Johnson & Johnson MedTech

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For immediate release

Biosense Webster Announces Regulatory Approval of VARIPULSE™ Pulsed Field Ablation (PFA) Platform in Japan

- *First regulatory approval for the first-of-its-kind fully-integrated PFA system with a 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 (AFib)*
- *First and only PFA system approved in Japan*

Irvine, CA (January 9, 2024) – Biosense Webster, Inc., a global leader in cardiac arrhythmia treatment and part of Johnson & Johnson MedTech,[i] today announced approval from the Japanese Ministry of Health, Labour and Welfare (MHLW) for the VARIPULSE™ Platform for the treatment of symptomatic drug refractory recurrent paroxysmal atrial fibrillation (AFib) 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.

"At Biosense Webster, we are working to deliver a differentiated PFA portfolio integrated with 3D cardiac mapping to address the real-world unmet needs of electrophysiologists and the patients they treat. Today, we celebrate this milestone approval of the VARIPULSE™ Platform, the first and only PFA system approved in Japan," said Jasmina Brooks, President, Biosense Webster. "We are excited to continue to advance PFA clinical studies globally and look forward to the positive impact this innovation will deliver to patients everywhere."

The inspIRE trial early clinical results with the VARIPULSE™ Platform in Europe demonstrated a one-year clinical success of 78.9%, defined as freedom from documented symptomatic atrial arrhythmia recurence.[1] The trial also demonstrated a notable safety profile, reporting no primary adverse events (0%)[1]. The Platform's proprietary pulse sequence, catheter design, and CARTO™ 3 System integration enabled a simplified workflow, and resulted in minimal fluoroscopy time (7.8 minutes) and efficient procedures (70 minutes)[1].

"The innovation in catheter ablation therapy for atrial fibrillation has been remarkable. The approval of ablation therapy using pulsed-field energy in Japan will further advance the treatment of arrhythmias. Together with the integrated 3D mapping system, this innovation has the potential to provide more advanced treatment and further improve safety", said Dr. Wataru Shimizu, President of the Japan Heart Rhythm Society (Professor, Department of Cardiovascular Medicine, Graduate School of Medicine, Nippon Medical School)[ii]. "The increasing diversity of treatment technologies means that healthcare providers who seek to cure atrial fibrillation have options tailored to each patient's condition."

Catheter ablation is a minimally invasive procedure performed by an electrophysiologist to treat heart rhythm disorders, including AFib, by interrupting irregular electrical pathways in the heart by delivering either heat (radiofrequency ablation) or cold (cryoablation). PFA represents a new approach to treating AFib, utilizing a

[i] Johnson & Johnson MedTech comprises the surgery, orthopedics, vision, and interventional solutions businesses within Johnson & Johnson's MedTech segment.
[ii] Dr. Shimizu is a paid consultant for Biosense Webster, Inc.

controlled electric field to selectively ablate cardiac tissue that causes the irregular heartbeat through a process called irreversible electroporation (IRE). 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.[2]

AFib is the most common type of cardiac arrhythmia, impacting nearly 37.5 million people worldwide and approximately 1.3 million people in Japan.[3,4] Despite these projections, many people are unfamiliar with AFib symptoms, available treatment options and the importance of early treatment to avoid risk of stroke and disease progression.[5]

The VARIPULSE™ Platform is pending CE mark in the European Union; it is not available for sale in the EU or United States.

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 www.biosensewebster.com and connect on LinkedIn and X, formerly Twitter.

About Johnson & Johnson MedTech[i]
At Johnson & Johnson MedTech,[i] 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, orthopaedics, 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 Japanese Ministry of Health, Labour and Welfare (MHLW) 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 January 1, 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. Neither Biosense Webster, Inc.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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