Check-Cap Initiates U.S. Pilot Study of C-Scan® for Colorectal Cancer Screening

ISFIYA, Israel, April 8, 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 ingestible capsule for the prevention of colorectal cancer through the detection of precancerous polyps, today announced the initiation of its U.S. pilot study of the C-Scan® system, following Institutional Review Board (IRB) approval and full Investigational Device Exemption (IDE) application approval by the U.S. Food and Drug Administration (FDA). The first patients have ingested the C-Scan® capsule at the New York University School of Medicine.

"The pilot study initiation is a critical milestone on our path for developing and potentially commercializing the C-Scan® system in the U.S.," said Alex Ovadia, chief executive officer of Check-Cap. "We have also provided the FDA with the additional required information that allowed us to be granted with the full approval of the IDE. We look forward to sharing the results of the study in the near future as we truly believe that our patient-friendly scanning capsule can redefine the colorectal cancer screening landscape and decrease the overall incidence of this highly-preventable disease."

"We are pleased to participate in this pilot study of C-Scan®, a preparation-free capsule-based system for the prevention of colorectal cancer being tested in the U.S.," noted Seth A. Gross MD, gastroenterologist and Associate Professor of Medicine, NYU Langone Health. "Unfortunately, colorectal cancer remains the second-leading cause of cancer death in the U.S. But we know that with the utilization of colorectal cancer screening, we can reduce the incidence and mortality rates related to this disease. The potential addition of a new screening option that is capsule-based and does not require a bowel prep offers the promise of increasing our screening rates. We are looking to the results of this study and the potential for an effective new screening option for the prevention and early detection of colorectal cancer."

The single-arm pilot study (NCT03735407) will enroll up to 45 subjects considered to be of average risk for polyps and colon cancer. The study is evaluating 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 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 standa screening can prevent CRC, adherence remains low due to the required bowel preparation, invasiveness, and i 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 recordin 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. 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 "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, 2018 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.

Investor Contacts
Jeremy Feffer
LifeSci Advisors, LLC
+1-212-915-2568
jeremy@lifesciadvisors.com

Meirav Gomeh-Bauer (Israel)
LifeSci Advisors, LLC
+972(0)-54-476-4979
Meirav@lifesciadvisors.com

Media Contacts
Alison Chen
LifeSci Public Relations
+1-646-876-4932
achen@lifescipublicrelations.com

Meirav Gomeh-Bauer (Israel)
LifeSci Advisors, LLC
+972(0)-54-476-4979
Meirav@lifesciadvisors.com

SOURCE Check-Cap Ltd.
