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Biosense Webster Reports Compelling Results from Ground-Breaking SMART-AF IDE Study on the Safety and Effectiveness of the THERMOCOOL® SMARTTOUCH™ Catheter

THERMOCOOL® SMARTTOUCH™ Catheter and Software Module Enables Contact Force Sensing in the Ablation of Atrial Fibrillation

DIAMOND BAR, Calif.--(BUSINESS WIRE)-- Biosense Webster, Inc., a worldwide leader in the diagnosis and treatment of cardiac arrhythmias, announced the 12-month safety and effectiveness results of the THERMOCOOL® SMARTTOUCH™ Catheter and Software Module in the treatment of symptomatic, drug refractory, paroxysmal atrial fibrillation from the ground-breaking SMART-AF Investigational Device Exemption (IDE) clinical trial. The results of the trial were presented at the Heart Rhythm Society's 34th Annual Scientific Sessions in Denver, CO, by Dr. Andrea Natale, a member of the study Advisory Committee and Executive Medical Director of the Texas Cardiac Arrhythmia Institute at St. David's Medical Center in Austin, TX.

"The THERMOCOOL® SMARTTOUCH™ Catheter represents a major advance in RF catheter ablation technology," said Shlomi Nachman, Worldwide President, Biosense Webster, Inc. "It enables physicians to directly measure contact force, rather than having to rely on surrogate measures, as is required for all currently marketed ablation catheters in the US today." The THERMOCOOL® SMARTTOUCH™ Catheter measures in real time the catheter tip contact force and direction inside the heart during cardiac ablation procedures. The THERMOCOOL® SMARTTOUCH™ Catheter is approved for investigational use only (IDE) and is not for sale in the United States. The results from this study will be submitted later this month for the THERMOCOOL® SMARTTOUCH™ Catheter Premarket Approval application to the FDA.

The 12-month study enrolled 172 subjects (72 percent male and 28 percent female) at 21 leading centers across the United States. To date, the study met its prospective safety and effectiveness endpoints with no unanticipated device-related adverse events and 72 percent of subjects were free from AF recurrence at the end of the 12-month follow up period. 80 percent of subjects who were off AADs at 12 months were free from AF recurrence.

The THERMOCOOL® SMARTTOUCH™ Catheter represents the industry-leading catheter technology coming from Biosense Webster, Inc. The data it produces are graphically displayed on the CARTO® 3 System mapping and navigation system with Software Version 2 or higher, the market's technological leader in 3D mapping systems, to create a fully integrated solution combining contact force and 3D mapping and navigation capabilities.

In discussing the study results, Dr. Natale said, "SMART-AF showed a 12-month success rate of 72 percent with comparable safety to previous studies. Furthermore, increased percent of time within physician-targeted contact force range correlated with increased freedom from arrhythmia recurrence, with 84.4% of subjects arrhythmia-free at 12 months when the force was within the targeted range > 82% of the time. This is exciting data for the EP community which has been working tirelessly to provide better treatments for AF. This will provide an important new tool for treating paroxysmal AF patients."

About AF and cardiac ablation

Atrial Fibrillation is the most prevalent arrhythmia, and is a leading cause of stroke among people 65 years and older. Worldwide, it is estimated that 20 million people have AF, yet only ~130,000 are treated with ablation every year. The public health implications of AF are a growing concern because those with AF are at an increased risk of morbidity and mortality as well as a reduced quality of life.

Most patients with AF today are treated with anti-arrhythmic drugs (AADs), even though about half of them are refractory to these drugs. During cardiac ablation, energy is delivered through the catheter to those areas of the heart muscle causing the abnormal heart rhythm. This energy "disconnects" the pathway of the abnormal rhythm. Cardiac ablation is commonly used for "simple" arrhythmias, like Wolff-Parkinson-White Syndrome and atrioventricular nodal re-entry tachycardia (AVNRT), and is increasingly being used for more complex arrhythmias like ventricular tachycardia and atrial fibrillation. THERMOCOOL® Navigation Catheters are approved for drug refractory recurrent symptomatic paroxysmal atrial fibrillation, when used with CARTO® Systems (excluding NAVISTAR® RMT THERMOCOOL Catheter).

About Biosense Webster, Inc.

Biosense Webster, Inc., a Johnson & Johnson company, pioneered EP diagnostic catheters more than 20 years ago and continues to lead the industry as an innovative provider of advanced cardiac diagnostic, therapeutic, and mapping tools. As the leader in EP navigation systems and ablation therapy, Biosense Webster, Inc. has technology that includes the largest installed base of cardiac mapping navigation systems worldwide in leading hospitals and teaching institutions. For more information about Biosense Webster and its products, please visit: www.biosensewebster.com.

Dr. Natale is compensated for his services as a member of the company's scientific advisory board and provides other consulting services.

Always verify catheter tip location using fluoroscopy or IC signals and consult the CARTO® System User Guide regarding recommendations for fluoroscopy use.

(This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995. The reader is cautioned not to rely on these forward-looking statements. These statements are based on current expectations of future events. If underlying assumptions prove inaccurate or unknown risks or uncertainties materialize, actual results could vary materially from the expectations and projections of Biosense Webster, Inc. and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to, general industry conditions and competition; economic factors, such as interest rate and currency exchange rate fluctuations; technological advances, new products and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approvals; challenges to patents; changes in behavior and spending patterns or financial distress of purchasers of health care products and services; changes to governmental laws and regulations and domestic and foreign health care reforms; trends toward health care cost containment; and increased scrutiny of the health care industry by government agencies. A further list and description of these risks, uncertainties and other factors can be found in Exhibit 99 of Johnson & Johnson's Annual Report on Form 10-K for the fiscal year ended December 30, 2012. Copies of this Form 10-K, as well as subsequent filings, are available online at www.sec.gov, www.jnj.com or on request from Johnson & Johnson. Neither Biosense Webster, Inc. nor Johnson & Johnson undertake to update any forward-looking statements as a result of new information or future events or developments.)

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