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**BIOSENSE WEBSTER ANNOUNCES INITIAL RESULTS FROM FIRST IN-HUMAN STUDY OF NOVEL
HIGH POWER-SHORT DURATION ABLATION CATHETER FOR ATRIAL FIBRILLATION**

Researchers Report QDOT MICRO Radiofrequency Ablation Catheter Demonstrates Safety and Achieves Pulmonary Vein Isolation with Shorter Procedure and Fluoroscopy Times



SAN FRANCISCO -- May 10, 2019 – Johnson & Johnson Medical Devices Companies* today announced that Biosense Webster, Inc.'s QDOT MICRO, a novel catheter that facilitates high power-short duration radiofrequency (RF) ablation, demonstrated safety and efficacy in achieving pulmonary vein isolation in patients with symptomatic drug-refractory paroxysmal atrial fibrillation (AF) in QDOT-FAST,** the first in-human multicenter study of the device. Procedure and fluoroscopy times were also reported to be shorter than ablation with conventional catheters. Reducing use of fluoroscopy alleviates the burden of lead for physicians and staff, and reduces exposure to radiation for patients.

The findings were published today in [JACC: Clinical Electrophysiology](#) and presented at Heart Rhythm 2019, the Heart Rhythm Society's 40th Annual Heart Rhythm Scientific Sessions, by Vivek Y. Reddy, MD, Director of Cardiac Arrhythmia services for The Mount Sinai Hospital and the Mount Sinai Health System and the Helmsley Trust Professor of Medicine in Cardiac Electrophysiology at Icahn School of Medicine at Mount Sinai in New York. The study was funded by Biosense Webster.

QDOT MICRO, which is only available for investigational use in the U.S. and Europe, is the first irrigated contact force catheter to deliver up to 90 watts of RF power in up to four seconds in a temperature-controlled ablation mode. The current practice of RF ablation with irrigated catheters involves the delivery of moderate power (20 to 40 watts) for a relatively long duration (20 to 40 seconds).¹

In the three-month multicenter prospective study, researchers reported pulmonary vein isolation (PVI) was successful in all 52 paroxysmal AF patients treated with a total average procedure time of 105.2 minutes. PVI was achieved in 44.3 minutes and most fluoroscopy times were between 2.5 and 5.7 minutes. Primary adverse events occurred in 3.8 percent of patients (1 pseudoaneurysm, 1 asymptomatic thromboembolism) and one non-serious adverse event (esophageal ulcer) was device/procedure related.

“The results are very promising and may lead to better patient outcomes and improved procedural efficiencies, including short overall procedure and fluoroscopy times,” said Dr. Reddy,*** study co-author. “Additional prospective studies are needed to assess for the durability of the lesion set and long-term freedom from recurrent atrial arrhythmias.”



"We continue to study QDOT MICRO and generate the evidence necessary to offer a next generation device that we expect to be groundbreaking for catheter ablation procedures," said Uri Yaron, Worldwide President of Biosense Webster. "This study is one of many that we hope elevates the standard of care for atrial fibrillation patients throughout the world."

In addition to the QDOT-FAST Study, Biosense Webster is also currently enrolling and treating patients [in a U.S. Investigational Device Exemption \(IDE\) study](#) of QDOT MICRO.

An estimated 33 million people worldwide have been diagnosed with AF and its prevalence is projected to increase significantly as the population ages.² Approximately 70 percent of patients with AF are between the ages of 65 and 85.³

About Johnson & Johnson Medical Devices Companies

As the world's most comprehensive medical devices business, we are building on a century of experience, leveraging science and technology, to shape the future of healthcare. With unparalleled breadth, depth and reach in surgery, orthopaedics, vision and interventional solutions we are working to profoundly change the way care is delivered. We are in this for life.

About Biosense Webster, Inc.

Biosense Webster, Inc. is a 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. Biosense Webster, Inc. is part of the Johnson & Johnson Family of Companies. More information can be found at www.biosensewebster.com.

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

***Pulmonary Vein Isolation with Very High Power–Short Duration Temperature-Controlled Lesions: The First-in-Human QDOT-FAST Multicenter Trial*

****Dr. Reddy is a consultant to Biosense Webster, Inc.*

The device is approved for investigational use only. It is not approved or available for sale.

Cautions Concerning Forward-Looking Statements

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding QDOT Micro RF Ablation 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 30, 2018, 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., the 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.

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¹ <http://electrophysiology.onlinejacc.org/content/early/2018/02/02/j.jacep.2017.11.018>

² European Heart Journal, Volume 37, Issue 38, 7 October 2016, Pages 2893–2962,
<https://doi.org/10.1093/eurheartj/ehw210>

³ Amin A, Houmsse A, Ishola A, Tyler J, Houmsse M. The current approach of atrial fibrillation management. Avicenna J Med. 2016 Jan-Mar; 6(1): 8–16.