



Microbot Medical Announces Successful Outcome of its Discussions with FDA Regarding Regulation of Self-Cleaning Shunt

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FDA Feedback Reflects Strength of Pre-Clinical Safety Data; Maintains Q3 2022 Projected Commencement of First-in-Human Clinical Trial

HINGHAM, Mass., Jan. 27, 2021 (GLOBE NEWSWIRE) -- Microbot Medical Inc. (Nasdaq: MBOT) announced the completion of successful discussions with the U.S. Food and Drug Administration (FDA) for its Self-Cleaning Shunt (SCS). After review of the Company's existing pre-clinical data, the FDA's feedback will allow the Company to apply for a limited clinical investigation known as an Early Feasibility Study (EFS), which is designed for novel technologies such as the SCS. Consequently, the Company reiterates its timeline for the First-in-Human (FIH) clinical trial under the EFS, expected to commence in the third quarter of 2022.

"The FDA's response is a significant milestone for our SCS product, as it affirms the novelty of the technology and our pathway as we advance to the next developmental, clinical and regulatory phase," commented Harel Gadot, Chief Executive Officer, President, and Chairman. "Throughout the pre-submission process with the FDA, we have sufficiently provided information which we believe exhibits the strength of our data and provides us with high level of confidence in the continued progression towards the successful commercialization of our novel SCS."

As anticipated, the FDA review focused on product-specific, regulatory and scientific topics related to the SCS, and included in the pre-submission were pre-clinical study data conducted by leading U.S. academic institutions. The Company expects to continue to work with the FDA towards finalizing the SCS device design, and to incorporate their feedback prior to submitting the Investigational Device Exemption (IDE) to seek authorization to begin the EFS clinical trial. While there can be no assurance that the FDA will approve the EFS study, the agency's recent feedback indicates that the agency will be receptive to allowing this FIH study to proceed based on existing data. After completing the EFS, the Company would then seek FDA input on the device design as finalized through the EFS process in a subsequent IDE filing for approval of a clinical study proposal.

The Company's innovative SCS is designed to be a transformative device which prevents obstruction in the cerebrospinal fluid (CSF) catheters implanted in the ventricle of the brain of patients who suffer from hydrocephalus or Normal Pressure Hydrocephalus (NPH).

About Microbot Medical

Microbot Medical Inc. (NASDAQ: MBOT) is a pre-clinical medical device company that specializes in transformational micro-robotic technologies, focused primarily on both natural and artificial lumens within the human body. Microbot's current proprietary technological platforms provide the foundation for the development of a Multi Generation Pipeline Portfolio (MGPP).

Microbot Medical was founded in 2010 by Harel Gadot, Prof. Moshe Shoham, and Yossi Bornstein with the goals of improving clinical outcomes for patients and increasing accessibility through the use of micro-robotic technologies. Further information about Microbot Medical is available at <http://www.microbotmedical.com>.

Safe Harbor

Statements pertaining to the registered direct offering, timing, the amount and anticipated use of proceeds and statements pertaining 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 and the satisfaction of customary closing conditions, risks inherent in the development and/or commercialization of potential products, including LIBERTY™ and SCS, the outcome of its studies to evaluate LIBERTY, SCS and other existing and future technologies, uncertainty in the results of pre-clinical and clinical trials or regulatory pathways and regulatory approvals, 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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