Boston Scientific

Boston Scientific Position on Conclusion of FDA Circulatory System Devices Panel about Peripheral Devices

We appreciate the perspectives shared about the safety and benefits of peripheral paclitaxel devices during the FDA's meeting of the Circulatory System Devices Panel. Boston Scientific shares the agency's dedication to providing the best care possible for the 8.5 million patients in the U.S. suffering from peripheral artery disease (PAD).[i] Peripheral devices with paclitaxel, including the Boston Scientific Eluvia™ Drug-Eluting Vascular Stent (DES) System, are a critically important therapeutic option which have provided relief to hundreds of thousands of patients worldwide who are suffering from PAD.[ii]

When considering the panel recommendations, it is important to understand that data on the Eluvia stent was not included in the meta-analyses demonstrating a late mortality signal. Additionally, the Eluvia stent is unique in its design, dose and drug delivery, as it is the only paclitaxel-based device which uses a polymer to enable a controlled, sustained drug release. The Eluvia stent has the lowest drug dose density of any paclitaxel-based peripheral device, up to 20 times lower than other drug-coated devices.

We will work with the FDA and key stakeholders to address the questions and recommendations discussed during the panel meeting and continue our robust collection of long-term data on patients treated with the Eluvia stent.

We remain steadfast in our commitment to providing effective treatment options to the millions of patients who experience this debilitating condition.

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[i] https://www.cdc.gov/dhdsp/data_statistics/fact_sheets/fs_pad.htm
[ii] Boston Scientific Corp. *FDA Executive Summary: Circulatory Systems Device Panel Meeting* 36-37 (2019).
