Microbot Medical Accelerates Patient Enrollment of its Pivotal Human Clinical Trial; Expects to Complete the Trial Earlier Than Anticipated as 80% of Patients Have Completed Follow up

September 30, 2024

Confirms the Company on Track for FDA 510(k) Submission by end of 2024

Completes All IDE required Tests and Receives Final IDE Approval from the FDA for the ACCESS-PVI Study

BRAINTREE, Mass., Sept. 30, 2024 (GLOBE NEWSWIRE) -- Microbot Medical Inc. (Nasdaq: MBOT), developer of the innovative LIBERTY® Endovascular Robotic Surgical System, today announced that it is currently experiencing an acceleration of patient enrollment for ACCESS-PVI human clinical trial for LIBERTY®. As a result of the increased rate of patient enrollment, 80% of the patients have completed the follow up period, and the Company now anticipates completing the trial ahead of its prior expectation. The Company remains on track to file its 510(k) submission with the U.S. Food and Drug Administration (FDA) by of the end of 2024.

"The trial is progressing well, and I am pleased with the level of enthusiasm at all three clinical sites which has resulted in the acceleration of patient enrollment. This gives us additional confidence that we can complete the trial and submit for FDA clearance by the end of 2024," commented Harel Gadot, Chairman, CEO and President.

"I applaud the entire team at Microbot Medical and the physicians participating in the study as we near the finish line. I believe their continued commitment will allow us to maintain the positive momentum over the next several weeks and allow us to achieve our near-term milestones, including the completion of the study," commented Juan Diaz-Cartelle, MD, Chief Medical Officer of Microbot Medical.

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 also announced that is has successfully completed all biocompatibility tests, as required by its Investigational Device Exemption (IDE) application and received full approval for the IDE study from the FDA. The Company had previously disclosed that it had received approval from the FDA to commence its clinical trial, and in parallel complete biocompatibility testing. In parallel with the clinical trial, the Company is performing additional customary bench testing, and these final results will be included in the Company's 510(k) submission.

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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