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Biosense Webster, Inc. VISTAX Study Results Show High Rate of 12-Month Freedom from Arrhythmia

Data presented at the 25th Annual International AF Symposium demonstrate standardized workflow for atrial fibrillation led to durable pulmonary vein isolation and 12-month freedom from arrhythmia for nearly four of five patients¹

WASHINGTON, D.C. – January 24, 2020 – Johnson & Johnson Medical Devices Companies* today announced that Biosense Webster, Inc.'s VISITAG SURPOINT® Module, a standardized workflow for catheter ablation, evaluated in the VISTAX study conducted in Europe, resulted in freedom from atrial arrhythmia at 12 months following catheter ablation for nearly four out of five study participants (78.3 percent).¹ The standardized workflow, which displays parameters of lesion formation and allows objective ablation parameters demonstrated in final datasets reproducibility of the standardized workflow, a low primary adverse event rate and durable pulmonary vein isolation (PVI) in patients with paroxysmal atrial fibrillation (PAF). Data also showed low fluoroscopy times.

These late-breaking 12-month data from the VISTAX study were presented at the 25th Annual International AF Symposium in Washington, D.C., by Mattias Duytschaever, MD, PhD, the study's primary investigator. The VISTAX study was funded by Biosense Webster, Inc.

"I'm encouraged that nearly four out of five patients in the VISTAX study were free of atrial arrhythmia at 12 months," said Dr. Duytschaever. "These results lend support for greater procedure standardization across centers, that ultimately may lead to improved patient outcomes."

In this postmarket, multicenter prospective study involving 329 evaluable participants, researchers reported first-pass PVI was successful in nearly 90% of PV encirclement. For all patients in the study, average fluoroscopy time was 7.9 ± 6.9 minutes. Primary adverse events occurred in 3.6 percent of patients. The VISITAG SURPOINT™ Module is currently the subject of a post-market study in the United States assessing the safety and 12-month effectiveness for pulmonary vein isolation of subjects with drug refractory symptomatic PAF.

"We continue to study our standardized VISITAG SURPOINT™ Module workflow to provide physicians with better visibility into ablation strategies to help drive improved outcomes for patients," said Uri Yaron, Worldwide President of Biosense Webster, Inc. "We are committed to elevating the standard of care for atrial fibrillation patients throughout the world."

About Atrial Fibrillation

Atrial fibrillation (AFib) is the most common type of cardiac arrhythmia (abnormal heart rhythm) and affects nearly one percent of the population.² During AFib, 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 AFib symptoms. Atrial fibrillation may not be life threatening, however it is important to seek treatment to control the symptoms, as AFib can lead to stroke.

About Johnson & Johnson Medical Devices Companies

At Johnson & Johnson Medical Devices Companies, we are helping people live their best lives. Building on more than a century of expertise, we tackle pressing healthcare challenges, and take bold steps that lead to new standards of care while improving people's healthcare experiences. In surgery, orthopaedics, vision and interventional solutions, we are helping to save lives and paving the way to a healthier future for everyone, everywhere.

About Biosense Webster, Inc.

Biosense Webster, Inc., part of Johnson & Johnson Medical Devices Companies, 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. For more information, visit www.biosensewebster.com or follow us on [Twitter](#) and [LinkedIn](#).

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

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Important information: Prior to use, refer to the instructions for use supplied with this device for indications, contraindications, side effects, warnings and precautions.

Caution: US law restricts this device to sale by or on the order of a physician.

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- 1 Duytschaever, M., et al. The Safety and Effectiveness of Pulmonary Vein Isolation with Standardized Ablation Index Workflow. Presented at the 25th Annual International AF Symposium, January 23-25, 2020.
 - 2 Johan E.P. Waktare, MB, ChB, MRCP, Atrial Fibrillation, AHA Journals.org.