Boston Scientific

Boston Scientific Receives FDA Approval for TheraSphere™ Y-90 Glass Microspheres

Treatment is the only radioembolization treatment approved for U.S. patients with hepatocellular carcinoma

MARLBOROUGH, Mass., March 18, 2021 /PRNewswire/ -- Boston Scientific Corporation (NYSE: BSX) announced it has received U.S. Food and Drug Administration (FDA) approval of the TheraSphere™ Y-90 Glass Microspheres, developed for the treatment of patients with hepatocellular carcinoma (HCC). The approval expands access to this life-prolonging therapy for a greater number of patients, which, to date, has been utilized under a humanitarian device exemption (HDE) – an FDA classification which required institutional review board approval and limited the number of patients treated with the therapy per year. TheraSphere is now the only radioembolization technology indicated for the treatment of unresectable HCC in the U.S.

HCC is one of the most prevalent cancers in the world and the most common type of primary liver cancer, with more than half a million new global cases diagnosed annually.[i] The American Cancer Society estimates that approximately 32,000 new cases of HCC will be diagnosed in the U.S. in 2021.[ii] It is most often treated through surgery, liver transplantation, chemotherapy or embolization, including both chemoembolization and radioembolization – also commonly referred to as selective internal radiation therapy (SIRT). TheraSphere treatment, a type of SIRT with low toxicity, is comprised of millions of microscopic glass beads containing radioactive yttrium (Y-90), which are delivered directly to liver tumors via catheter and result in minimal exposure to surrounding healthy tissue.

Approval of TheraSphere was based on results from the LEGACY study, designed to evaluate the safety and efficacy of the therapy for the treatment of early and advanced HCC. The study analyzed data from 162 patients and met both primary endpoints of objective response rate and duration of response rate (72.2% at four weeks and 76.1% at six months, respectively).[iii, iv,v,vi] Data demonstrated 100% complete or partial patient response up to two TheraSphere treatments – disappearance of all lesions or >/= 30% decrease in target lesion diameter – and a 93% overall survival rate in patients with transplant or resection following treatment at three years.

"I am honored to have spearheaded the LEGACY trial in which we found that patients with early and advanced HCC exhibited very high response rates as well as clinically meaningful durations of response and survival, establishing TheraSphere as a standard treatment for this patient population," said Riad Salem, M.D., M.B.A, interventional radiologist at Northwestern Memorial Hospital and principal investigator of the LEGACY trial. "The trial results, which have been accepted for publication in *Hepatology*, produced one of the most comprehensive databases for TheraSphere, empowering physicians to make informed, data-driven decisions for their patients."

Treatment with TheraSphere does not require hospitalization and is typically performed as an outpatient procedure in as little as an hour, potentially alleviating pressure on healthcare systems in an increasingly complex care environment. Recognition of the benefits of SIRT – both to patients and hospitals – were reflected in recently issued guidance from the National Institute for Health and Care Excellence (NICE) when they recommended the use of TheraSphere for the treatment of patients with HCC through the National Health Service (NHS) in England, Wales and Northern Ireland.

"The FDA approval and the recent NICE recommendation will expand access to TheraSphere, which has demonstrated improvement in both survivability and quality of life through 20 years of clinical trials and real-

world outcomes in the more than 70,000 patients globally," said Peter Pattison, president of Interventional Oncology, Peripheral Interventions, Boston Scientific. "We expect to continue to focus our efforts on bringing this treatment to more patients, both by planning a randomized trial to study the combination of TheraSphere and immunotherapy in patients with HCC not eligible for curative treatments, as well as further investigating the therapy for different cancer segments, including prostate and brain."

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] Mittal S, El–Serag HB. Epidemiology of hepatocellular carcinoma: consider the population. J Clin Gastroenterol. 2013; 47(suppl): S2– S6.

[ii] Cancer Facts & Figures 2021. American Cancer Society. Available at https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/annual-cancer-fact-and-figures/2021/cancer-facts-and-figures-2021.pdf. Accessed: January 30, 2021.

[iii] Complete Response (CR) and Partial Response (PR) within the treatment area according to localized mRECIST

[iv] Duration of Response (DoR) According to localized mRECIST

[v] Objective Response Rate defined as CR or PR using localized mRECIST (defined as the response within theY-90 glass microsphere treatment area) with confirmation of response (>4 weeks)

[vi] Duration of Response using localized mRECIST

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Additional assets available online: Photos (1)

https://news.bostonscientific.com/2021-03-18-Boston-Scientific-Receives-FDA-Approval-for-TheraSphere-TM-Y-90-Glass-Microspheres