Microbot Medical Announces the Successful Enrollment of 50% of the Patients in its Pivotal Human Clinical Trial for the LIBERTY Endovascular Robotic Surgical System

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Completion of enrollment expected in Q4 with FDA submission for commercialization anticipated by the end of 2024

BRAINTREE, Mass., Sept. 17, 2024 (GLOBE NEWSWIRE) -- Microbot Medical Inc. (Nasdaq: MBOT), developer of the innovative LIBERTY® Endovascular Robotic Surgical System, today announced that it has successfully reached the midpoint of the ACCESS-PVI pivotal human clinical trial, enrolling and completing the follow up of 50% of the patients participating in the trial to evaluate the LIBERTY® Endovascular Robotic Surgical System. The Company expects to complete enrollment and follow up in the fourth quarter of 2024 and file its 510(k) submission with the U.S. Food and Drug Administration (FDA) by the end of 2024.

ACCESS-PVI is a prospective, multi-center, single-arm, clinical trial designed to evaluate the performance and safety of LIBERTY® in human subjects undergoing Peripheral Vascular Interventions. The trial is expected to support the future 510(k) submission to the FDA and, when approved, subsequent commercialization.

“I have performed several procedures using LIBERTY ® during the trial and I am continuing to enroll patients,” commented Dr. Dmitry Rabkin, MD, PhD (Assistant Chief, Division of Angiography & Interventional Radiology) at Brigham and Women's Hospital in Boston. “I am pleased with the ease of use and quick set-up of the robot, requiring, in my experience, a very short learning curve.”

“We are excited by both the achievement of this milestone, and physician feedback. We remain on track to complete the trial and subsequent submission of the 510(k) to the FDA before year end,” commented Juan Diaz-Cartelle, MD, Chief Medical Officer.

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, any failure or inability to recruit physicians and clinicians to serve as primary investigators to conduct regulatory studies which could adversely affect or delay such studies, disruptions resulting from new and ongoing hostilities between Israel and the Palestinians and other neighboring countries, any lingering uncertainty resulting from the COVID-19 pandemic, 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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