FDA Circulatory System Devices Panel Voted Favorably on Safety, but Does Not Provide a Favorable Recommendation Regarding Lutonix™ 014 Drug Coated Balloon for Below-the-Knee Procedures

FRANKLIN LAKES, N.J. (Feb. 17, 2021) – BD (Becton, Dickinson and Company) (NYSE: BDX), a leading global medical technology company, today announced that the U.S. Food and Drug Administration's (FDA) Circulatory System Devices Advisory Panel did not provide a favorable recommendation to the FDA for use of the Lutonix™ 014 Drug Coated Balloon (DCB) in the treatment of below-the-knee (BTK) arteries in patients with critical limb ischemia (CLI).

The Panel voted 15 to 2 in favor on the issue of safety when used as intended and voted 15 to 2 against on the issue of a reasonable assurance of effectiveness. The third vote was 14 to 3 against whether the benefits outweigh the risks. There was one abstention in all three votes.

The Panel was convened to provide expert input and recommendations to FDA to support the Agency's review of Lutonix™ 014 DCB used in the treatment of below-the-knee arteries in patients with CLI, which would be the first and only DCB available for this vulnerable patient population in the United States.

Information presented at today's panel meeting included six-month primary endpoint data, and safety data out to 36 months from the Lutonix BTK IDE pivotal trial, which is a global, multicenter, prospective, single-blind, randomized, 51-site study that enrolled 462 patients from the United States, Europe, Canada and Japan.

The Lutonix™ 014 DCB remains under review by FDA for the treatment of patients with CLI who have obstructive de novo or non-stented restenotic lesions in native popliteal, tibial and peroneal arteries up to 320 mm in length and 2.0 to 4.0 mm in diameter.

"While the Panel's vote on the question of safety was favorable, their votes on effectiveness and risk-benefit focused on study design and the challenges of executing a trial over eight years in this complex patient population," said Dr. J.D. Meler, Vice President of Medical Affairs for BD's Peripheral Intervention business. "We thank FDA and the Panel for the opportunity to bring these important data to light in this area of unmet need, and thank the clinicians, patients and advocates who shared their personal thoughts and experiences with the Panel."

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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 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/ and Twitter @BDandCo.

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