



Microbot Medical Announces the Successful Completion of its Pivotal Human Clinical Trial; Accelerates Go-to-Market Strategy to Prepare for Commercial Launch of LIBERTY® during 2Q 2025

October 15, 2024

U.S. Food and Drug Administration (FDA) Submission Expected by end of 2024

Clinical Data to be Presented at Medical Conference in Early 2025

BRAINTREE, Mass., Oct. 15, 2024 (GLOBE NEWSWIRE) -- Microbot Medical Inc. (Nasdaq: MBOT), developer of the innovative LIBERTY® Endovascular Robotic Surgical System, today announced that it has successfully completed enrollment and follow up for all patients in its ACCESS-PVI human clinical trial. The Company remains on track to file its 510(k) submission with the U.S. Food and Drug Administration (FDA) by the end of 2024.

The Company also announced that it is accelerating its go-to-market strategy. It expects to begin building out the commercial infrastructure, including the hiring of a seasoned healthcare executive to lead its sales efforts, upon the FDA clearance, which is expected during 2Q 2025.

"We are very pleased with the performance of LIBERTY® throughout the study," commented Juan Diaz-Cartelle, MD, Chief Medical Officer. "We want to thank all our investigators for their enthusiastic commitment to the trial. We expect to share the results of the clinical trial with the medical community and the public at a conference in early 2025."

"This is a monumental moment and a significant achievement for Microbot Medical," commented Harel Gadot, Chairman, CEO and President. The conclusion of the trial and physician feedback is an encouraging development, and our immediate task is to prepare and finalize the FDA 510(k) submission package so we can file it by the end of the year. Concurrently, we will deploy our go-to-market strategy and begin to build out a commercial infrastructure to ensure we are fully prepared to launch LIBERTY® upon the FDA's clearance, which we expect during 2Q 2025.

ACCESS-PVI is a prospective, multi-center, single-arm, trial to evaluate the performance and safety of LIBERTY® in human subjects undergoing Peripheral Vascular Interventions. The trial will support the 510(k) submission to the FDA and subsequent commercialization. The Company wants to thank the patients, physicians and clinical sites for their participation in the trial.

About Microbot Medical

Microbot Medical Inc. (NASDAQ: MBOT) is a clinical-stage medical device company that specializes in transformational micro-robotic technologies, with the goals of improving clinical outcomes for patients and increasing accessibility through the natural and artificial lumens within the human body.

The Investigational LIBERTY® Endovascular Robotic Surgical System aims to improve the way surgical robotics are being used in endovascular procedures today, by eliminating the need for large, cumbersome, and expensive capital equipment, while reducing radiation exposure and physician strain. The Company believes the LIBERTY® Endovascular Robotic Surgical System's remote operation has the potential to be the first system to democratize endovascular interventional procedures.

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, 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, market conditions, risks inherent in the development and/or commercialization of the LIBERTY® Endovascular Robotic Surgical System, the outcome of its studies to evaluate the LIBERTY® Endovascular Robotic Surgical System, uncertainty in the results of pre-clinical and clinical trials or regulatory pathways and regulatory approvals, including whether the Company's pivotal study in humans is successful, 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, need and ability to obtain future capital, 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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