Microbot Medical Has Received FDA Approval to Proceed with its Pivotal Human Clinical Trial

June 3, 2024

The trial will be conducted in the U.S. and its results will complement the preclinical data on the LIBERTY® Endovascular Robotic Surgical System, which together are expected to support a future 510(k) submission

BRAINTREE, Mass., June 03, 2024 (GLOBE NEWSWIRE) -- Microbot Medical Inc. (Nasdaq: MBOT), developer of the innovative LIBERTY® Endovascular Robotic Surgical System, today announces that it has received the U.S. Food and Drug Administration's ("FDA") approval to proceed with its pivotal human clinical trial as part of its Investigational Device Exemption ("IDE") application for its LIBERTY ® Endovascular Robotic Surgical System.

The study will be conducted in the U.S., and the Company has already signed a clinical trial service agreement with a leading academic medical center. The Company is also in the process of engaging additional leading centers to participate in the trial.

In parallel to commencing the pivotal human clinical trial, the Company is completing its biocompatibility tests as required by its IDE application.

"The recent authorization by the FDA to commence our pivotal clinical study, following submission of the results of our extensive pre-clinical studies and tests, reinforces our confidence in our innovative technology," commented Harel Gadot, CEO, President and Chairman. "It is also a testament to our commitment to meet meaningful milestones as we continue our path towards potential regulatory clearance and subsequent commercialization in the US and other regions across the globe".

About Microbot Medical

Microbot Medical Inc. (NASDAQ: MBOT) is a pre-clinical 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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Source: Microbot Medical Inc.