April 11, 2009) and presented at the *American College of Cardiology* and *Transcatheter Cardiovascular Therapeutics* meetings in 2009.

Specifically, the presentation noted that the 40-minute procedure safely produced a significant and sustained reduction in blood pressure averaging -27/-15 mmHg at the 18 month follow-up point. Procedural and chronic safety results were also reported. Imaging of the renal arteries at 6 months revealed no evidence of treatment-related vascular abnormalities or stenoses. Further, there were no orthostatic or electrolyte disturbances, and serial measures of serum creatinine and calculation of glomerular filtration rate (GFR) showed that kidney function in the study cohort remained stable through 12 months.

Ardian has recently completed enrollment in Symplicity HTN-2, a randomized study comparing renal denervation plus medical treatment to medical therapy alone. This study, which was initiated last year, completed enrollment three months ahead of schedule and aims to have primary endpoint data available by the end of 2010.

“We are honored to receive an award from such a prestigious group acknowledging the clinical importance of our new technology,” said Andrew Cleeland, President and CEO of Ardian. “We remain committed to the ongoing clinical development of the treatment and appreciate the ongoing collaboration of our clinical sites.”

### **About the Symplicity® Catheter System™**

Ardian’s Symplicity Catheter System delivers radiofrequency (RF) energy from within the renal artery to block conduction in the surrounding renal nerves, thereby counteracting chronic activation of the sympathetic nervous system. In addition to blood pressure reduction, this treatment has shown promising results for chronic kidney disease, insulin resistance and heart failure. The treatment is performed in the catheterization laboratory using routine interventional techniques similar to those used in renal stent procedures. The 40-minute treatment is minimally invasive and does not involve a permanent implant. The Symplicity Catheter System has received CE Mark approval in Europe but remains investigational in the United States.

### **About Ardian**

Ardian, Inc., headquartered in Palo Alto, California, is a private medical device company developing a novel catheter-based treatment for diseases related to sympathetic hyperactivity, including hypertension, chronic kidney disease, insulin resistance and heart failure. These interdependent disease states represent a significant, escalating global health issue. Ardian is the eighth company created by The Foundry, a leading medical device incubator based in Menlo Park, California. For more information, please visit [www.ardian.com](http://www.ardian.com).

### **About Hypertension**

Hypertension (high blood pressure) is the leading attributable cause of death worldwide. In the United States alone, high blood pressure affects approximately 75 million people, only two-thirds of whom are treated. Close to half of all people receiving therapy for their hypertension are not achieving target blood pressure levels. Each incremental 20/10 mmHg increase of blood pressure above normal levels is associated with a doubling of cardiovascular mortality over a 10 year period.

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