



Media Contact:

Kara Ryan
(949) 430-9064
kryan32@its.inj.com

Investor Contact:

Matt Stuckley
(215) 962-5923
mstuckle@its.inj.com

Biosense Webster Unveils Late-Breaking Results from PRECEPT Study in Patients with Persistent Atrial Fibrillation

PRECEPT study demonstrated 15-month freedom from symptomatic persistent atrial fibrillation in 80.4 percent of patients who underwent cardiac ablation using THERMOCOOL SMARTTOUCH® SF Catheter¹

IRVINE, CA – May 8, 2020 – Johnson & Johnson Medical Devices Companies* today announced that Biosense Webster, Inc.'s THERMOCOOL SMARTTOUCH® SF Ablation Catheter, evaluated in the [PRECEPT](#) study for the treatment of persistent atrial fibrillation (AF), resulted in freedom from any documented, symptomatic atrial arrhythmias at 15 months post-procedure for eight out of ten study participants (80.4 percent).¹ Use of the THERMOCOOL SMARTTOUCH SF CATHETER for persistent atrial fibrillation is investigational only. This PRECEPT study data support a Premarket Approval supplement application to the U.S. Food and Drug Administration.

In lieu of the Heart Rhythm Society (HRS) 2020 Heart Rhythm Scientific Sessions, these late-breaking data were presented and recorded by Dr. Moussa Mansour, Associate Professor in Medicine at Harvard Medical School and Cardiac Electrophysiologist at Massachusetts General Hospital and study investigator, and are now available on [Heart Rhythm 365](#) as part of the HRS 2020 Late-Breaking Clinical Trials. Data from the PRECEPT study was also recently published in [JACC: Clinical Electrophysiology](#).

Atrial fibrillation (AF) is a significant public health issue affecting millions of people and placing a critical burden on healthcare systems. In the U.S., there are 5.5 million patients diagnosed with AF, and it's estimated to grow to more than 7 million by 2035.²

“Catheter ablation therapy is a widely accepted treatment option for atrial fibrillation, and the success in paroxysmal atrial fibrillation has been well established,” said Dr. Mansour.** “This data is encouraging and demonstrates that patient-tailored, radiofrequency catheter ablation therapy may provide a clinically meaningful benefit to patients with persistent atrial fibrillation, who are at an even higher risk for stroke and other complications.”



Persistent AF is defined as continuous AF that lasts for more than seven days, while paroxysmal AF stops on its own or with intervention within seven days.³ Approximately one-third of patients with paroxysmal AF will progress to persistent AF⁴ with 15 percent progressing within one year.⁵ There is an increased physical and economic burden resulting from persistent AF, and it is associated with a higher risk of stroke, heart failure, and mortality.⁶ The management of persistent AF aims to prevent AF recurrence and associated disabilities while reducing side effects from treatment.

The PRECEPT study is the first prospective, multicenter investigational device exemption study designed to evaluate the safety and effectiveness of radiofrequency catheter ablation in patients with persistent AF, and was conducted using the THERMOCOOL SMARTTOUCH SF Catheter. The primary effectiveness endpoint was freedom from documented recurrence of atrial flutter/atrial tachycardia episodes of 30 seconds or longer and freedom from additional five failure modes: acute procedural failure, use of non-study catheter, repeat procedures, use of new/higher dose antiarrhythmic drugs, surgical AF ablation. At 15 months post-procedure, 86.1 percent of patients had freedom from the need for repeat ablation, and 80.4 percent of patients remained free from any documented, symptomatic atrial arrhythmias.¹

“Atrial fibrillation is a progressive disease that becomes harder to treat as symptoms become more severe,” said Uri Yaron, Worldwide President of Biosense Webster, Inc. “We are committed to advancing clinical evidence in partnership with physicians, and this data is encouraging as we continue on our quest to help people live their best lives possible – making sure AF never stands in the way.”

About the PRECEPT Study

The PRECEPT study utilized the VISTAG[®] Module included in the CARTO[®] 3 System and THERMOCOOL SMARTTOUCH SF Catheter to conduct patient-specific tailored ablation strategies requiring the isolation of all pulmonary veins and allowed for additional left atrium ablations when needed. A total of 381 patients with drug-refractory symptomatic persistent AF were enrolled at 27 centers in the U.S. and Canada. All patients received pulmonary vein isolation of all veins, and 44.5 percent of patients also received additional left atrium ablations. Primary adverse events occurred in 3.8 percent of patients, a rate similar to those reported in paroxysmal atrial fibrillation studies.^{7,8} The average procedure time was under three hours (178.0 minutes), with an average fluoroscopy time of 15.3 minutes.¹

About Atrial Fibrillation

Atrial fibrillation (AF) is the most common type of cardiac arrhythmia (abnormal heart rhythm) and affects nearly one percent of the population.⁹ During AF, the upper chambers of the heart, the atria, beat rapidly or in an uncontrolled manner, which can feel like a flutter. When the heart beats erratically, it does not pump blood as efficiently as it should. When oxygen is not being properly delivered to all parts of the body, the patient may feel ill or experience other AF symptoms. Atrial fibrillation may not be life-threatening; however, it is important to seek treatment to control the symptoms, as AF can lead to stroke.



About Johnson & Johnson Medical Devices Companies

As the world's most comprehensive medical devices business, we are building on a century of experience, merging science and technology, to shape the future of health and benefit even more people around the world. With our unparalleled breadth, depth and reach across surgery, orthopedics, vision and interventional solutions, we're working to profoundly change the way care is delivered. We are in this for life. For more information, visit www.jnjmedicaldevices.com.

About Biosense Webster, Inc.

Biosense Webster, Inc., is the global market leader in the science and technology behind the diagnosis and treatment of cardiac arrhythmias. Part of the Johnson & Johnson Family of Companies, the specialized medical-technology company is headquartered in Irvine, Ca., and works across the world to advance the tools and solutions that help electrophysiologists identify, treat, and deliver care. Learn more at www.biosensewebster.com and connect on [LinkedIn](#) and [Twitter](#).

Cautions Concerning Forward-Looking Statements

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding THERMOCOOL SMARTTOUCH® SF Catheter. 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 known or unknown risks or uncertainties materialize, actual results could vary materially from the expectations and projections of Biosense Webster, Inc., any of the other Johnson & Johnson Medical Devices Companies and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to: uncertainty of regulatory approvals; uncertainty of commercial success; challenges to patents; competition, including technological advances, new products and patents attained by competitors; manufacturing difficulties and delays; product efficacy or safety concerns resulting in product recalls or regulatory action; changes to applicable laws and regulations, including global health care reforms; changes in behavior and spending patterns of purchasers of health care products and services; and trends toward health care cost containment. A further list and descriptions of these risks, uncertainties and other factors can be found in Johnson & Johnson's Annual Report on Form 10-K for the fiscal year ended December 29, 2019, including in the sections captioned "Cautionary Note Regarding Forward-Looking Statements" and "Item 1A. Risk Factors," and in the company's most recently filed Quarterly Report on Form 10-Q, and the company's subsequent filings with the Securities and Exchange Commission. Copies of these filings are available online at www.sec.gov, www.jnj.com or on request from Johnson & Johnson. Neither Biosense Webster, Inc., any of the other Johnson & Johnson Medical Devices Companies nor Johnson & Johnson undertakes to update any forward-looking statement as a result of new information or future events or developments.

**Comprising the surgery, orthopedics, vision and interventional solutions businesses within Johnson & Johnson's Medical Devices segment*

****Dr. Mansour is a paid consultant to Biosense Webster, Inc., and is an investigator for the PRECEPT study.**

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1. Mansour M, Calkins H, Osorio J, et al. Persistent atrial fibrillation ablation with a contact force sensing catheter: the prospective multicenter PRECEPT trial. *JACC Clin Electrophysiol*. Year;Volume(Issue):pages.
 2. Khavjou, Olga, D. Phelps, and A. Leib. Projections of cardiovascular disease prevalence and costs:2015–2035. November 2016. Dallas: American Heart Association (2016).
 3. Hugh Calkins, Gerhard Hindricks, Ricardo Cappato, et al. 2017 HRS/EHRA/ECAS/APHS/SOLAECE expert consensus statement on catheter ablation and surgical ablation of atrial fibrillation. 2017.
 4. Pillarisetti J, Patel A, Boc K, et al. Evolution of Paroxysmal Atrial Fibrillation to Persistent or Permanent Atrial Fibrillation: Predictors of Progression. *J Atr Fibrillation*. 2009;2(1):191. Published 2009 Jun 1. doi:10.4022/jafib.191
 5. de Vos CB, Pisters R, Nieuwlaat R, Prins MH, Tieleman RG et al. (2010) Progression from paroxysmal to persistent atrial fibrillation clinical correlates and prognosis. *J Am Coll Cardiol*. 55 (8): 725-731.
 6. Chen LY, Chung MK, Allen LA, et al. Atrial fibrillation burden: moving beyond atrial fibrillation as a binary entity: a scientific statement from the American Heart Association. *Circulation*. 2018;137(20):e623-e644.
 7. Natale A, Reddy VY, Monir G, et al. Paroxysmal AF catheter ablation with a contact force sensing catheter: results of the prospective, multicenter SMART-AF trial. *J Am Coll Cardiol*. 2014;64(7):647-656.
 8. Chinitz LA, Melby DP, Marchlinski FE, et al. Safety and efficiency of porous-tip contact-force catheter for drug-refractory symptomatic paroxysmal atrial fibrillation ablation: results from the SMART SF trial. *Europace*. 2018;20(FI_3):f392-f400.
 9. Johan E.P. Waktare, MB, ChB, MRCP, Atrial Fibrillation, AHA Journals.org.