BD Newsroom

BD Statement on Paclitaxel-Coated Devices

PR Newswire

FRANKLIN LAKES, N.J., March 21, 2019 /PRNewswire/ -- BD (Becton, Dickinson and Company) (NYSE: BDX), a leading global medical technology company, today issued the following statement related to the recent letter from FDA to health care providers regarding paclitaxel-coated devices:

On March 15, the FDA issued a letter to health care providers regarding paclitaxel-coated devices used to treat peripheral arterial disease in the femoropopliteal artery. It is of critical importance that BD's customers and shareholders know that BD believes in its LUTONIX(®) drug-coated balloon (DCB) formulation and stands behind the robustness of its pre-clinical and clinical data. The totality of evidence from seven, separate LUTONIX(®)DCB studies continues to collectively demonstrate the safety and efficacy of these products, which offer an important treatment option for a vulnerable patient population. Over the past several months, BD has completed an extensive, comprehensive review of all available LUTONIX(®) DCB clinical data and these analyses continue to confirm the safety and efficacy of our products.

In its March 15 letter, the FDA stated, based upon their preliminary analysis of long-term follow-up data, that they see a potentially concerning signal of increased long-term mortality regarding the paclitaxel-coated device use. The FDA acknowledged that the cause for the increased risk of mortality is unknown, that there is a limited amount of long-term data (which creates variability in estimating mortality risk) and that the data was not designed to be pooled. Yet, the FDA determined to issue the letter primarily, it would appear, on a limited review of data from less than 1,000 patients combined from three studies with five-year data (completed by BD, Medtronic and Cook Medical).

BD's LEVANT 2 study enrolled 1,189 patients for the FDA panel's safety evaluation; this intent-to-treat (ITT) population was reevaluated at five years and we do not see a signal of increased long-term mortality in this large patient cohort (p=.198). While subset analysis of the randomized portion (476 patients) of the LEVANT 2 study did cross the line to significance (p=.046) at five years, the broader data set confirms the safety of this product and is larger than the pooled dataset referenced in the FDA letter.

BD has reviewed the patient level data from randomized portion of the LEVANT 2 study extensively. There are several known confounding factors for mortality over the five-year period. Said simply, there are causes of mortality for some participants that could not reasonably be attributed to paclitaxel (e.g., pre-existing cancer). When excluding those individual deaths, the subset analysis of the randomized portion no longer crosses the line to significance at five years. We have also engaged an independent third-party contract research organization (CRO) to repeat our analyses and perform its own.

In addition, we are collaborating with other industry stakeholders, the FDA and the VIVA Physicians Group to support an independent patient-level meta-analysis. We plan to complete these independent analyses prior to the FDA's Advisory Committee Meeting (panel) that is anticipated for mid-June 2019.

Patient safety and product quality are the top priorities at BD. We remain confident in our LUTONIX(®) DCB formulation, and we look forward to collaborating with global regulators, academic societies and other thought leaders in the analysis of long-term, patient-level data and further investigating the important issue of safety and DCBs.

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 healthcare by developing innovative technology, services and solutions that help advance both clinical therapy for patients and clinical process for healthcare 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 healthcare. For more information on BD, please visit bd.com.

Contacts:

Troy Kirkpatrick
Monique N. Dolecki

BD Public Relations
BD Investor Relations

858.617.2361
201.847.5378

troy.kirkpatrick@bd.com

Monique_Dolecki@bd.com

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