Inari Medical Announces First Patient Enrolled in FLAME Study

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IRVINE, Calif., April 05, 2021 (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 the enrollment of the first high-risk pulmonary embolism (“PE”) patient in the FlowTriever for Acute Massive Pulmonary Embolism study (“FLAME”). One in 20 PE diagnoses is categorized as high-risk and these are associated with a mortality rate of up to 40% at 90 days.

The first FLAME patient was enrolled at the Penn Presbyterian Hospital & Hospital of the University of Pennsylvania (“HUP”) by co-principal investigators Dr. Sameer J. Khandhar and Dr. Jay S. Giri. “We are pleased to be the first site to enroll a patient in FLAME,” said Dr. Khandhar, Interventional Cardiologist, Clinical Assistant Professor of Medicine, Penn Medicine. “We frequently see on-table normalization of hemodynamics using FlowTriever to extract large clots in PE patients. We are eager to formally study this effect in high-risk PE patients in whom the immediacy of this impact might reverse the death spiral and save lives,” said Dr. Khandhar.

FLAME is a prospective, multicenter, parallel group observational study evaluating treatment outcomes for up to 250 high-risk PE patients. It is the largest ever high-risk PE study of any intervention and its design, informed by evidence development guidance from the American Heart Association (“AHA”), aims to change the high-risk PE treatment guidelines. “Conservatively managed high-risk PE is associated with high mortality, but there is limited data supporting interventional treatment. We have designed FLAME to prospectively examine all patients at participating centers with high-risk PE, including those not treated with FlowTriever, to maximize generalizability of the study,” said Dr. Giri, Interventional Cardiologist, Director of Peripheral Intervention in the Cardiovascular Division at HUP.

Beyond FLAME, Inari continues to invest heavily in its robust clinical study pipeline. Positive long-term late-breaking results were recently presented at the American Venous Forum annual meeting from both the CLOUT and FLASH studies. FLASH – already the largest prospective hemodynamic study of any PE treatment ever – is being doubled in size to 1,000 patients to collect data from a conservatively managed sub-group and include sites outside the US. In addition, for the first time ever, 200 patients will be monitored and studied using the Apple Watch.

“FLASH and FLAME are breaking new ground in the study of pulmonary embolism,” said Bill Hoffman, Inari’s Chief Executive Officer. “We are studying real world patients and much sicker patients, and we are measuring outcomes that matter both in the immediate and longer term for these patients. We remain committed to this disease state, to our patients, and to producing the most robust outcomes data in the space.”

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

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