Boston Scientific

HI-PEITHO trial demonstrates Boston Scientific EKOS™ Endovascular System is superior to standard of care for treatment of acute pulmonary embolism

Global randomized trial demonstrated statistically significant reduction in clinical event rates in patients with intermediate-risk PE when treated with the EKOS device plus anticoagulation vs. anticoagulation alone

Late breaking findings presented at ACC.26 and simultaneously published in The New England Journal of Medicine

MARLBOROUGH, Mass. and NEW ORLEANS, March 28, 2026 /PRNewswire/ -- Boston Scientific Corporation (NYSE: BSX) today announced positive data from the HI-PEITHO global randomized clinical trial evaluating the use of the EKOS™ Endovascular System in patients with intermediate-risk pulmonary embolism (PE). The study met the composite primary endpoint, with data demonstrating that the EKOS system plus anticoagulation was superior to the current standard of care – anticoagulation alone – for the treatment of acute PE. Findings from the trial were presented in a late-breaking science session at the American College of Cardiology's Annual Scientific Session & Expo and simultaneously published in *The New England Journal of Medicine*.

PE is a blood clot that causes a blockage in one or more pulmonary arteries that bring blood to the lungs, and is the third leading cause of cardiovascular mortality.[1] Current medical guidelines for treating PE recommend medical management with anticoagulation as the standard of care for patients at all risk levels. A minimally invasive intervention, the EKOS system delivers a low dose of clot-dissolving medication directly to the blood clot and uses ultrasound energy to facilitate the dispersion of the medication deep into the clot to dissolve it.

"The data presented today offer clinicians a greater understanding of the impact of intervention via ultrasound-facilitated catheter-directed thrombolysis with the EKOS system," said Dr. Stavros Konstantinides, MD, PhD, FESC, principal investigator of the HI-PEITHO trial and medical director, Center for Thrombosis and Hemostasis, University Medical Center Mainz, Germany.* "These highly anticipated findings underscore the clinical efficacy for patients treated with this therapy, while also demonstrating that treatment was not accompanied by an increased risk of major bleeding and offered the added benefit of a shorter hospital stay compared to patients treated with anticoagulation alone."

The trial met the combined primary endpoint of PE-related mortality, non-fatal hemodynamic cardiorespiratory decompensation or collapse and non-fatal symptomatic recurrence of PE within seven days. The EKOS system plus anticoagulation demonstrated superiority to anticoagulation alone (4.0% vs. 10.3%; P=0.005), representing a 61% reduction in primary endpoint events. Data from patients treated with the EKOS system also demonstrated a lower rate of cardiorespiratory decompensation or collapse (3.7% vs. 10.3%), in which inability of the heart to maintain adequate blood flow can lead to serious complications, often requiring emergency intervention. These results were achieved with no episodes of bleeding within the brain through 30 days.

"The HI-PEITHO trial evaluated clear, clinically meaningful endpoints using rigorous patient enrollment criteria and demonstrated a definitive impact with the EKOS system over the standard of care for treating acute PE," said Dr. Michael R. Jaff, vice president and chief medical officer, Vascular Therapies, Boston Scientific. "For the first time, we have robust randomized clinical trial data available to inform treatment decisions by interventionalists and referring physicians and support consideration of EKOS plus anticoagulation as a first-line therapy."

The randomized, controlled HI-PEITHO trial enrolled 544 patients with intermediate-risk PE across 59 sites in the United States and Europe. The trial is a joint research study led by Boston Scientific in partnership with The PERT Consortium® and the University Medical Center of Mainz and in collaboration with the PEITHO International Study Network. Patients will be followed to one year post procedure.

For more information on the HI-PEITHO trial, visit **https://www.bostonscientific.com/hi-peitho.**

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 45 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 follow us on **LinkedIn**.

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, product performance and impact, and clinical trials. 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: economic conditions, including the impact of foreign currency fluctuations; future U.S. and global political, competitive, reimbursement and regulatory conditions, including changing trade and tariff policies; geopolitical events, conflicts and tensions; manufacturing, distribution and supply chain disruptions and cost increases; disruptions caused by cybersecurity events; disruptions caused by public health emergencies or extreme weather or other climate change-related events; labor shortages and increases in labor costs; variations in outcomes of ongoing and future clinical trials and market studies; new product introductions; expected procedural volumes; the closing and integration of acquisitions; demographic trends; intellectual property; litigation; financial market conditions; the execution and effect of our business strategy, including our cost-savings and growth initiatives; 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, except as required by law. This cautionary statement is applicable to all forward-looking statements contained in this document.

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

[1] Wendelboe, A.M, et al. Global Burden of Thrombosis: Epidemiologic Aspects.*Circulation Research*.2016 Apr 29; 118(9): 1340-1347. doi: 10.1161/CIRCRESAHA.115.306841.

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