Microbot Medical Submits an IDE Application to Gain FDA Approval to Commence Its Pivotal Clinical Trial in the US

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The Investigational Device Exemption (IDE) application follows the completion of multiple activities necessary to file this application

BRAINTREE, Mass., Feb. 05, 2024 (GLOBE NEWSWIRE) -- Microbot Medical Inc. (Nasdaq: MBOT), developer of the LIBERTY® Endovascular Robotic Surgical System, announced that it has filed an Investigational Device Exemption (IDE) application with the US Food and Drug Administration (FDA). The IDE application follows the completion of multiple preclinical activities performed to provide preliminary safety and effectiveness information, and its approval by the FDA would allow the company to commence its pivotal human clinical trial in the United States.

“This is an important milestone for the company, and it is another step forward in our journey to achieve FDA clearance for the LIBERTY ® Endovascular Robotic Surgical System,” said Harel Gadot, CEO, President and Chairman of Microbot Medical.

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 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 potential products, including LIBERTY, the outcome of its studies to evaluate LIBERTY, whether the Company’s core business focus program and cost reduction plan are sufficient to enable the Company to continue to focus on its LIBERTY technology while it stabilizes its financial condition and seeks additional working capital, 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, uncertainty in the results of pre-clinical and clinical trials or regulatory pathways and regulatory approvals, disruptions resulting from new and ongoing hostilities between Israel and the Palestinians, 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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