Microbot Medical® Announces FDA Submission for the Commercialization of the LIBERTY® Endovascular Robotic System

December 10, 2024

FDA 510(k) Submission Follows the Successful Completion of the Pivotal Human Clinical Trial

FDA 510(k) Clearance Anticipated During the Second Quarter of 2025

Company Preparing to Commence Commercialization Following FDA 510(k) Clearance

BRAINTREE, Mass., Dec. 10, 2024 (GLOBE NEWSWIRE) -- Microbot Medical Inc. (Nasdaq: MBOT), developer of the innovative single use LIBERTY® Endovascular Robotic System, today announced that it has submitted a 510(k) premarket notification to the U.S. Food and Drug Administration (FDA) for LIBERTY®. LIBERTY® is the world's first single-use, fully disposable robotic system for endovascular procedures. The 510(k) submission follows the successful completion of its multi-center, single-arm, trial to evaluate the performance and safety of LIBERTY® in human subjects undergoing Peripheral Vascular Interventions.

The Company anticipates FDA marketing clearance during the second quarter of 2025, with U.S. commercialization activities expected to commence after the clearance.

"This is a pivotal milestone for our Company, as the 510(k) submission reflects the commencement of our transition to a commercially focused company," commented Harel Gadot, Chairman, CEO and President. "We are excited to transition our focus towards preparing for our expected U.S. launch in the second quarter of 2025 and targeting the more than 2 million peripheral vascular procedures performed in the U.S. each year. We believe, based on feedback from physicians and the medical community, that LIBERTY® is positioned to redefine the peripheral endovascular space with the introduction of the world's first commercially available single-use robotic system."

As the world's first single-use, fully disposable endovascular robotic system, LIBERTY ® eliminates the need for large and expensive capital equipment and streamlines customers' access to robotics. With its remote control, LIBERTY ® is designed to significantly reduce radiation exposure to physicians and staff, and improve ergonomics, which has the potential to reduce the physical strain on healthcare providers. The Company also believes that LIBERTY® has the potential to lower procedure costs, increase procedure efficiency and improve the overall quality of care.

About Microbot Medical®
Microbot Medical Inc. (NASDAQ: MBOT) is a pre-commercial stage medical technology company with a vision to improve the quality of care for millions of patients and providers globally. The Company has developed the world's first single-use, fully disposable endovascular robotic system, which aims to eliminate traditional barriers to accessing advanced robotic systems.

Further information about Microbot Medical® is available at http://www.microbotmedical.com.

Safe Harbor

Statements to future financial and/or operating results, future growth in research, technology, clinical development, commercialization and potential opportunities for Microbot Medical Inc. and its subsidiaries, along with other statements about the future expectations, beliefs, goals, plans, or prospects expressed by management, constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and the Federal securities laws. Any statements that are not historical fact (including, but not limited to statements that contain words such as "will," "believes," "plans," "anticipates," "expects" and "estimates") should also be considered to be forward-looking statements. Forward-looking statements involve risks and uncertainties, including, without limitation, the Company's need for and ability to obtain additional working capital to continue its transition to a commercially focused company, market conditions, risks inherent in the development and/or commercialization of the LIBERTY® Endovascular Robotic Surgical System, uncertainty in the results of regulatory pathways and regulatory approvals, including whether the FDA will grant 510(k) clearance to commercially market the LIBERTY® Endovascular Robotic Surgical System in the United States, disruptions resulting from new and ongoing hostilities between Israel and the Palestinians and other neighboring countries, and maintenance of intellectual property rights. Additional information on risks facing Microbot Medical® can be found under the heading "Risk Factors" in Microbot Medical's periodic reports filed with the Securities and Exchange Commission (SEC), which are available on the SEC's web site at www.sec.gov. Microbot Medical® disclaims any intent or obligation to update these forward-looking statements, except as required by law.

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Source: Microbot Medical Inc.