BD Initiates International Study to Expand Treatment Options for Patients with Peripheral Arterial Disease

First Patient Enrollment in AGILITY Study Begins Investigations of Safety and Effectiveness of BD Vascular Covered Stent for Treatment of PAD

FRANKLIN LAKES, N.J., March 4, 2024 /PRNewswire/ -- BD (Becton, Dickinson and Company) (NYSE: BDX), a leading global medical technology company, today announced the enrollment of the first patient in the investigational device exemption (IDE) study, "AGILITY," which will assess the safety and effectiveness of the BD Vascular Covered Stent for the treatment of Peripheral Arterial Disease (PAD).

The investigational Vascular Covered Stent is a self-expanding, low profile, polytetrafluoroethylene encapsulated nitinol implant. It is deployed from a delivery system that provides controlled stent release.

"When we're addressing advanced PAD, a self-expanding covered stent can play an important role," said Dr. Sean Lyden, chairman of the Department of Vascular Surgery at Cleveland Clinic and National Principal Investigator of the AGILITY study. "We need a stent that can track to the lesion, apposes the vessel wall and ultimately provides long-term durability. We're excited to see how this technology performs."

According to BD, the global, prospective, multi-center, single-arm, non-randomized AGILITY clinical study will include 315 patients at up to 40 clinical study sites across the United States, Europe, Australia and New Zealand. Follow-up for all treated patients will be performed at various points after treatment — starting at one month and ending at 36 months.

PAD affects more than 18 million Americans and more than 236 million people worldwide.[1,2] It is a potentially debilitating disease that can lead to increased risk of cardiovascular complications and limb amputation. A healthy diet, exercise and cessation of smoking can help mitigate the development of PAD, which includes the formation of atherosclerosis and blood clots in arteries in the legs. Minimally invasive techniques using devices such as angioplasty balloons, drug-coated balloons, atherectomy and covered stents can be used to increase blood flow through the diseased areas.

"There continues to be significant unmet needs in the treatment of PAD patients," said Tim Hug, vice president and general manager at BD Peripheral Intervention. "We are excited to have initiated this study and evaluate the treatment benefits of this potentially differentiated technology. This stent could give interventionalists an important new solution in the fight against PAD, expand our portfolio and enable us to better serve our customers and the patients they treat."

The first patient in the AGILITY study was enrolled at Trinity Medical Center in Bettendorf, Iowa by Dr. Nicolas Shammas, Interventional Cardiologist, Cardiovascular Medicine, PLLC; Founder and President of the Midwest Cardiovascular Research Foundation, Davenport, Iowa; and Adjunct Professor of Medicine, University of Iowa.

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About BD

BD is one of the largest global medical technology companies in the world and is advancing the world of health by improving medical discovery, diagnostics and the delivery of care. The company supports the heroes on the frontlines of health care by developing innovative technology, services and solutions that help advance both clinical therapy for patients and clinical process for health care providers. BD and its more than 70,000 employees have a passion and commitment to help enhance the safety and efficiency of clinicians' care delivery process, enable laboratory scientists to accurately detect disease and advance researchers' capabilities to develop the next generation of diagnostics and therapeutics. BD has a presence in virtually every country and partners with organizations around the world to address some of the most challenging global health issues. By working in close collaboration with customers, BD can help enhance outcomes, lower costs, increase efficiencies, improve safety and expand access to health care. For more information on BD, please visit bd.com or connect with us on LinkedIn at www.linkedin.com/company/bd1/, X (formerly Twitter) @BDandCo or Instagram @becton_dickinson.

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[1] "THE SAGE GROUP Releases New Estimates for the United States Prevalence of Peripheral Artery Disease (PAD) and Critical Limb," September 30, 2010, https://www.fiercehealthcare.com/healthcare/sage-group-releases-new-estimates-for-united-states-prevalence-peripheral-artery-disease

[2] *Epidemiology of Peripheral Artery Disease: Narrative Review*. (2022, July 12). National Library of Medicine. Retrieved February 21, 2024, from https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9320565/

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