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BD Statement on FDA Circulatory System Devices Panel Regarding Paclitaxel-Coated Devices

FRANKLIN LAKES, N.J., June 20, 2019 /PRNewswire/ -- BD (Becton, Dickinson and Company) (NYSE: BDX), a leading global medical technology company, today issued the following statement following the U.S. Food and Drug Administration (FDA) Circulatory System Devices Panel of the Medical Devices Advisory Committee meeting related to the potential increase in mortality associated with the use of paclitaxel-coated devices in patients with peripheral arterial disease (PAD) in the superficial femoropopliteal artery (SFA):



The panel discussed the benefits of paclitaxel-coated devices relative to the potential risks and noted strong evidence of benefit and recommended additional efforts to evaluate long-term safety. Additionally, BD presented its own data confirming that the benefits outweigh the risks for LUTONIX[®] Drug-Coated Balloons (DCBs) in SFA. Over the past several months, BD has been working diligently to obtain all available patient follow up data and collaborating with FDA, professional clinical organizations and industry to investigate the important issue of DCB safety. BD continues to stand behind the safety of its LUTONIX[®] DCBs and is committed to improving the quality of life for patients with PAD. BD will continue to collaborate with FDA, industry and professional organizations to collect and analyze data for the benefit of patients. To ensure patients with PAD continue to receive the best care possible, BD will continue to ensure physicians and patients have access to BD's broad range of treatment options for this serious disease.

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 65,000 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.

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