

Inari Medical Announces Presentation of Positive 30-Day Follow-Up Results from First Patients in Real World FLASH Registry

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IRVINE, Calif., Nov. 13, 2020 (GLOBE NEWSWIRE) -- Inari Medical, Inc. (NASDAQ: NARI) ("Inari"), a commercial-stage medical device company focused on developing products to treat and transform the lives of patients suffering from venous diseases, today announced follow-up results of the first 230 patients enrolled in its FLASH study. FLASH is a real world registry to study the FlowTriever system in intermediate- and high-risk pulmonary embolism ("PE") patients. The results were strongly positive. Just one death (0.4%) was reported at 30 days. By contrast, the national PERT Consortium[®] Quality Database recently showed 30-day mortality rates of 25.9% and 6.1% for high- and intermediate-risk PE patients. In addition, the FLASH Registry showed a readmission rate of 6.7%, compared to the nearly 25% readmission rate shown in the PERT Database. Efficacy data were equally compelling, showing normalization or near normalization in a battery of hemodynamic variables like pulmonary artery pressure, RV/LV ratio, and heart rate, as well as dyspnea (shortness of breath) metrics.

FLASH is a 500-patient prospective, multicenter, single-arm registry evaluating real world patient outcomes after treatment of PE with FlowTriever. Interim data were obtained across 19 US sites, and results were presented virtually by National Principal Investigator, Catalin Toma, MD, Director of Interventional Cardiology at UPMC Heart & Vascular Institute in Pittsburgh, PA at the American Heart Association ("AHA") Scientific Sessions 2020.

These data follow the presentation of equally compelling acute data from the same patient set delivered two weeks ago at the annual TCT meeting. The acute results showed, at 48 hours, no deaths, no cardiac injuries, no pulmonary injuries, no procedure-related clinical deteriorations, and no intracranial hemorrhages in this highly compromised PE patient population. The TCT data also showed clinically and statistically significant improvement in hemodynamic parameters while the patient was still on the table. Post-procedure median ICU stay was 0 days. The new FLASH data released at AHA extends the study follow-up period to 30 days and demonstrates the durability of these acute results with continued improvement in outcomes over time.

"FLASH has shown us that PE patients experience symptom relief and improved cardiac function immediately upon removal of significant clot burden. These outcomes continue to improve over time. In fact, for a high percentage of these patients, measurements for dyspnea, right heart strain, pulmonary artery pressure and heart rate actually normalized after FlowTriever thrombectomy. We believe this suggests that removal of large clot burden with the FlowTriever system not only has an important impact acutely, but might have an important positive effect on long term implications of PE, like CTED and CTEPH," said Dr. Toma.

"With over 60% of patients in FLASH having no contraindication to lytics, the study data suggests that FlowTriever is emerging as a frontline therapy for intermediate and high-risk PE patients, regardless of patient eligibility for other treatment options. PE care pathways are evolving," said Thomas Tu, MD, Chief Medical Officer of Inari Medical. "Venous thromboembolism ("VTE") patients are central to everything that we do at Inari, and we remain committed to advancing the treatment of this disease through clinical research and the continued development of purpose-built devices."

About Inari Medical, Inc.

Inari Medical, Inc. is a commercial-stage medical device company focused on developing products to treat and transform the lives of patients suffering from venous diseases. Inari has developed two minimally-invasive, novel catheter-based mechanical thrombectomy devices that are designed to remove large clots from large vessels and eliminate the need for thrombolytic drugs. The company purpose-built its products for the specific characteristics of the venous system and the treatment of the two distinct manifestations of venous thromboembolism, or VTE: deep vein thrombosis and pulmonary embolism. The ClotTriever system is 510(k)-cleared by the FDA for the treatment of deep vein thrombosis. The FlowTriever system is 510(k)-cleared by the FDA for the treatment of pulmonary embolism.

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