



ARDIAN

Ardian[®] Demonstrates Durable Blood Pressure Reduction in Hypertension Patients Treated with Symplicity[®] Catheter System[™]

Palo Alto, CA September 25, 2009 – Data supporting the long-term safety and effectiveness of renal sympathetic denervation (RDN) in treating patients with chronic hypertension were presented today at the Transcatheter Cardiovascular Therapeutics (TCT) conference in San Francisco, California. The data were presented at a late-breaking trial session and showed that patients in the study maintained a clinically significant reduction in blood pressure at one -year following treatment.

The results stemmed from the Symplicity I Trial which was the first clinical study to evaluate a catheter-based treatment for chronic hypertension. The study enrolled patients who had persistent elevated blood pressure despite taking an average of 4.7 medications. The multicenter study was conducted in Australia and Europe, using the Symplicity[®] Catheter System[™] manufactured by Ardian, Inc. Early results from this same trial were also recently reported in the prestigious medical journals *The Lancet* (April 11, 2009) and *The New England Journal of Medicine* (August 27, 2009).

The study's co-principal investigator, Professor Henry Krum, (Director, Center of Cardiovascular Research & Education in Therapeutics, Monash University, Melbourne Australia) reported that the simple, 40 minute procedure safely produced a mean blood pressure reduction of -27/-17 mmHg at 12 months in the study cohort. These findings suggest that the single, catheter-based intervention may achieve a durable, clinically important reduction in blood pressure in this very difficult to treat population.

Both vascular and renal safety were also carefully assessed in the study and reported during the conference. Renal vascular safety was assessed by imaging treated arteries both acutely and chronically for up to 9 months. No evidence of treatment-related abnormalities or stenoses was reported. Kidney function was assessed with serial measures of serum creatinine and calculation of glomerular filtration rate (GFR). The mean GFR in the study cohort remained stable at 12 months.

Commenting on these results, Professor Krum stated, "I am very excited by these latest findings. These data demonstrate that the reductions in blood pressure we observed at 12 months in our initial *Lancet* paper have been found to be durable amongst a much larger cohort of patients who have now completed the study."

Based on these results Ardian, Inc. has initiated the Symplicity HTN-2 trial, a prospective, multicenter randomized study comparing patients treated with renal denervation to those receiving rigorous medical therapy. The trial will enroll 110 patients with blood pressure over 160 mmHg, despite taking 3 or more anti-hypertensive medications. The primary endpoint for the trial will be blood pressure reduction at 6 months. Kidney function, vascular safety and additional efficacy measures will also be assessed. Patients will be followed for 3 years.

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, heart failure and metabolic syndrome. 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 pioneering, private, clinical-stage medical device company developing a novel catheter-based treatment for diseases related to sympathetic hyperactivity, including hypertension, chronic kidney disease, metabolic syndrome 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 about the Symplicity[®] Catheter System[™], Ardian or its clinical trials, please visit 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 receiving therapy for their hypertension are not achieving target blood pressure levels. Each incremental 20 mmHg increase of systolic blood pressure above normal levels is associated with a doubling of cardiovascular mortality over a 10 year period.

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