Check-Cap Announces Institutional Review Board Approval to Initiate U.S. Pilot Study of C-Scan®

ISFIYA, Israel, Feb. 12, 2019 /PRNewswire/ -- Check-Cap Ltd. (the "Company" or "Check-Cap") (NASDAQ: CHEK) (NASDAQ: CHEKW), (NASDAQ: CHEKZ), a clinical-stage medical diagnostics company advancing the development of C-Scan®, the first and only preparation-free capsule based screening method for the prevention of colorectal cancer through the detection of precancerous polyps, today announced it has received Institutional Review Board (IRB) approval from New York University School of Medicine to initiate a U.S. pilot study of the C-Scan® system.

"We are excited to receive IRB approval as this important milestone enables Check-Cap to bring the C-Scan® system into the clinic in the U.S.," said Alex Ovadia, chief executive officer of Check-Cap. "Following the CE Mark clearance and approval to initiate commercial sales of the C-Scan® system in Israel last year, IRB approval is a critical step towards developing clear paths to commercialization in major markets worldwide. We look forward to the initiation of the pilot study evaluating our patient-friendly screening method for colorectal cancer as we aim to increase screening adherence and ultimately decrease the overall incidence for this highly-preventable disease."

The U.S. pilot study (NCT03735407) will be a single-arm study enrolling up to 45 subjects considered to be of average risk for polyps and colon cancer. The study will evaluate the safety, usability, and subject compliance of the C-Scan® system. The study will be conducted at New York University School of Medicine.

About Colorectal Cancer

It is estimated that in 2018, there were approximately 881,000 deaths and more than 1.8 million new cases of colorectal cancer (CRC) worldwide. CRC typically begins as precancerous polyps or abnormal growths in the colon or rectum, which can be present for up to 10 years before developing into invasive cancer. As a result, screening for precancerous polyps is the most direct method for CRC prevention. Despite evidence that standard screening can prevent CRC, adherence remains low due to the required bowel preparation, invasiveness, and in some communities, limited access.

About Check-Cap

Check-Cap is advancing the development of C-Scan®, the first and only preparation-free ingestible scanning capsule for the prevention of colorectal cancer (CRC) through the detection of precancerous polyps. The patient-friendly test has the potential to increase screening adherence and reduce the overall incidence of CRC. The C-Scan® system utilizes 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. C-Scan® is non-invasive and requires no preparation or sedation, allowing the patient to continue their daily routine with no interruption as the capsule is propelled through the gastrointestinal tract by natural motility.

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. Factors that could cause our actual results to differ materially from those expressed or implied in such forward-looking statements include, but are not limited to our history of losses and our ability to continue as a going concern; our needs for additional capital to fund our operations and our inability to obtain additional capital on acceptable terms, or at all; the initiation, timing, progress and results of our clinical trials and other product development efforts; our reliance on one product or product line; the clinical development, commercialization and market acceptance of our C-scan system; our ability to receive de novo classification and other regulatory approvals for our C-Scan system; our ability to successfully complete clinical trials; our reliance on single-source suppliers; our reliance on third parties; our ability to establish and maintain strategic partnerships and other corporate collaborations; our ability to achieve reimbursement and coverage from government and private third-party payors; the implementation of our business model and strategic plans for our business; the scope of protection we are able to establish and maintain for intellectual property rights covering our C-Scan system and our ability to operate our business without infringing the intellectual property rights of others; competitive companies, technologies and our industry; statements as to the impact of the political and security situation in Israel on our

business. 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, 2017 and other filings with the Securities and Exchange Commission (SEC). Investors and security holders are urged to read these documents fre 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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