Boston Scientific

Boston Scientific Issues Perspective on the FDA Circulatory System Devices Panel about Peripheral Devices with Paclitaxel

On June 19-20, 2019, the U.S. Food and Drug Administration (FDA) held a meeting of the Circulatory System Devices Panel about peripheral devices with paclitaxel. Although data on the Boston Scientific Eluvia™ Drug-Eluting Vascular Stent (DES) System were not included in any of the meta-analyses that were contributing catalysts for the panel meeting, we presented updated clinical data affirming the safety of paclitaxel and the Eluvia stent.

We are dedicated to helping physicians provide the best care possible for their patients through access to life-saving technologies and are committed to working collaboratively with the FDA and other regulatory bodies.

The Eluvia stent is intentionally different from other paclitaxel-containing peripheral products and is more similar – in design, drug dose and polymer matrix – to our family of FDA-approved coronary drug-eluting stents. The polymer matrix used on Eluvia has been implanted in more than 20 million vessels and studied in more than 100,000 patients in clinical trials. **[i]**,**[ii]** The five-year data on our paclitaxel-eluting coronary stents did not demonstrate an increase in long-term mortality, nor does the currently available data on the Eluvia stent show an increased mortality risk.

We will continue our collection of long-term data on patients treated with the Eluvia stent and add to our existing body of clinical evidence supporting the safety of our paclitaxel-polymer technologies.

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[i] Data on file at Boston Scientific. Represents total global sales of the PROMUS (Boston Scientific) and XIENCE (Abbott) stents since 2006.

[ii] Data on file at Boston Scientific. Represents total population of patients studied in the PROMUS and XIENCE series of clinical trials.

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