Microbot Medical Received Confirmation for the Commencement of Its CE Mark Approval Process During the First Half of 2024

October 24, 2023

The Company's designated Notified Body confirmed dates for conducting audits for ISO 13485 certification to ensure Microbot complies with the QMS requirements of the EU MDR

The Company expects that the full CE Mark approval process of obtaining clearance of sales in the European Union for the LIBERTY® Robotic Surgical System, will be carried out in parallel with the FDA regulatory process

BRAINTREE, Mass., Oct. 24, 2023 (GLOBE NEWSWIRE) -- Microbot Medical Inc. (Nasdaq: MBOT), developer of the innovative LIBERTY® Robotic Surgical System, today announces it has received confirmation for the commencement of the process to support its future CE Mark approval, and to ultimately allow the Company to market the LIBERTY® Robotic Surgical System in Europe as well as other regions who accept the CE Mark.

According to the confirmation, the Company will commence audits for ISO 13485 certification to ensure its compliance with the Quality Management System (QMS) requirements of the EU Medical Devices Regulation (MDR 2017/745), during the first half of 2024. The Company had previously taken the first step to advance its European program by engaging with a leading Notified Body, who recently confirmed dates for conducting the required audits.

The audits for Microbot's ISO 13485 certification will incorporate an off-site audit that includes a review of the Company's quality system and the LIBERTY® Robotic Surgical System Technical File, followed by an on-site audit at the Company's facilities.

"We are confident that we have taken the right measures to successfully complete these audits, which will serve as the first step in our commercial approval process for Europe as well as other regions across the globe which allow commercialization under the CE Mark," said Noa Ofer, Sr. Director QA/RA. "We intend that this process will be conducted in parallel with our FDA approval efforts, to allow us to capture as many markets across the globe as we prepare for future commercialization."

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® 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® 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, such as employees of Microbot and its vendors and business partners being called to active military duty, 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.

Investor Contact:

Michal Efraty
+972-(0)52-3044404
IR@microbotmedical.com

Source: Microbot Medical Inc.