Boston Scientific

Boston Scientific Receives FDA Approval for the AGENT™ Drug-Coated Balloon

First coronary drug-coated balloon in U.S. provides safe, effective alternative to treat coronary in-stent restenosis and reduce risk of reoccurrence

MARLBOROUGH, Mass., March 1, 2024 /PRNewswire/ -- Boston Scientific Corporation (NYSE: BSX) today announced it has received U.S. Food and Drug Administration (FDA) approval for the AGENT™ Drug-Coated Balloon (DCB), which is indicated to treat coronary in-stent restenosis (ISR) in patients with coronary artery disease. ISR is the obstruction or narrowing of a stented vessel by plaque or scar tissue.

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"With more than 100,000 patients treated globally to date in both clinical and commercial settings, we are very pleased to introduce this proven therapy as the first drug-coated coronary balloon in the U.S," said Lance Bates, president, Interventional Cardiology Therapies, Boston Scientific. "The AGENT DCB addresses a critical unmet need by providing a dedicated treatment option for the challenging condition of ISR and we look forward to offering U.S. physicians the opportunity to treat their patients with this novel device."

While the stenting of coronary lesions continues to show a substantial improvement in quality of life for patients with coronary artery disease, ISR still encompasses 10 percent of percutaneous coronary interventions in the U.S.[1,2] Serving as an alternative to traditional therapies such as balloon angioplasty, additional layers of stenting or radiation, the AGENT DCB is a paclitaxel-coated balloon catheter that transfers a therapeutic dose of drug to the vessel wall to help prevent ISR reoccurrence.

Following Breakthrough Device Designation granted for the technology by the FDA in 2021, the approval was supported by positive results from the multicenter, prospective, randomized controlled AGENT IDE trial, which enrolled 600 patients at 40 U.S. sites.[3] In the prespecified interim analysis of the first 480 patients enrolled, the study met the primary endpoint of target lesion failure (TLF) at 12 months with the AGENT DCB demonstrating statistical superiority to uncoated balloon angioplasty (17.9% vs. 28.7%; P=0.006).[4,5] Findings also included zero definite/probable cases of clotting within the stent (0.0% vs. 3.9%, P=0.001), a 49% risk reduction in heart attack at the target vessel (6.4% vs. 12.3%, P=0.03) and low adverse event rates at 12 months.

"The AGENT IDE trial demonstrated that the AGENT DCB is an effective and safe treatment option for coronary in-stent restenosis, even in a high-risk population, which included many individuals with multi-layer stents or diabetes," said principal investigator Dr. Robert W. Yeh, section chief of interventional cardiology at the Beth Israel Deaconess Medical Center. "Treating ISR has been challenging in the U.S. with limited therapies available, and this new technology will help physicians reduce the risk of restenosis without radiation or introducing additional metal layers, which do not provide an adequate result for some patients."

The AGENT DCB is available in Europe, parts of Asia Pacific and Latin America for the treatment of patients with ISR and previously untreated small vessel coronary disease. Boston Scientific plans to launch the technology in the U.S. in the coming months.

More information on the AGENT DCB is available here.

About Boston Scientific
Boston Scientific transforms lives through innovative medical technologies that improve the health of patients around the world. As a global medical technology leader for more than 40 years, we advance science for life by providing a broad range of high-performance solutions that address unmet patient needs and reduce the cost of healthcare. Our portfolio of devices and therapies helps physicians diagnose and treat complex cardiovascular, respiratory, digestive, oncological, neurological and urological diseases and conditions. Learn more at **www.bostonscientific.com** and connect on **LinkedIn** and **X**, formerly Twitter.

Cautionary Statement Regarding Forward-Looking Statements

This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Forward-looking statements may be identified by words like "anticipate," "expect," "project," "believe," "plan," "estimate," "intend" and similar words. These forward-looking statements are based on our beliefs, assumptions and estimates using information available to us at the time and are not intended to be guarantees of future events or performance. These forward-looking statements include, among other things, statements regarding our business plans and product performance

and impact, and new and anticipated product approvals and launches. If our underlying assumptions turn out to be incorrect, or if certain risks or uncertainties materialize, actual results could vary materially from the expectations and projections expressed or implied by our forward-looking statements. These factors, in some cases, have affected and in the future (together with other factors) could affect our ability to implement our business strategy and may cause actual results to differ materially from those contemplated by the statements expressed in this press release. As a result, readers are cautioned not to place undue reliance on any of our forward-looking statements.

Factors that may cause such differences include, among other things: future economic, competitive, reimbursement and regulatory conditions; manufacturing, distribution and supply chain disruptions and cost increases; new product introductions; demographic trends; intellectual property; litigation; financial market conditions; and future business decisions made by us and our competitors. All of these factors are difficult or impossible to predict accurately and many of them are beyond our control. For a further list and description of these and other important risks and uncertainties that may affect our future operations, see Part I, Item 1A – *Risk Factors* in our most recent Annual Report on Form 10-K filed with the Securities and Exchange Commission, which we may update in Part II, Item 1A – *Risk Factors* in Quarterly Reports on Form 10-Q we have filed or will file hereafter. We disclaim any intention or obligation to publicly update or revise any forward-looking statements to reflect any change in our expectations or in events, conditions or circumstances on which those expectations may be based, or that may affect the likelihood that actual results will differ from those contained in the forward-looking statements. This cautionary statement is applicable to all forward-looking statements contained in this document.

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* *Dr. Robert Yeh is a paid consultant of Boston Scientific Corporation. He has not been compensated in connection with this press release.*

[1] Shlofmitz E, Iantorno M, Waksman R. Restenosis of Drug-Eluting Stents: A New Classification System Based on Disease Mechanism to Guide Treatment and State-of-the-Art Review. Circ Cardiovasc Interv. 2019 Aug;12(8):e007023. doi: 10.1161/CIRCINTERVENTIONS.118.007023.

[2] Moussa ID, Mohananey D, Saucedo J, et al. Trends and outcomes of restenosis after coronary stent implantation in the United States. *J Am Coll Cardiol*. 2020;76:1521-1531.

[3] Yeh RW, Bachinsky W, Stoler R, et al. Rationale and design of a randomized study comparing the AGENT drug coated balloon to plain old balloon angioplasty in patients with In-stent restenosis. *American Heart Journal.* 2021;241:101-107. doi:10.1016/j.ahj.2021.07.008.

[4] AGENT IDE Clinical Trial data presented at TCT 2023 by Dr. Robert Yeh.

[5] TLF was defined as myocardial infarction relative to the target vessel, the need for a target lesion revascularization (TLR) procedure or cardiac mortality.

SOURCE Boston Scientific Corporation

Additional assets available online: Photos (1)

https://news.bostonscientific.com/2024-03-01-Boston-Scientific-Receives-FDA-Approval-for-the-AGENT-TM-Drug-Coated-Balloon