Check-Cap Announces FDA Approval of Amended IDE Application for Pivotal Study of C-Scan

Company anticipates initiation of first part of pivotal study in the March-April 2022 timeframe

ISFIYA, Israel, Feb. 7, 2022 /PRNewswire/ -- Check-Cap Ltd. (the "Company" or "Check-Cap") (NASDAQ: CHEK), (NASDAQ: CHEKZ), a clinical stage medical diagnostics company advancing the development of C-Scan®, the firs and only patient-friendly preparation-free screening test to detect polyps before they may transform into colorectal cancer (CRC), today announced that the Company has received approval from the U.S. Food and Drug Administration (FDA) for its amended Investigational Device Exemption (IDE) application, enabling initiation of the U.S. pivotal study.

Alex Ovadia, chief executive officer of Check-Cap, commented, "Now that we have received approval from the FD of our amended protocol, we are focused on final preparations to initiate the first part of the U.S. pivotal study, which we anticipate will begin in March-April 2022, followed by initiation of the second part of the study in Q4 2022. Initiation of the study signifies a major step in the clinical development of our device, which is designed to detect precancerous polyps."

The U.S. pivotal study consists of two parts. The first part is designed to enable further calibration of the system f the average risk U.S. population. The second part will include a statistically powered, randomized study which wil compare the performance of C-Scan to traditional colonoscopy.

About Check-Cap

Check-Cap is a clinical stage medical diagnostics company aiming to redefine colorectal cancer (CRC) screening through the introduction of C-Scan®, the first and only patient-friendly preparation-free screening test to detect polyps before they may transform into colorectal cancer and enable early intervention and cancer prevention. Th Company's disruptive capsule-based screening technology aims to help millions of people to stay healthy through preventive CRC screening. C-Scan uses an ultra-low dose X-ray capsule, an integrated positioning, control and recording system, as well as proprietary software to generate a 3D map of the inner lining of the colon as it trave naturally along the gastrointestinal tract. C-Scan is non-invasive and requires no sedation. It requires no bowel preparation, allowing the patients to continue their daily routine with no interruption. C-Scan is not intended to replace colonoscopy. A positive C-Scan result should be followed by colonoscopy. C-Scan is an investigational device and is not available for sale in the United States.

Legal Notice Regarding Forward-Looking Statements

This press release contains "forward-looking statements" about the Company's expectations, beliefs or intentions regarding, among other things, its product development efforts, business, financial condition, results of operations, strategies or prospects. Words such as "may," "should," "could," "would," "predicts," "potential," "continue," "expects," "anticipates," "future," "intends," "plans," "believes," "estimates," and similar expressions, as well as statements in future tense, often signify forward-looking statements. Forward-looking statements should not be read as a guarantee of future performance or results and may not be accurate indications of when such performance or results will be achieved. Forward-looking statements are based on information that the Company has when those statements are made or management's good faith belief as of that time with respect to future events, and are subject to risks and uncertainties that could cause actual performance or results to differ materially from those expressed in or suggested by the forward-looking statements. For a discussion of these and other risks that could cause such differences and that may affect the realization of forward-looking statements, please refer to the "Forward-looking Statements" and "Risk Factors" in the Company's Annual Report on Form 20- for the year ended December 31, 2020 and other filings with the Securities and Exchange Commission (SEC). Investors and security holders are urged to read these documents free of charge on the SEC's web site at http://www.sec.gov. The Company assumes no obligation to publicly update or revise its forward-looking statements as a result of new information, future events or otherwise.

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