

For Immediate Release

First Patients in Europe Treated with Biosense Webster VARIPULSE[®] Catheter for Atrial Fibrillation Treatment

IRVINE, CA – October 1, 2020 – Johnson & Johnson Medical Devices Companies* announced today that Biosense Webster, Inc., a worldwide leader in the diagnosis and treatment of heart arrhythmias, enrolled and treated the first patients in its inspIRE clinical study in Europe. The study will evaluate the safety and effectiveness of the VARIPULSE[®] Catheter and TRUPULSE[™] Generator, investigational technologies using pulsed field ablation (PFA), in treating symptomatic drug refractory recurrent paroxysmal (intermittent) atrial fibrillation (AF).

AF is the most common type of cardiac arrhythmia affecting an estimated 33 million people globally.¹ By 2030 the number of people with AF is projected to increase by up to 70 percent.²

A variety of techniques, catheter designs and energy sources have been investigated to advance the treatment of AF. PFA represents a new approach to treating AF, utilizing a controlled electric field – instead of thermal energy – to ablate and scar cardiac tissue through a process called irreversible electroporation (IRE). This ablation technique may spare other tissue types from inadvertent ablation, including the esophagus, pulmonary vein connective tissue and the phrenic nerve (which controls the diaphragm).

“IRE has the potential to be a disruptive breakthrough for PVI, and I have high expectations,” said Tom de Potter**, MD, FEHRA, Associate Director, Cardiovascular Center Department of Cardiology, Electrophysiology Section at OLV Hospital. “After completing several cases, I am now even more eager to see the final safety and efficacy results.”

inspIRE is a prospective, multi-center, non-randomized, study that will enroll more than 300 patients who will be treated with the investigational VARIPULSE Catheter, a steerable, multi-electrode, catheter enabling cardiac mapping and PFA using the investigational TRUPULSE Generator.³

“The inspIRE study is an important step toward a potentially significant advancement in treatment options for atrial fibrillation patients,” said Uri Yaron, Worldwide President, Biosense Webster, Inc. “We eagerly await data from the study as more investigators have access to this novel technology aimed at advancing the treatment of cardiac arrhythmias.”

To learn more about the inspIRE study, visit clinicaltrials.gov.

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](#).

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.

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

**Dr. de Potter is a paid consultant to Biosense Webster, Inc.

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1 Chugh SS, Havmoeller R, Narayanan K, et al. Worldwide epidemiology of atrial fibrillation: a Global Burden of Disease 2010 Study. *Circulation* 2014;129:837-47.

2 Zoni-Berisso M, Lercari F, Carazza T, Domenicucci S (2014) Epidemiology of atrial fibrillation: European perspective. *Clin Epidemiol.* 6: 213-220.

3 ClinicalTrials.gov. A Study for Treatment of Paroxysmal Atrial Fibrillation (PAF) by Pulsed Field Ablation (PFA) System With Irreversible Electroporation (IRE) (inspire). <https://clinicaltrials.gov/ct2/show/NCT04524364#contacts>.