Check-Cap Announces FDA Conditional Approval of IDE to Initiate U.S. Pilot Study of C-Scan®

Study to begin upon review and approval of Institutional Review Board (IRB)

ISFIYA, Israel, Dec. 13, 2018 /PRNewswire/ --

Check-Cap Ltd. (the "Company" or "Check-Cap") (NASDAQ: CHEK) (NASDAQ: CHEKW), (NASDAQ: CHEKZ), a clinical-stage medical diagnostics company offering 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 that the U.S. Food and Drug Administration (FDA) has conditionally approved the Company's Investigational Device Exemption (IDE) application to initiate a U.S. pilot study of the C-Scan® system. The FDA's conditional approval of the IDE requires Check-Cap to provide additional information to the FDA and Check-Cap may begin enrolling patients immediately upon approval by the study site's Institutional Review Board (IRB).

Alex Ovadia, chief executive officer of Check-Cap, stated: "We are pleased to have received FDA approval of our IDE application, and we look forward to initiating our pilot study of the C-Scan® system. This is a significant milestone for our company as we work to advance the clinical development of our novel technology in the U.S. As the first and only preparation-free capsule based screening method for colorectal cancer prevention through precancerous polyp detection, we believe C-Scan® can significantly increase screening adherence, resulting in improved patient outcomes and significant savings to the healthcare system. We look forward to results from this first U.S. study."

The U.S. pilot study (NCT03735407) will be a single-arm study enrolling 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.

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 color 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 a clinical-stage medical diagnostics company developing C-Scan®, the first and only preparation-fre capsule-based screening method 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 dai 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. For a discussion of these and other risks that could cause such differences and that may affect the realization of forwar looking statements, please refer to the "Special Note On 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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