NEWS RELEASE

First-in-Human Study Shows Investigational Multi-Electrode Radiofrequency Balloon Catheter Is Efficient for Acute Pulmonary Vein Isolation

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IRVINE, Calif., May 15, 2017 /PRNewswire/ -- Biosense Webster, Inc., part of the Johnson & Johnson Medical Devices Companies*, recently announced clinical trial results from a first-in-human study evaluating the acute feasibility of an investigational radiofrequency (RF) balloon catheter in treating patients with atrial fibrillation, or Afib. The study showed the RF balloon catheter could uniformly achieve pulmonary vein isolation (PVI) in all patients without the need for "touch-up" with a focal ablation catheter.

The PV Isolation with a Novel Multi-electrode Radiofrequency Balloon Catheter that Allows Directionally-Tailored Energy Delivery (RADIANCE) study was a multicenter, single-arm, first-in-human feasibility study conducted between December 2, 2016 and March 8, 2017 in Europe. A total of 39 patients were treated with the RF balloon catheter at four centers with nine different operators from both the US and Europe.

The study showed the RF balloon catheter could deliver directionally-tailored energy using multiple electrodes for efficient acute PVI in patients with paroxysmal atrial fibrillation - the heart rhythm disorder impacting the quality of life for over 3 million Americans and over 30 million people worldwide.

"Existing balloon catheters are limited in a number of ways, the most significant limitation being a single ablative element that delivers identical amounts of energy along the full pulmonary vein ostium circumference," said Dr. Vivek Y. Reddy, director of Cardiac Arrhythmia Services for the Mount Sinai Hospital and the Mount Sinai Health System and study investigator. "This can lead to over-ablation of thin tissue, under-ablation of thick tissue, and unnecessary complications. The investigational RF balloon is designed to both optimize safety and efficacy and reduce procedure time."

Data from the RADIANCE study was presented for the first time during a late-breaking clinical trial session at Heart Rhythm 2017, the Heart Rhythm Society's 38th Annual Scientific Sessions in Chicago.

"Alarmingly, Afib increases a patient's risk of stroke by five times, but millions of patients go untreated year after year," said Shlomi Nachman, Company Group Chairman of Cardiovascular and Specialty Solutions at Johnson & Johnson. "This latest innovation comes from our obsession with solving the everyday challenges our customers face, so more patients can be treated. We're thrilled with the results from this first-in-human study and will continue studying the RF balloon catheter's safety and efficacy."

About the RADIANCE Study

Paroxysmal atrial fibrillation patients were treated with an investigational Biosense Webster, Inc. RF balloon catheter with 10 irrigated, flexible gold surface electrodes intended to independently deliver varying amount of power. Patients underwent pulmonary vein isolation where RF energy was delivered simultaneously from all electrodes - up to 30 seconds posteriorly and 60 seconds anteriorly.

The primary endpoint was the incidence of primary procedure-related adverse events occurring within seven days of the procedure. Of note, any pulmonary vein stenosis, unresolved diaphragmatic paralysis or atrio-esophageal fistula that occurred also were analyzed as primary adverse events regardless of timing. Secondary endpoints included serious adverse events occurring over the course of the study and the effectiveness of electrical pulmonary vein isolation despite provocative pharmacological challenge.

In addition, the study included:

- Pre-procedure (baseline) testing included: a 12-lead electrocardiogram (ECG), transthoracic echocardiogram, cardiac computed tomography (CT) or magnetic resonance imaging (MRI), a cerebral MRI, and a neurological exam with administration of the NIH Stroke Scale.
- Repetition of the 12-lead ECG, transthoracic echocardiogram, cerebral MRI and the neurological exam with the NIH Stroke Scale post-procedure (prior to hospital discharge).
- Post-procedure: Esophageal endoscopy of all patients to assess for any evidence of thermal esophageal damage.

Results showed the RF balloon catheter was able to achieve electrical isolation of all pulmonary veins with a high rate of first-pass isolation and low evidence of latent pulmonary vein re-conduction. The procedural performance with the device was favorable, with 100 percent of the treated pulmonary veins electrically isolated without the need for a focal ablation catheter.

About Biosense Webster, Inc.

Biosense Webster, Inc., part of Johnson & Johnson Medical Devices Companies, is the global leader in the science of diagnosing and treating heart rhythm disorders. The company partners with clinicians to develop innovative technologies that improve the quality of care for arrhythmia patients worldwide. More information can be found at **www.biosensewebster.com**.

*The Johnson & Johnson Medical Devices Companies comprise the surgery, orthopaedics, and cardiovascular businesses within Johnson & Johnson's Medical Devices segment.