Johnson&Johnson MedTech

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For immediate release (US)

Biosense Webster Presents Late-Breaking Data from admIRE Clinical Trial at the Heart Rhythm Society Annual Meeting

In the pivotal phase of the admIRE trial, the VARIPULSE™ Platform demonstrated 85% peak primary effectiveness with minimal adverse events, short PFA application times, and low fluoroscopy exposure

Additional findings presented at HRS show the potential of the VARIPULSE™ Platform in treating patients with diverse arrythmias

Irvine, CA – May 17, 2024 – Biosense Webster, Inc., a global leader in cardiac arrhythmia treatment and part of Johnson & Johnson MedTech, announced late-breaking results from the pivotal phase of the admIRE pivotal clinical trial, plus additional results from the VIRTUE study, presented at the Heart Rhythm Society (HRS) Annual Meeting in Boston from May 16-19. Both studies explore the potential of the VARIPULSE™ pulsed field ablation (PFA) Platform to treat patients with cardiac arrythmias including atrial fibrillation (AFib).

Twelve-month data from the pivotal phase of the admIRE study assessed the safety and efficacy of the VARIPULSE™ Platform among 277 participants with paroxysmal AFib treated across 30 healthcare centers in the U.S. by 39 operators. Presentation highlights include:[1]

- 75% overall primary effectiveness success[i]
  - 85% peak primary effectiveness for participants receiving 73-96 PFA applications for PVI[ii]
- 2.9% overall primary adverse event rate[iii]
  - There were no reported incidents of device or procedure-related death, atrioesophageal fistula, coronary spasm, or hemolysis-related renal failure requiring hemodialysis
- 100% of patients achieved acute procedural success;[iv] 98% first-pass isolation recorded per vein[v]
- Median procedure time of 81 minutes in pulmonary vein isolation (PVI)-only procedures, 90 minutes in all procedures, and a fluoroscopy time of 7 minutes
  - 43% of patients were able to leave the healthcare facility on the same day as their procedure
- 25% of procedures were performed without fluoroscopy, with no impact to safety or efficacy due to the full integration of the VARIPULSE™ Platform with the CARTO™ 3 System

The admIRE study evaluated the safety and efficacy of the VARIPULSE™ Platform to treat paroxysmal atrial fibrillation (PAF), and supported the recent Premarket Approval Application to the U.S. Food & Drug Administration for the VARIPULSE™ Platform.

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

“The admIRE study demonstrated good safety and effectiveness results. The primary effectiveness success was 74.6%, and among the subset of participants receiving 73-96 PFA applications for PVI, 85% achieved success. Primary safety events occurred in 2.9%, demonstrating promising evidence of the capabilities of the VARIPLUSE Platform,” said Vivek Reddy, M.D., director of electrophysiology, Mount Sinai Fuster Heart Hospital, New York. “Differentiated by its unique CARTO™ 3 System integration, this was the first PFA IDE study to support a substantial number of fluoro-free procedures; 25% of procedures were performed with zero fluoroscopy.”

Findings from the admIRE study build on previous data from the inspIRE study published earlier this year, which evaluated the efficacy and safety of the VARIPULSE™ Platform in patients with PAF in Europe and Canada. These latest data are part of Biosense Webster’s comprehensive global clinical trial strategy across PFA solutions including the recently announced

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three-month results from the SmartfIRE clinical trial published in April 2024, the SmartPulse study announced in December 2023, and the Omny-IRE clinical trial announced in September 2023.

Data from the VIRTUE study were also presented at the HRS Annual Meeting, evaluating the further use of the investigational VARIPULSE™ Platform in patients more reflective of usual clinical practice, including patients with paroxysmal and persistent atrial fibrillation as well atypical atrial flutter, either as first-time or redo procedures. The inclusion criteria for VIRTUE extended beyond what is typical for catheter ablation trials and reflected the range of patients more commonly seen in clinical practice. For example, of the 125 patients in the VIRTUE trial, only 23% would have met the criteria for the admIRE trial. Ablation beyond PVI was performed in 80% of study participants. The VARIPULSE™ Platform was demonstrated to be able to treat a variety of paroxysmal and persistent atrial fibrillation patients, as well as those with atypical atrial flutter, with lesions beyond PVI.[2]

“Findings from the admIRE study add to our comprehensive PFA evidence generation strategy and continue to point to the safety and efficacy of the VARIPULSE™ Platform, and other PFA tools,” said Jennifer Currin, Ph.D., Vice President, Scientific Affairs, Cardiovascular & Specialty Solutions, Johnson & Johnson MedTech. “The breadth of data presented by Biosense Webster at this year’s meeting underscores our commitment advancement of knowledge and innovation in the treatment of cardiac arrhythmias.”

AFib is the most common type of cardiac arrhythmia and affects more than 8 million people in the United States and nearly 50 million people worldwide.[3] Approximately 1 in 4 adults over the age of 40 are at risk for developing AFib.[4] Despite these projections, about one-third of patients with AFib are not aware they have the condition, and AFib often goes unrecognized until the onset of complications.[5,6] Catheter ablation is a safe and effective procedure when drugs don’t work to help restore the heart’s incorrect electrical signals, which cause an abnormal heart rhythm.[7]

Additional information on Biosense Webster’s data presented at HRS can be found here.

About the VARIPULSE™ Platform
The VARIPULSE™ Platform is Biosense Webster’s Irreversible Electroporation ablation system. The fully integrated platform includes the VARIPULSE™ Catheter, TRUPULSE™ Generator, and CARTO™ 3 Mapping System VARIPULSE™ Service Pack Software. In January 2024, Biosense Webster announced that the VARIPULSE™ Platform received its first regulatory approval from the Japan Ministry of Health, Labour and Welfare for the treatment of symptomatic drug refractory recurrent PAF using PFA. In Europe, the TRUPULSE™ generator received CE mark in late 2023 and the VARIPULSE™ Platform received CE mark in February 2024. In the U.S., the VARIPULSE™ Catheter and TRUPULSE™ Generator are currently investigational and are not approved by regulatory authorities. In March 2024, Biosense Webster announced the submission of the VARIUPLSE™ Platform for Premarket Approval Application to the U.S. Food & Drug Administration.

About admIRE
The admIRE study (Assessment of Safety and Effectiveness in Treatment Management of Atrial Fibrillation With the Biosense Webster IRE Ablation System) (NCT05293639) is a prospective, multi-center, single-arm study to demonstrate the safety and long-term effectiveness of the VARIPULSE™ Platform when used for isolation of pulmonary veins in treatment of patients in the United States with symptomatic drug refractory paroxysmal AFib. Pulmonary vein isolation (PVI) was achieved using the VARIPULSE™ Platform. The study consisted of a pilot phase, which assessed initial device safety and effectiveness, and a pivotal phase, which assessed these against pre-specified performance goals. The primary safety endpoint was incidence of early onset (within seven days) primary adverse events; atrioesophageal fistula (within 90 days); cardiac tamponade or perforation (within 30 days); and PV stenosis (within 12 months). Acute procedure success (defined as confirmed entrance block at the end of procedure) and freedom from documented atrial arrhythmia recurrence at 12 months were also assessed.

About VIRTUE
The VIRTUE study is a collaborative, investigator-sponsored, prospective, single-center, nonrandomized, interventional clinical study to evaluate the safety and efficacy of using the Biosense Webster VARIPULSE™ Platform, inclusive of the VARIPULSE™ Catheter in combination with the TRPULSE™ Generator, and the compatible EAM system to treat patients

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with a variety of atrial arrhythmias during clinically-indicated ablation procedures. A total of 125 evaluable subjects were enrolled including all types of AFib-related arrhythmias and were evaluated for 12 months post-procedure.

About Biosense Webster
Biosense Webster, part of Johnson & Johnson MedTech, leads in cardiac arrhythmia diagnosis and treatment worldwide. We are dedicated to advancing electrophysiology and interventional cardiology tools and solutions for improved patient care. Learn more at biosensewebster.com and connect on LinkedIn and X, formerly Twitter.

About Johnson & Johnson MedTech[vii]
At Johnson & Johnson MedTech,[vii] 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 the VARIPULSE™ Platform clinical trials. 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. Neither of Biosense Webster, Inc. nor Johnson & Johnson undertakes to update any forward-looking statement as a result of new information or future events or developments.

[i.] Primary effectiveness was defined as 12-month freedom from documented (symptomatic or asymptomatic) atrial tachyarrhythmia (atrial fibrillation [AF]/atrial tachycardia [AT]/atrial flutter [AF]) episodes of ≥30 seconds duration based on rhythm monitoring during the post-blanking evaluation period (day 91-365), as well as freedom from other failure modes: failure to achieve entrance block in all PVs; >1 repeat ablation for atrial tachyarrhythmia during the 3-month blanking period or any repeat ablation during the evaluation period; use of a nonstudy catheter to treat the PVs and/or to ablate left atrial non-PV AF targets during the index procedure or to perform a repeat procedure during the 3-month blanking period; taking new or previously failed Class I/III AADs at greater doses during the evaluation period; continuous AF/AT/AFL of unknown origin during the evaluation period; or direct-current cardioversion during the evaluation period for AF/AT/AFL recurrences. The protocol defined performance goal is 50%.
[ii.] Peak primary effectiveness was defined in a post-hoc analysis as receiving 73-96 applications for PVI (n=85).
[iii.] Primary adverse events were defined as: Device- or procedure- related death, major vascular access complications or bleeding, myocardial infarction, pericarditis, heart block, permanent phrenic nerve paralysis, stroke, thromboembolism, transient ischemic attack, pulmonary edema, and vagal nerve injury/gastroparesis within 7 days of the index ablation. PAEs also included cardiac tamponade/perforation occurring up to 30 days postprocedure, atrioesophageal fistula occurring up to 90 days post-procedure, and PV stenosis occurring anytime during the 12-month follow-up period. The protocol-defined performance goal is 12%.[iv.] Acute procedural success was defined as the percent of participants with electrical isolation of all PVs with confirmed entrance block at the end of the procedure (n=255).
v. First pass-isolation was defined as achievement of entrance block after first encirclement evaluated prior to the adenosine challenge (979/1004 of targeted veins, n=255).

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[vi.] Dr. Reddy served as a study investigator and as a consultant for BWI. Dr. Reddy was not compensated for this authorship contribution.
[vii.] Johnson & Johnson MedTech comprises the surgery, orthopedics, vision, and interventional solutions businesses within Johnson & Johnson's MedTech segment.

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