



# ARDIAN

## Ardian<sup>®</sup> Demonstrates Substantial and Sustained Blood Pressure Reduction in Hypertension Patients Treated with Symplicity<sup>®</sup> Catheter System<sup>™</sup>

*Landmark Trial Results Simultaneously Reported in Lancet Publication and at American College of Cardiology Meeting*

Palo Alto, CA March 30, 2009 – Compelling results from the first clinical study evaluating an innovative catheter-based treatment for chronic hypertension were presented today, as part of the Late Breaking Clinical Trials III: Emerging Technologies Session (Session No. 407) held at the 58<sup>th</sup> Annual Scientific Session of the American College of Cardiology in Orlando, Florida. These trial results, which evaluated the effects of renal denervation on hypertension, were published simultaneously in the medical journal, *The Lancet*, with an accompanying editorial noting the clinical importance of the technology and results.

The study enrolled 50 patients across 5 centers in Australia and Europe, using the Symplicity<sup>®</sup> Catheter System<sup>™</sup> to treat patients with drug-resistant hypertension. Professor Henry Krum, (Director, Center of Cardiovascular Research & Education in Therapeutics, Monash University, Melbourne Australia) Co-Principal Investigator, reported that the simple, 40-minute procedure safely produced a substantial blood pressure reduction that was sustained through the one-year follow-up.

The 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 and lowering blood pressure. The treatment is performed in the catheterization laboratory using routine techniques similar to those used in renal stent procedures. The intervention is minimally invasive and does not involve a permanent implant.

Significant blood pressure reductions of -21/-10, -22/-11, -24/-11 and -27/-17 mmHg were observed at 3, 6, 9 and 12 months, respectively. These findings suggest a durable clinical benefit following the single treatment.

Both vascular and renal safety were carefully assessed in the study. Renal vascular safety was assessed using imaging both acutely (15 to 45 days) and chronically (6 to 9 months) with no evidence of abnormalities or stenosis at any treatment site. Kidney function was assessed with serial measures of serum creatinine and calculation of glomerular filtration rate (GFR). Again, in all instances GFR remained stable with a slight and non significant trend towards improvement.

Commenting on these results, Professor Krum stated, "I am very excited by the initial results of this pioneering treatment. We have demonstrated that catheter-based renal sympathetic denervation is straightforward, safe and well-tolerated. With a single procedure, we are able to achieve lasting reductions in blood pressure in a group of patients unresponsive to other medical alternatives."

"We are proud to have sponsored this landmark research," said Andrew Cleeland, President and CEO of Ardian, Inc. "Our clinical studies have been scientifically rigorous and have significantly advanced our knowledge of this emerging treatment. We greatly appreciate the dedication and effort of the patients, clinical investigators, research staff and the Ardian team."

Based on these results, prospective randomized clinical trials examining the treatment in hypertension are planned to begin this year in Europe and Australia. Trials for heart failure, cardiorenal syndrome, and chronic kidney disease are also anticipated.

### **About the Symplicity<sup>®</sup> Catheter System<sup>™</sup>**

Ardian's Symplicity Catheter System allows interventionalists to quiet renal sympathetic nerve activity via a straightforward, catheter-based procedure. It is anticipated that this quieting will result in significant and meaningful reductions in blood pressure and the level of systemically damaging neurohormones. 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 pioneering, private, clinical-stage medical device company developing a novel catheter-based treatment for hypertension, chronic kidney disease and heart failure; three interdependent disease states that 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 about the Symplicity<sup>®</sup> Catheter System<sup>™</sup>, Ardian or clinical trials, 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 73 million people, only two thirds of whom are treated. Close to half of all people with hypertension in treatment are not currently reaching their target blood pressure. Each incremental 20mmHg increase of systolic blood pressure above normal levels is associated with a doubling of cardiovascular mortality over a ten year period.

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