PEERLESS Results Show Superiority of FlowTriever® Compared to Catheter-Directed Thrombolytics for Intermediate-Risk Pulmonary Embolism

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Primary endpoint win driven by both hard clinical outcomes and hospital resource utilization

IRVINE, Calif., Oct. 29, 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 diseases, today announced positive results from the prospective PEERLESS Randomized Controlled Trial (RCT) comparing FlowTriever to catheter-directed thrombolytics (CDT). The results were presented by Dr. Wissam Jaber, Professor of Medicine at Emory University School of Medicine and Co-Global Principal Investigator (PI), during the Late-Breaking Clinical Trial Session at the 2024 Transcatheter Cardiovascular Therapeutics (TCT) Annual Scientific Symposium in Washington, D.C. In recognition of the clinical relevance of the study, results were also simultaneously published in *Circulation*, the premier peer-reviewed journal of the American Heart Association (AHA).

PEERLESS met its primary composite endpoint (win ratio 5.01, p<0.001), driven by patients experiencing significantly fewer clinical deteriorations or therapy escalations, fewer ICU admissions, and shorter ICU lengths of stay with FlowTriever versus CDT. Patients also had faster recovery of clinical symptoms and hemodynamics, shorter hospital length of stay, and fewer 30-day readmissions.

"These results are crucial to guiding optimal PE treatment decisions, providing strong evidence that FlowTriever may reduce clinical deterioration and the need for reintervention through more effective early thrombus resolution," said Dr. Jaber. "As the only randomized trial evaluating mechanical thrombectomy in PE, PEERLESS allows us to now confidently say that treatment with FlowTriever is safe, effective, and superior to CDT."

The PEERLESS study was conducted across 57 centers worldwide, enrolling 550 intermediate-risk PE patients randomized to receive either FlowTriever thrombectomy or CDT. The primary RCT cohort excluded patients with absolute contraindications to thrombolytics and enrolled very few patients with relative contraindications. In addition to Dr. Jaber, study leadership includes Co-global PI Dr. Carin Gonsalves, Professor of Radiology and Co-Director of the Division of Interventional Radiology at Thomas Jefferson University, and European PI Prof. Stefan Stortecky, Associate Professor, Bern University Hospital, Inselspital, Switzerland.

"These findings underscore FlowTriever's unique effectiveness in helping PE patients feel better more rapidly," said Dr. Gonsalves. "What stands out is that large-bore thrombectomy and blood return with the FlowTriever system produced superior clinical outcomes and maintained an excellent safety profile. This shows we can facilitate faster recovery from PE, discharge patients sooner, and do so without additional risks."

PEERLESS RCT Highlights:

- **Reduced Deteriorations/Bailouts:** FlowTriever patients had 3X fewer clinical deteriorations and/or therapy escalations to bailout compared to CDT.
- **Faster Recovery:** FlowTriever patients had greater improvement of clinical symptoms and hemodynamics at 24 hours, and fewer 30-day readmissions.
- **Decreased Hospital Resource Use:** FlowTriever patients had significantly less ICU admission, ICU length of stay (LOS), and hospital LOS.
- **Conclusive FlowTriever Safety Profile:** In the FlowTriever arm, there were 0 patient deaths at discharge or 7 days, 0 deteriorations related to cardiac arrest, high-grade AV block, or respiratory failure, and low 0.4% all-cause mortality at 30-day follow-up.

"PEERLESS, the first major randomized PE study in over a decade, reiterates our commitment to practice- and guideline-changing research and sets the new standard for clinically meaningful endpoints," said Dr. Thomas Tu, Inari's Chief Medical Officer. "The results of this study position FlowTriever as the primary interventional tool for intermediate-risk PE. PEERLESS is the first in a series of randomized controlled studies that Inari and others are bringing to light, kicking off the golden age of PE research. I wish to thank our dedicated steering committee and investigators for bringing this trial to reality and contributing to its ongoing impact on patient care."

View the PEERLESS Results Summary Presentation: Link

Accepted for simultaneous publication in Circulation: Link

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.

The FlowTriever system is 510(k)-Cleared by FDA and CE Mark approved for the treatment of pulmonary embolism and clot in transit in the right atrium.

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