Check-Cap Issues an Update to Shareholders

ISFIYA, Israel, March 21, 2023 /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 first and only patient-friendly bowel prep-free screening test to detect polyps before they may transform into colorectal cancer (CRC), today issued the following letter from its chief executive officer, Alex Ovadia, to its shareholders and the investment community:

Dear Check-Cap Shareholders,

We greatly appreciated your support throughout 2022, a year during which we continued to conduct the C-Scan clinical programs in the U.S. and Israel, while strengthening our manufacturing capabilities and production line. In this communication we wanted to share updates about our C-Scan program.

In May 2022, we initiated the first part of the U.S. pivotal study of C-Scan, which focuses on device calibration and enhancement of C-Scan algorithms among the average risk U.S. population.

In parallel, to support the calibration portion of the U.S. pivotal study, we continued enrolling average risk patients in our study in Israel. To date, the Company has enrolled more than 300 average risk patients as part of its Israeli study and only 17 average risk patients in the first part of its U.S. pivotal study, mainly as a result of slower than expected U.S. site recruitment pace, due to licensing requirements with local states associated with the X-ray technology within our C-Scan capsule.

While prior C-Scan trial performance was based on an enriched population (i.e., subjects with known polyps), the current calibration studies' target is to optimize the C-Scan device for the average risk population prior to commencing the powered portion of the U.S. pivotal study, which aims to demonstrate C-Scan performance in a statistically significant manner. The initiation of the powered potion of the U.S. pivotal study was dependent upon successful completion of the calibration portion of the U.S. pivotal study.

Following our internal assessment of the clinical data collected to date from our calibration studies, the Company has determined that the current efficacy results do not meet our goal in order to proceed to the powered portion the U.S. pivotal study.

As a result, the Company adopted a plan of action that includes conducting additional clinical data analysis and approaching the FDA to make amendments to the U.S. pivotal study protocol that are expected to be part of an IDE supplement submission to the FDA, and which are subject to FDA approval. In addition, the Company plans to continue conducting its calibration studies, albeit at a slower pace, to collect additional clinical data and the Company is also implementing a cost reduction plan, in order to extend its cash runway.

The initiation of the powered portion of the U.S. pivotal study that was expected in mid-2023 is therefore temporarily postponed.

We would like to thank our team and their enormous effort to advance C-Scan, and you, our shareholders, for your ongoing engagement during our important journey. We appreciate your ongoing support, particularly through this period, and plan to provide further updates throughout 2023.

Sincerely,

Alex Ovadia
Chief Executive Officer
Check-Cap

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. The Company's disruptive capsule-based screening technology aims to significantly increase screening adherence worldwide and 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 travels naturally along the gastrointestinal tract. C-Scan is non-invasive and requires no sedation. Unlike other capsule technologies, 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.

Legal Notice Regarding Forward-Looking Statements
This press release contains "forward-looking statements." 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-F for the year ended December 31, 2021 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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