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Biosense Webster Announces CE Mark approval in Europe for VARIPULSE™ Pulsed Field Ablation (PFA) Platform

Irvine, Calif. (ots/PRNewswire) -

- *Regulatory approval for the first fully integrated PFA system with a CARTO-enabled simple and reproducible workflow.*
- *Integrated with the world's leading CARTO™ 3D Cardiac Mapping System for the treatment of symptomatic drug refractory recurrent paroxysmal atrial fibrillation (AF).*
- *CE Mark follows recent approval of the VARIPULSE™ Platform in Japan.*

Biosense Webster, Inc., a global leader in cardiac arrhythmia treatment and part of Johnson & Johnson MedTech, today announced European CE mark approval of the VARIPULSE™ Platform for the treatment of symptomatic drug refractory recurrent paroxysmal atrial fibrillation (AF) using pulsed field ablation (PFA). The VARIPULSE™ Platform is comprised of the VARIPULSE™ Catheter, a variable-loop multielectrode catheter; the TRUPULSE™ Generator, a multichannel PFA generator; and CARTO™ 3 System, the world's leading 3D cardiac mapping system. The VARIPULSE™ Platform is the first and only CARTO™ -integrated PFA system, enabling an intuitive and reproducible workflow with real-time visualization and feedback mechanisms.

The safety and efficacy of the VARIPULSE™ Platform was investigated in the inspIRE trial, which included 186 patients in Canada and Europe.[1] Updated one-year follow-up data was presented this month at the AF Symposium in Boston, demonstrating that among participants receiving optimal PFA applications, 80% achieved freedom from recurrence with zero primary adverse events.[2]** Furthermore, the primary effectiveness endpoint (PEE) of acute pulmonary vein isolation and 12-month freedom from atrial arrhythmia recurrence (AF, Atrial Tachycardia, or Atrial Flutter) was 75.6%.[2] The study reported a low fluoroscopy time of 7.8 minutes, partly attributed to the integration of the VARIPULSE™ Catheter to the CARTO™ 3 System and a good safety profile with no (0.0%) primary adverse events reported.[2]

"CE mark approval of the VARIPULSE™ Platform represents a significant advance in catheter ablation technology, allowing electrophysiologists to offer patients in Europe pulsed field ablation treatment with real-time integrated 3D mapping," said Tom De Potter,***MD, Associate Director, Cardiovascular Center, OLV Hospital Aalst, Belgium. "Significantly, the VARIPULSE™ Platform is fully integrated with the CARTO™ 3 System, enabling a simplified workflow with minimal fluoroscopy time. Most importantly, the recent published data on the VARIPULSE™ Platform demonstrates the safety using pulsed field ablation for patients being treated for AF."

Catheter ablation is a minimally invasive procedure performed by an electrophysiologist to treat heart rhythm disorders, including AF, by interrupting irregular electrical pathways in the heart by delivering either heat (radiofrequency ablation) or cold (cryoablation).[3] PFA represents a new approach to treating AF, utilizing a controlled electric field to selectively ablate cardiac tissue that causes the irregular heartbeat through a process called irreversible electroporation (IRE).[4] Because the pulsed field energy is minimally thermal, IRE offers the potential to reduce the risk of damage to surrounding tissues including esophageal, pulmonary vein, and phrenic nerve injury.[4]

"At Biosense Webster, we continually seek to push the boundaries of science and technology innovation in cardiac ablation. CE mark approval of the VARIPULSE™ Platform is testament to this, now offering healthcare professionals the potential to improve outcomes for people living with atrial fibrillation while setting a new standard in cardiac electrophysiological mapping," said Jasmina Brooks, President, Biosense Webster. "We believe pulsed field ablation has the potential to offer safer, more consistent and efficient workflows, and the VARIPULSE™ Platform uniquely offers physicians a simple and reproducible PFA workflow with 3D visualization, in real-time."

AF is the most common type of cardiac arrhythmia, affecting over 11 million people in Europe.[5],[6],[7] If left untreated, patients face a fivefold increased risk of stroke[7], while their risk of death doubles[7]. By 2030, prevalence is projected to increase by up to 70 percent[7] presenting an urgent need for innovative treatment solutions that deliver better outcomes for people living with AF while providing healthcare professionals with increased flexibility and efficiency.

The VARIPULSE™ Platform is not available for sale in the United States.

**The TRUPULSE™ Generator received CE Mark in Europe in December 2023.*

***Based on the final analysis of the InspIRE study focused on the pivotal phase (Wave II) per-protocol population of 186 patients with 12 months of follow up.*

****Dr de Potter is a paid consultant to Biosense Webster Inc. He was not compensated for any media work.*

ABOUT BIOSENSE WEBSTER

Biosense Webster, Inc. is the global market leader in the science and technology behind the diagnosis and treatment of cardiac arrhythmias. Part of Johnson & Johnson MedTech, the specialized medical technology company is headquartered in Irvine, California, and works across the world to advance the tools and solutions that help electrophysiologists identify, treat, and

deliver care. Learn more at http://www.biosensewebster.com/and connect on LinkedIn and X, formerly Twitter.

ABOUT JOHNSON&JOHNSON MEDTECH

At Johnson & Johnson MedTech, we unleash diverse healthcare expertise, purposeful technology, and a passion for people to transform the future of medical intervention and empower everyone to live their best life possible. For more than a century, we have driven breakthrough scientific innovation to address unmet needs and reimagine health. In surgery, orthopedics, vision, and interventional solutions, we continue to help save lives and create a future where healthcare solutions are smarter, less invasive, and more personalized.

CAUTIONS CONCERNING FORWARD-LOOKING STATEMENTS

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding European CE Mark approval of the VARIPULSE™ Catheter and TRUPULSE™ Generator. 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. 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; 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 healthcare products and services; and trends toward healthcare 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 31, 2023, including in the sections captioned "Cautionary Note Regarding Forward-Looking Statements" and "Item 1A. Risk Factors," and in Johnson & Johnson's subsequent Quarterly Reports on Form 10-Q and other filings with the Securities and Exchange Commission. Copies of these filings are available online at sec.gov, jnj.com or on request from Johnson & Johnson. None Biosense Webster, Inc. nor Johnson & Johnson undertakes to update any forward-looking statement as a result of new information or future events or developments.

[1] ClinicalTrials.gov. A Study for Treatment of Paroxysmal Atrial Fibrillation (PAF) by Pulsed Field Ablation (PFA) System With Irreversible Electroporation (IRE) (inspIRE). Available at: https://clinicaltrials.gov/study/NCT04524364. Last accessed: January 2024.

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[3] British Heart Foundation. Catheter Ablation. Available at: https://www.bhf.org.uk/informationsupport/heart-matters-magazine/medical/catheter-ablation. Last accessed: January 2024.

[4] Reddy VY, Neuzil P, Koruth JS, et al. Pulsed Field Ablation for Pulmonary Vein Isolation in Atrial Fibrillation. JACC 2019;74(3)315-326.

[5] Johan E.P. Waktare, MB, ChB, MRCP. Atrial Fibrillation. Circulation. 2002;106:14-16.

[6] Velleca M, Costa G, Goldstein L, et al. A Review of the Burden of Atrial Fibrillation: Understanding the Impact of the New Millennium Epidemic across Europe. EMJ Cardiol. 2019; 7[1]:110-118.

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

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