



Study Finds Catheter Ablation with the NAVISTAR(R) THERMOCOOL(R) Catheter Superior to Anti-Arrhythmic Drug Therapy for the Treatment of Symptomatic, Paroxysmal Atrial Fibrillation

NEW ORLEANS, Nov 11, 2008 (BUSINESS WIRE) -- In a multicenter study, catheter ablation has been shown in a randomized clinical trial to significantly outperform anti-arrhythmic drug (AAD) therapy for the treatment of symptomatic paroxysmal atrial fibrillation. Atrial fibrillation, or AFib as it is more commonly referred to, is the most prevalent cardiac arrhythmia (heart rhythm disorder) and one of the most common causes of stroke.

In data presented here today at the American Heart Association's Annual Scientific Sessions, patients receiving cardiac ablation with the NAVISTAR(R) THERMOCOOL(R) Catheter, manufactured by Biosense Webster, Inc., were significantly more likely to be free of recurring AFib at nine months after initiation of treatment and experienced fewer serious adverse events after 90 days than those receiving AAD therapy.

"This is the first time in an FDA-monitored, controlled clinical study that catheter ablation has been shown to outperform traditional medical therapy," said David Wilber, M.D., Primary Investigator of the study and the George M. Eisenberg Professor of Cardiovascular Sciences and Director, Division of Cardiology, Loyola University Medical Center in Maywood, Illinois. "These data are extremely important to the electrophysiology community widely adopting alternative treatments to traditional medical therapy, which can often cause significant side effects for patients suffering from this debilitating condition."

In addition to his role as Primary Investigator, Dr. Wilber is compensated for his services as a member of the Company's scientific advisory board and provides other consulting services.

Currently, there are no ablation catheters approved for marketing by the Food and Drug Administration (FDA) for the treatment of AFib in the United States. Biosense Webster submitted a Pre-Market Approval (PMA) Supplement for an AFib indication for its THERMOCOOL(R) Catheter, based on this study data. The PMA Supplement was granted priority review by FDA, which will convene the Circulatory System Devices Advisory Panel on November 20th in Gaithersburg, MD to review the application.

"We are pleased that our application was granted priority review and we look forward to discussing this potential treatment advance with members of the advisory panel," said Shlomi Nachman, Worldwide President, Biosense Webster, Inc.

This clinical trial was a randomized, unblinded and controlled evaluation of symptomatic, paroxysmal AFib patients who were refractory to at least one AAD and had at least three episodes of AFib in the six months prior to randomization. A total of 167 patients were enrolled from 19 sites throughout the world and the primary effectiveness endpoint (chronic success) was freedom from documented symptomatic AFib recurrence following procedural endpoint confirmation and absent new AAD use or repeat ablation outside of protocol-defined criteria.

The probability of chronic success was 62.7% for patients receiving NAVISTAR(R) THERMOCOOL(R) Catheter ablation at the 9-month effectiveness evaluation period, which is significantly superior (p less than 0.0001) to the 17.2% probability for the group of patients treated with AAD. The THERMOCOOL(R) Catheter ablation group also demonstrated a substantial reduction in symptomatic AFib recurrence compared with patients treated with AAD (75% vs 21%, p less than 0.0001).

Additionally, the THERMOCOOL(R) Catheter ablation group demonstrated an excellent safety profile with no device-related serious adverse events such as death, heart attack, stroke, cerebrovascular accident, heart block or atrial perforation within seven days post ablation. Importantly, there was no clinically significant pulmonary vein stenosis in patients receiving ablation, and the incidence of serious adverse events in the THERMOCOOL(R) Catheter group in the 90 days following initiation of therapy was observed to be approximately half that in the AAD group (35.1 vs. 18.4%, $p = 0.0221$).

The NaviStar ThermoCool Catheter is currently approved in the United States for the treatment of Type 1 atrial flutter, and recurrent drug/device refractory sustained monomorphic ventricular tachycardia due to prior myocardial infarction (heart attack), two types of cardiac arrhythmia.

AFib: Growing Statistics and Current Treatment Options

AFib is the most prevalent arrhythmia, affecting between 2.3 to 5.6 million adults in the United States, and is a leading cause of stroke among people 65 years and older. Worldwide, it is estimated that 10 million people have AFib, yet fewer than 80,000 are treated through ablation. The public health implications of AFib are a growing concern because those with the condition are at an increased risk of morbidity and mortality as well as a reduced quality of life.

Most patients with AFib today are treated with AADs even though about half of them are refractory to these drugs. During cardiac ablation, a catheter is inserted into the heart and 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 an important therapeutic tool in treating arrhythmias. It is the standard of care for 'simple' arrhythmias, like Wolff-Parkison-White Syndrome, Type I atrial flutter and atrioventricular nodal re-entry tachycardia (AVNRT). It is increasingly being used for more complex arrhythmias like ventricular tachycardia and atrial flutter.

In 2006, the leading medical societies including the American Heart Association, American College of Cardiology and the European Society of Cardiology recognized catheter ablation as second-line therapy for AFib.

About Biosense Webster, Inc.

Biosense Webster, Inc., a Johnson & Johnson company (NYSE:JNJ), pioneered electrophysiology diagnostic catheters more than 30 years ago and continues to lead the industry as an innovative provider of advanced diagnostic, therapeutic and mapping tools. As the leader in navigation systems and ablation therapy, Biosense Webster, Inc.'s technology includes the largest installed base of navigation systems worldwide in leading hospitals and teaching institutions. With proprietary products such as the CARTO(R) XP System, the CARTOSOUND(TM) Image Integration Software Module, the THERMOCOOL(R) Irrigated Tip Catheter and the LASSO(R) Circular Variable Mapping Catheter, the company is changing the way electrophysiologists diagnose and treat arrhythmias.

SOURCE: Biosense Webster, Inc.

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