

Inari Medical Announces Reimbursement Approval for ClotTriever® Thrombectomy System in Japan and New Distribution Partnership with Medikit Co., Ltd.

December 2, 2024

Reimbursement approval supports expanded access to effective, safe thrombus removal for patients suffering from deep vein thrombosis (DVT) in Japan

IRVINE, Calif., Dec. 02, 2024 (GLOBE NEWSWIRE) -- Inari Medical, Inc. (NASDAQ: NARI) ("Inari"), a medical device company with a mission to treat and transform the lives of patients suffering from venous and other vascular diseases, announced today that on December 1, 2024, it received national reimbursement approval from the Japanese Ministry of Health, Labor and Welfare (MHLW) for its ClotTriever Thrombectomy System for DVT. This announcement follows the regulatory approval of the ClotTriever system by the Pharmaceuticals and Medical Devices Agency (PMDA) in December 2023.

Due to ClotTriever's unique mechanism of action for complete, wall-to-wall thrombus removal in patients suffering from DVT, MHLW created a new functional category that is separate from other catheter-based therapies. This new functional category comes with a reimbursement premium based upon ClotTriever's wealth of clinical data showing safety and efficacy in removing various types of thrombi.

To facilitate commercialization of the ClotTriever system in Japan, Inari has entered into a distribution agreement with Medikit Co., Ltd., a market leading vascular medical device manufacturer serving Japan, the U.S. and over 30 other countries. With this new partnership, Inari plans to accelerate initiation of its 100-patient Post Market Surveillance study, followed by broader commercial expansion.

"MHLW's approval of reimbursement for ClotTriever under a newly designated functional category marks a transformative milestone for Inari in Japan," said Drew Hykes, Chief Executive Officer of Inari. "This decision underscores the value of ClotTriever in addressing unmet clinical needs, and we are thrilled to collaborate with Medikit to bring this innovative solution to Japanese DVT patients, improving lives and advancing care in the near future. Over time, we look forward to bringing our broader portfolio of purpose-built tools to the Japanese market."

The ClotTriever system is 510(k)-cleared by U.S. FDA and CE-Marked for treatment of DVT. More than 75,000 procedures have been conducted with ClotTriever globally. Recently, two-year outcomes were reported from the 500-patient ClotTriever CLOUT Registry showing a strong safety profile, significant clot removal, and low rates of post-thrombotic syndrome. 1,2,3 ClotTriever is the most studied thrombectomy device for DVT, including the ongoing Randomized Controlled Trial, DEFIANCE, comparing ClotTriever to anticoagulation alone for patients with DVT. 4

About Inari Medical, Inc.

Patients first. No small plans. Take care of each other. These are the guiding principles that form the ethos of Inari Medical. We are committed to improving lives in extraordinary ways by creating innovative solutions for both unmet and underserved health needs. In addition to our purpose-built solutions, we leverage our capabilities in education, clinical research, and program development to improve patient outcomes. We are passionate about our mission to establish our treatments as the standard of care for venous thromboembolism and four other targeted disease states. We are just getting started. Learn more at www.inarimedical.com and connect with us on LinkedIn, X (Twitter), and Instagram.

About Medikit Co., Ltd.

Medikit Co., Ltd., based in Tokyo, established in 1973, is a global medical device company and is publicly traded on the Tokyo Stock Exchange (Code: 7749). Medikit's mission is to deliver the highest standards of excellence in operating as a health care company whose products and services help to enhance healthy life by minimizing unnecessary suffering and death from disease. Medikit is a market leader in Japan in interventional products, including vascular access devices such as hemodialysis catheters, intravenous catheters, sheaths, and guiding catheters. Medikit products are sold in Japan, the United States, and over 30 other countries. The company has sales, R&D, and manufacturing capabilities with more than 1,300 consolidated employees. For more information, visit the company's website at www.medikit.co.jp.

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¹ Bisharat, et al. One-Year Clinical Outcomes Following Mechanical Thrombectomy for Deep Vein Thrombosis: A CLOUT Registry Analysis. JSCAI. 2024.

² Shaikh, et al. Six-Month Outcomes of Mechanical Thrombectomy for Treating Deep Vein Thrombosis: Analysis from the 500-Patient CLOUT Registry. Cardiovasc Int Rad. 2023.

³ Dexter, D. Interim two-year outcomes from the fully enrolled CLOUT registry. Presented at AVF 2024 (Tampa, FL).

⁴ Abramowitz, et al. Rationale and Design of the DEFIANCE Study: A Randomized Controlled Trial of Mechanical Thrombectomy Versus Anticoagulation Alone for Iliofemoral Deep Vein Thrombosis. American Heart Journal. doi.org/10.1016/j.ahj.2024.10.016