Boston Scientific

Late-Breaking Clinical Trial Data for TheraSphere™ Y-90 Glass Microspheres Demonstrates Improved Survival in Primary Liver Cancer

Data presented at SIR 2021 confirm safety and dose-efficacy relationship

MARLBOROUGH, Mass., March 25, 2021 /PRNewswire/ -- Boston Scientific Corporation (NYSE: BSX) announced positive data from the TARGET study of the TheraSphere™ Y-90 Glass Microspheres (TheraSphere) – a type of radioembolization comprised of millions of microscopic glass beads containing radioactive yttrium (Y-90) – during a late-breaking clinical trial presentation at the annual scientific meeting for the Society of Interventional Radiology (SIR).

The global, retrospective TARGET study evaluated the safety and efficacy of TheraSphere therapy in patients with hepatocellular carcinoma (HCC) – the most common type of primary liver cancer – using a dosing method known as multicompartment dosimetry, which maximizes the dose of Y-90 reaching the tumor while minimizing the radiation dose that reaches normal liver tissue. In the study, imaging software was used retroactively to calculate the dose delivered within each patient's liver tissue. Data confirmed treatment was safe and well tolerated, with only 4.8% of patients experiencing adverse events, defined in the primary endpoint as ≥ Grade 3 hyperbilirubinemia. Hyperbilirubinemia, commonly referred to as jaundice, is the build-up of bilirubin in the blood and can indicate abnormal liver function.

"The TARGET study findings create the opportunity for future TheraSphere treatment optimization and Y-90 dose escalation without compromising safety," said Prof. Marnix G.E.H. Lam, M.D., Professor of Nuclear Medicine, University Medical Center, Utrecht, Netherlands and one of the principal investigators of the TARGET study. "The study results are also generalizable and easily replicated as we included a global patient population with a wide spectrum of early, intermediate and advanced HCC."

Data from TARGET also demonstrated a correlation between the level of radiation absorbed by the tumor and an increase in survival probability through three years – with a median overall survival of 20.3 months. These findings are in line with recently published results showing that higher tumor absorbed dose leads to longer survival.[i,ii] In addition, a dose-efficacy relationship was established as the probability of tumor response was positively associated with the level of radiation absorbed by the tumor.

"TARGET adds to the robust body of evidence supporting TheraSphere as a safe and effective treatment option for the hundreds of thousands of patients around the world that are diagnosed with HCC each year," said Peter Pattison, president of Interventional Oncology, Peripheral Interventions, Boston Scientific. "These study insights and the Simplicit^{90}Y™ software provide physicians the opportunity to develop a personalized dosing approach for their patients with the potential to improve tumor response and optimize outcomes."

TheraSphere, which was approved by the U.S. Food and Drug Administration earlier this month, is the only radioembolization technology in the U.S. indicated for the treatment of unresectable HCC.

For more information on TheraSphere, visit www.therasphere.com.

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 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, clinical trials, product launches 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; 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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[i] Salem et al., 2019, EJNMMI, 46(8):1695-1704
[ii] Garin et al, 2021, Lancet Gastroenterol Hepatol, 6(1):17-29

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https://news.bostonscientific.com/2021-03-25-Late-Breaking-Clinical-Trial-Data-for-TheraSphere-TM-Y-90-Glass-Microspheres-Demonstrates-Improved-Survival-in-Primary-Liver-Cancer