Boston Scientific

Boston Scientific Receives FDA Approval for the POLARx™ Cryoablation System

First-of-its-kind expandable cryoballoon catheter advances cryoablation therapy, addresses key limitations with traditional systems

MARLBOROUGH, Mass., Aug. 8, 2023 /PRNewswire/ -- Boston Scientific Corporation (NYSE: BSX) today announced it has received U.S. Food and Drug Administration (FDA) approval for the POLARx™ Cryoablation System. The new system, which is indicated for the treatment of patients with paroxysmal atrial fibrillation (AF), features the POLARx FIT Cryoablation Balloon Catheter, a device with the unique capability of enabling two balloon sizes – 28 and 31mm – in one catheter.

Cryoablation is a minimally invasive procedure for treating AF during which a balloon catheter delivers cryotherapy to the pulmonary vein, freezing problematic tissue and creating scarring that blocks irregular electrical signals. The system addresses known limitations by reimagining existing cryoablation offerings, allowing physicians to adjust and expand the new POLARx FIT catheter to fit a patient's individual anatomy during an ablation procedure, which can help mitigate time-consuming and disruptive device changeouts. The device also allows physicians to treat a wider range of pulmonary vein anatomies and create lesions in optimal positions to better deliver therapy to areas of the heart where disruptive signals that cause AF originate.

"The new POLARx Cryoablation System, and the expandable cryoballoon catheter specifically, is an exciting development for the effective treatment of AF as it allows physicians to better tailor care for individual patients without sacrificing safety or efficiency," said Wilber Su, MD, FHRS, FACC, Director of Electrophysiology, Banner University. "As we saw in clinical evaluation, the combination of maneuverability and variable balloon sizes makes this system particularly useful in addressing longstanding challenges with varying cardiac anatomies and brings to the table occlusion capabilities physicians aren't used to seeing with traditional systems."

Data from the FROZEN-AF IDE clinical trial – a global, prospective, non-randomized, single-arm studypresented at Heart Rhythm 2023 – demonstrated the safety and effectiveness of the POLARx Cryoablation System for the treatment of 385 patients with paroxysmal AF. The primary event-free rate, or freedom from procedure- or device-related events, was 96.0% at 12 months, with no reports of moderate or severe pulmonary vein stenosis, persistent phrenic nerve palsy or esophageal fistulas. At 12 months, the rate of freedom from documented atrial arrhythmias was 79.9%.

"The U.S. approval of the POLARx Cryoablation System, which has been used in more than 25,000 patients worldwide to date, marks an exciting advancement for the treatment of AF and a new era of cryoablation capabilities," said Nick Spadea-Anello, president, Electrophysiology, Boston Scientific. "By prioritizing procedural flexibility and individualized care, this offering transforms a key therapy in the electrophysiology space, addresses the unmet needs of physicians and affirms our commitment to making meaningful innovations to established technologies."

The POLARx Cryoablation System received CE Mark in February of 2020 and Japanese Pharmaceuticals and Medical Devices Agency (PMDA) approval in October of 2021. The POLARx FIT catheter received approval in Europe, Japan, Canada and other Asia Pacific markets in 2023.

More information on the POLARx Cryoablation System is availablehere.

About Boston Scientific
Boston Scientific transforms lives through innovative medical solutions 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. For more information, visit www.bostonscientific.com and connect on Twitter and Facebook.

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. 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; new product introductions; product performance; 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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