Boston Scientific

Positive Late-breaking Clinical Trial Data for the EkoSonic™ Endovascular System Presented at VIVA21

Analysis found no intracerebral hemorrhages, low major bleeding rates; registry represents largest data set in interventional treatment of pulmonary embolism

LAS VEGAS and MARLBOROUGH, Mass., Oct. 5, 2021 /PRNewswire/ -- Today, Boston Scientific (NYSE: BSX) announced positive results for the EkoSonic™ Endovascular System (EKOS system) during a late-breaking clinical trial presentation at the Vascular InterVentional Advances (VIVA) meeting in Las Vegas. Data from the KNOCOUT PE registry – established to measure institutional adoption of a lower dose and lower-duration thrombolysis protocol for the EKOS system – confirmed the safety and efficacy of the EKOS system for the treatment of patients with intermediate-high and high-risk pulmonary embolism (PE).

"PE remains a life-threatening and complex disease, but these results provide an opportunity to advance patient care by showcasing evidence that proves a lower drug dose and shorter infusion duration of a thrombolytic agent may result in enhanced safety and efficacy," said Keith M. Sterling, M.D., FSIR, Inova Alexandria Hospital, Alexandria, VA, study principal investigator.[i] "The findings in this registry analysis are very reassuring to physicians making critical evidence-based decisions for their patients in what are oftentimes emergent treatment situations."

The international registry of 489 patients across 83 centers included data from patients treated with the EKOS system who were provided a lower drug dose and shorter infusion duration of a thrombolytic agent than administered in previous studies, reflecting contemporary clinical practice. In the data, there were no intracerebral hemorrhagic (ICH) events, or brain bleeding events, with a low major bleeding[ii] rate of 2.5%, compared to the rate previously observed with systemic thrombolysis treatment.[iii] Results also demonstrated a 23% post-procedure reduction in the main indicator of heart strain from PE, measured as right ventricular to left ventricular diameter ratio (RV/LV).

"As the largest prospective body of evidence in the interventional PE space to date, the KNOCOUT PE registry provides an accurate modern representation of patients with PE treated with the EKOS system every day," said Michael R. Jaff, D.O., chief medical officer and vice president clinical affairs, technology and innovation, Peripheral Interventions, Boston Scientific. "The strong safety and efficacy findings exhibited in this registry add to the existing clinical evidence supporting the EKOS system as a treatment option that physicians can trust, as it is already the most studied interventional device in the PE space."

The ultrasound technology used by the EKOS system accelerates thrombolysis – the breakdown of the clot – minimizing the time it takes to treat a patient and lowering the necessary thrombolytic dose, which can result in optimized outcomes and a lower risk of bleeding.

To learn more about the EKOS system, please visit www.bostonscientific.com/ekos.

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] Dr. Keith Sterling is a paid consultant for Boston Scientific Corporation. He has not been compensated for his quote within this press release.

[ii] Major bleeding as defined by International Society on Thrombosis & Haemostasis (ISTH).

[iii] Meyer G, et al. Fibrinolysis for patients with intermediate-risk pulmonary embolism. N Engl J Med. 2014 Apr 10;370(15):1402-11. doi: 10.1056/NEJMoa1302097.

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