Johnson&Johnson MedTech | Cardiovascular

Media Contacts:
Lindsey Diaz-MacInnis
ldiazmac@its.jnj.com

Kristina Kauffman
Kkauffm4@its.jnj.com

Investor Relations:
Tracy Menkowski
investor-relations@its.jnj.com

FOR IMMEDIATE RELEASE

Johnson & Johnson MedTech Presents 3-Month Data from Omny-IRE Clinical Trial at 2025 Heart Rhythm Society Annual Meeting

Omny-IRE data demonstrated the investigational OMNYPULSE™ Platform achieved 100% acute success and 84.5% pulmonary vein isolation (PVI) durability at three months, with promising safety outcomes[1]

Additional data presented from VARIPURE registry[2] and Dual Energy THERMOCOOL SMARTTOUCH™ SF Catheter[3] pre-clinical study underscore safety and real-world efficiency across Johnson & Johnson MedTech's expanding pulsed field ablation portfolio

Irvine, CA – April 25, 2025 – Johnson & Johnson MedTech, a global leader in cardiac arrhythmia treatment, today announced positive, initial 3-month results from the Omny-IRE study, evaluating the investigational OMNYPULSE™ Platform in patients with paroxysmal atrial fibrillation (PAF). The data, unveiled as a late breaking presentation at the 2025 Heart Rhythm Society (HRS) annual meeting, demonstrated the potential for both high acute effectiveness[i] and a promising safety profile: 100% acute PVI with durable isolation in 84.5% of pulmonary veins at 3-month remapping and a 3.0% primary adverse event rate, with only 0.7% being potentially catheter related.[1] The data has been simultaneously published in *JACC Clin Electrophysiology*.

Omny-IRE is a 12-month prospective, multi-center, non-randomized clinical trial that evaluates the safety and effectiveness of the OMNYPULSE™ Platform for the mapping and treatment of symptomatic PAF during standard ablation procedures.[ii4] The OMNYPULSE™ Platform consists of the OMNYPULSE™ Catheter, a novel focal pulsed field ablation (PFA) catheter, and the TRUPULSE™ Generator, and is fully integrated with the CARTO™ 3 System. The OMNYPULSE™ Catheter is the first large-tip, 12 mm focal catheter with contact force sensing and a TRUEref™ reference electrode to reduce the impact of far-field unipolar signals. The TRUPULSE™ Generator provides a bipolar, biphasic pulse application to the catheter's twelve electrodes. With the CARTO™ 3 System software used in the study, clinicians were able to obtain a Pulsed Field (PF) Index value for each ablation, which is a calculation using the real-time contact force feedback combined with the number of pulsed field applications.[5] As an integrated platform, OMNYPULSE™ brings together mapping precision, energy delivery, and real-time feedback into a single ecosystem—streamlining workflows and helping electrophysiologists deliver more consistent outcomes.[1]

"The 3-month data provide encouraging early evidence of the OMNYPULSE™ Platform," said Mattias Duytschaever M.D., Ph.D., Department of Cardiology, Electrophysiology Section, AZ Sint-Jan Hospital, Brugge,

[i] Acute efficacy was defined to be adenosine/isoproterenol-proof PVI at the end of the procedure and had a 90% performance goal.
[ii] 12-month results to be published once available (or upon study completion)

Belgium.[iii] "What's most compelling is the combination of 100% acute and strong remap success[1] with a low rate of safety events. These results reinforce the potential of OMNYPULSE and its integration with the CARTO™ 3 System to deliver reproducible, durable outcomes for patients with paroxysmal AFib."

In addition, data from the VARIPURE study are being shared at the HRS Annual Meeting, evaluating the real-world safety and operator learning curve associated with the use of the VARIPULSE™ Platform PVI procedures for atrial fibrillation. Conducted across 13 European sites, the prospective, post-market study included 247 patients and 40 operators with varying levels of experience, including first-time users. Notably, no serious adverse events were reported, and no complications were linked to the platform, including zero neurovascular events or coronary spasms. Among a subset of 115 patients treated by operators performing their first 10 VARIPULSE™ cases, results showed no measurable learning curve beyond a modest reduction in idle time between ablations, underscoring the efficiency and ease of adopting this innovative technology.[2] VARIPURE is an ongoing registry, with over 600 patients enrolled to date.

"The VARIPULSE™ Platform has both a strong safety profile and is highly accessible to new users, enabling safe and consistent outcomes from the very first case. As adoption of PFA expands, I believe VARIPULSE™ can play a key role in broadening access to safe and streamlined ablation procedures," said Francis Bessière M.D., Ph.D., Cardiac Electrophysiology Department, Hôpital Cardiologique Louis Pradel, Hospices Civils de Lyon, France.[iv]

Additional data presented at HRS by Dr. Hiroshi Nakagawa include new preclinical validation of a PF Index from the Dual Energy THERMOCOOL SMARTTOUCH™ SF Catheter, leveraging data from lesions created in a swine beating heart model. The analysis confirmed that lesion depth, which is crucial for effective treatment, correlates strongly with the number of PFA pulses and contact force using a logarithmic PF Index—accurately predicting lesion depth within ±1 mm in 92% of cases and ±1.5 mm in all cases. These findings reinforce the reliability of the pulse dosing protocol and underline the PF Index's value as a practical tool for guiding ablation. The index is specifically optimized to support durable lesion formation, offering physicians confidence in its outputs and enabling them to make informed, real-time decisions with a high degree of procedural predictability and clinical precision.[3]

These multiplatform findings advance the clinical and technical validation of Johnson & Johnson MedTech's PFA portfolio across focal, regional and dual energy catheter designs—each leveraging CARTO™ 3 System integration and real-time lesion feedback. These latest data are part of Johnson & Johnson MedTech's commitment to advancing understanding of PFA, including the recently announced 12-month results from the SmartfIRE clinical trial presented in March 2025.

"Our PFA portfolio is built around what matters most to physicians—durability, control, safety and efficiency," said Jennifer Currin, Ph.D., Vice President, Scientific Affairs, Johnson & Johnson MedTech. "The Omny-IRE, VARIPURE, and Dual Energy THERMOCOOL SMARTTOUCH™ SF Catheter data demonstrate our commitment to delivering safe, effective, and reliable PFA tools."

Additional information on Johnson & Johnson's data presented at HRS can be found here.

About The OMNYPULSE™ Platform
The investigational OMNYPULSE™ Platform uses pulsed electrical field energy to produce targeted intracardiac lesions for the treatment of atrial fibrillation. The platform includes the TRUPULSE™ multichannel generator and multi-electrode OMNYPULSE™ Catheter used in conjunction with the CARTO™ 3 System with the VISITAG SURPOINT™ Module PF Index to provide electroanatomical maps, contact force sensing, PF Index values and

[iii] AZ Sint-Jan Hospital entered into a clinical trial agreement with Biosense Webster, Inc., part of Johnson & Johnson MedTech for their participation in the Omny-IRE Study. Dr. Duytschaever served as a study coinvestigator. Dr. Duytschaever serves as a consultant for Johnson & Johnson but was not compensated for this announcement.
[iv] VARIPURE (*VARIPULSE™ Catheter data exchange Platform powered by SECURE*) is a SECURE substudy. Hospices Civils de Lyon - Bron entered into a clinical trial agreement with Biosense Webster, Inc., part of Johnson & Johnson MedTech for their participation in the SECURE Study. Dr. Bessière served as a site principal investigator. Dr. Bessière serves as a consultant for Johnson & Johnson but was not compensated for this announcement.

catheter localization information for ablations for the treatment of paroxysmal atrial fibrillation. The OMNYPULSE™ Platform is not currently approved in any region of the world.

About The Omny-IRE Study
Omny-IRE is a pivotal, prospective, multi-center, non-randomized study in Europe and Canada to demonstrate the safety and effectiveness of Johnson & Johnson MedTech's OMNYPULSE™ Platform, the principal components of which are the OMNYPULSE™ Catheter and the TRUPULSE™ Generator. The study is evaluating the system for the treatment of symptomatic paroxysmal atrial fibrillation during standard electrophysiology mapping and ablation procedures while also evaluating the incidence of primary adverse events within seven days post-procedure**.**

About the VARIPULSE™ Platform
The VARIPULSE™ Platform consists of the VARIPULSE™ Catheter, TRUPULSE™ Generator, and CARTO™ 3 Mapping System VARIPULSE™ Software. The VARIPULSE Catheter is a variable-loop circular catheter (VLCC) used for pulsed field ablation (PFA) in atrial fibrillation treatment, particularly for pulmonary vein isolation, and allows for adjustment of the loop size to conform to different patient anatomies.

About the Dual Energy THERMOCOOL SMARTTOUCH™ SF Catheter
The Dual Energy THERMOCOOL SMARTTOUCH™ SF Platform consists of the Dual Energy THERMOCOOL SMARTTOUCH™ SF Catheter – an irrigated, contact-force sensing catheter – and the TRUPULSE™ Generator, providing both RF and PF energy to the catheter through the toggling of the two energy sources on the generator monitor.[6] The catheter and the generator are fully integrated with the CARTO™ 3 System, enabling advanced 3D mapping visualization with integrated ultrasound during ablation procedures.[v] The Dual Energy THERMOCOOL SMARTTOUCH™ SF Catheter is the first dual energy PFA / RF ablation catheter integrated with a PF and RF tag index. The Catheter received European CE Mark in December 2024; it is investigational in the United States.

Cardiovascular Solutions from Johnson & Johnson MedTech
Across Johnson & Johnson, we are tackling the world's most complex and pervasive health challenges. Through a cardiovascular portfolio that provides healthcare professionals with advanced mapping and navigation, miniaturized tech, and precise ablation we are addressing conditions with significant unmet needs such as heart failure, coronary artery disease, stroke, and atrial fibrillation. We are the global leaders in heart recovery, circular restoration and the treatment of heart rhythm disorders, as well as an emerging leader in neurovascular care, committed to taking on two of the leading causes of death worldwide in heart failure and stroke. For more, visit biosensewebster.com and connect on LinkedIn and X, formerly Twitter.

About Johnson & Johnson
At Johnson & Johnson, we believe health is everything. Our strength in healthcare innovation empowers us to build a world where complex diseases are prevented, treated, and cured, where treatments are smarter and less invasive, and solutions are personal. Through our expertise in Innovative Medicine and MedTech, we are uniquely positioned to innovate across the full spectrum of healthcare solutions today to deliver the breakthroughs of tomorrow, and profoundly impact health for humanity. Learn more about our MedTech sector's global scale and deep expertise in cardiovascular, orthopaedics, surgery and vision solutions at https://thenext.jnjmedtech.com. Biosense Webster, Inc. is part of Johnson & Johnson MedTech.

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 OMNYPULSE™ Platform clinical trials, VARIPULSE™ Platform, CARTO™ 3 System, and Dual Energy THERMOCOOL SMARTTOUCH™ SF Catheter. 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

[v] Results reported after 9 months for patients with paroxysmal AFib who had failed 1 antiarrhythmic medication in randomized trial.

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 most recent Annual Report on Form 10-K, 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.

[1] Duytschaever M, Grimaldi M, De Potter T, et al. Safety, efficacy and PVI durability of a contact force-sensing large-tip focal pulsed field ablation catheter integrated with 3D mapping to treat paroxysmal atrial fibrillation: first-in-human Omny-IRE 3-month results. Presented at HRS 2025; April 25, 2025; San Diego, CA.
[2] Bessière F, Kronborg MB, Sommer P, et al. Evaluating Safety Profile and Learning Curve With a Pulsed Field Ablation Variable Loop Circular Catheter in Procedures for AF: Observations From a Prospective, Multicenter, Postmarket Clinical Trial. Presented at HRS 2025; April 27, 2025; San Diego, CA.
[3] Nakagawa H, Farshchi S, Maffre J, et al. Predicting Lesion Depth During Pulsed Field Ablation: Prospective Validation of a Novel Ablation Index Based on Contact Force and Number of Applications in a Swine Beating Heart Model. Presented at HRS 2025; April 24, 2025; San Diego, CA.
[4] A Study for Treatment of Paroxysmal Atrial Fibrillation (PAF) With the OMNYPULSE Catheter and the TRUPULSE Generator (Omny-IRE). Clinicaltrials.gov. Accessed April 8, 2025.
[5] Biosense Webster. (2023). OMNYPULSE™ Bi-Directional Catheter IFU.
[6] De Potter T, Scherr D, Pürerfellner H, et al. Safety, effectiveness, and healthcare benefits of a dual energy focal ablation technology to treat paroxysmal atrial fibrillation: SmartfIRE 12-month results. Presented at EHRA 2025; March 31, 2025; Vienna, Austria. Pending formal publication.