BD Statement on Meta-Analysis Published Regarding Drug-Coated Balloons for Below-the-Knee Applications

The meta-analysis published by Dr. Konstantinos Katsanos, et al in the *Journal of Vascular and Interventional Radiology* on January 14 focused on amputation-free survival (defined as freedom from all-cause mortality and major amputation) and target lesion revascularization of five different paclitaxel-coated devices studied specifically in below-the-knee (BTK) arteries in patients with critical limb ischemia (CLI) up to one year. The findings showed increased all-cause mortality and major amputation rates associated with higher-dose paclitaxel-coated products. However, the authors noted that "the single low-dose 2.0-ug/mm2 trial [LUTONIX® 014 Drug Coated Balloon] was found to be safe . . . and effective."

The safety findings for the LUTONIX® 014 Drug Coated Balloon (DCB) in this meta-analysis further support the positive safety outcomes reflected in the published 6-month safety data, and the 36-month interim safety data presented at VERVE, from the LUTONIX® 014 DCB IDE, level 1 clinical trial for the BTK indication. BD will be presenting additional LUTONIX® 014 DCB BTK interim three-year safety data at the upcoming Leipzig Interventional Course (LINC) 2020 Annual Conference in Leipzig, Germany later this month. The LUTONIX® 014 DCB has been commercially available in Europe, Canada and Australia for treatment of the BTK arteries associated with CLI since 2013. In the U.S., the LUTONIX® 014 DCB is an investigational device, limited by U.S. law to investigational use.

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