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BD Announces Completion of Enrollment in the Lutonix™ 014 Drug Coated Balloon Below-The-Knee Trial

FRANKLIN LAKES, N.J., Jan. 18, 2018 /PRNewswire/ -- BD (Becton, Dickinson and Company) (NYSE: BDX), a leading global medical technology company, today announced the completion of enrollment in the Lutonix below-the-knee (BTK) trial and plans to submit a pre-market approval application in late 2018.



The Lutonix BTK trial is a prospective, multicenter, randomized, controlled trial intended to demonstrate superior efficacy and non-inferior safety of the Lutonix 014 Drug Coated Balloon (DCB) as compared to standard angioplasty balloon catheters for treatment of severe claudication and critical limb ischemia (CLI) patients with stenotic or occlusive lesions in the below-the-knee arteries. The Lutonix BTK trial is the only on-going DCB trial for BTK arteries in the U.S. and has enrolled more than 450 patients over the past four years.

The Lutonix 014 DCB product for BTK has been commercially available in Europe, Canada and Australia for treatment of the arteries associated with CLI since 2013.

CLI is a severe obstruction of the arteries that seriously decreases blood flow to the lower leg arteries. An estimated 2 million people in the U.S. have CLI today, and the number is estimated to grow to nearly 2.8 million by 2020ⁱ. CLI is associated with major amputation rate of 10 percent to 40 percent and with mortality rates as high as 50 percentⁱⁱ.

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 improve patient outcomes, improve the safety and efficiency of clinicians' care delivery process, enable laboratory scientists to better diagnose 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. In 2017, BD welcomed C. R. Bard and its products into the BD family. For more information on BD, please visit bd.com.

Forward Looking Statements

This press release contains certain estimates and other forward-looking statements (as defined under Federal securities laws) regarding clinical trials and product development activities and the regulatory approval process. Forward looking statements may be identified by use of words such as "intend", "plan", "believe", "expect" or other words of similar meaning. All such statements are based upon the current expectations of BD and involve a number of business risks and uncertainties that could cause actual results to differ materially from anticipated results described, implied or projected in any forward-looking statement, including, without limitation, difficulties inherent in product development and risks relating to the regulatory approval process. We do not intend to update any forward-looking statements to reflect events or circumstances after the date hereof except as required by applicable laws or regulations.


ⁱ Bassar O, et al. Prevalence, Incidence, and Outcomes of Critical Limb Ischemia in the US Medicare Population. *Vascular Disease Management* 2013;10(2):E26-E36.

ⁱⁱ Teraa M, et al. Critical Limb Ischemia: Current Trends and Future Directions. *J Am Heart Assoc.* 2016;5:e002938

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