BD Announces Long-Term Safety Data for Below-the-Knee Drug-Coated Balloon

Three-year mortality and amputation data for Lutonix® 014 Drug-Coated Balloon Below-The-Knee IDE trial presented at LINC

FRANKLIN LAKES, N.J. (Jan. 29, 2020) – BD (Becton, Dickinson and Company), a leading global medical technology company, today announced that interim findings from the Lutonix below-the-knee (BTK) IDE trial show positive safety results at three years for freedom from mortality, freedom from major amputation and amputation-free survival.

The clinical study is a prospective, global, multicenter, single blind, randomized (2:1 randomization), controlled trial comparing the LUTONIX® 014 Drug Coated Balloon (DCB) to percutaneous transluminal angioplasty (PTA) for the treatment of narrowed or obstructed arteries below the knee. The safety endpoints were assessed using a Kaplan-Meier (K-M) analysis through 36 months for the intent-to-treat population, with 70% of patients having completed three-year follow up at the time of analysis. At 1,095 days, there is no significant difference in freedom from mortality (DCB: 81.0% and PTA: 81.0%, p=0.946), freedom from major amputation (DCB: 95.5% and PTA: 93.8%, p=0.268) or amputation-free survival (DCB: 77.8% and PTA: 77.8%, p=0.495). LUTONIX® 014 DCB demonstrated statistically improved primary efficacy at six months when compared to PTA (K-M analysis), with K-M curves merging at one year. There were no statistical differences in safety or efficacy beyond six months in this interim analysis. These results were presented at the Leipzig Interventional Course (LINC) 2020 Annual Conference in Leipzig, Germany, and show that versus PTA, LUTONIX® 014 DCB provided statistically significant efficacy outcomes at six months with no observed safety issues out to three years.

“Critical limb ischemia (CLI) is an aggressive disease affecting approximately 3.4 million patients in the U.S,” said Dr. JD Meler, vice president, Medical and Clinical Affairs at BD. “The interim long-term Lutonix BTK IDE safety and efficacy data presented at LINC is a step toward advancing CLI research and finding new treatment options for this difficult-to-treat disease.”

The LUTONIX® 014 DCB has been commercially available in Europe, Canada and Australia for treatment of the below-the-knee arteries in patients with CLI since 2013. The product is an investigational device in the U.S.

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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