Check-Cap Announces Initiation of the U.S. Pivotal Trial

ISFIYA, Israel, May 11, 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 the initiation of its U.S. pivotal trial of C-Scan® at Mayo Clinic in Rochester Minnesota.

The Company has successfully obtained Institutional review board (IRB) approval for the study and expects to promptly begin patient enrollment. Elizabeth Rajan, M.D., gastroenterologist, and professor of medicine at Mayo Clinic, will be the principal investigator of the study at this site.

"We are excited to announce the accomplishment of this important milestone in our path to demonstrate the potential of C-Scan to detect colorectal polyps before they may turn into cancer in the average-risk population," said Alex Ovadia, chief executive officer of Check-Cap. "We are pleased to have engaged with expert gastroenterologists at Mayo Clinic and continue to advance the participation of additional experienced clinical tria centers in this study. We have established a supply and distribution infrastructure and process of the C-Scan and our plan is to complete the calibration portion of the trial and begin the second statistically powered portion of th study during Q4 2022."

Mr. Ovadia continued, "Detecting precancerous polyps is needed to effectively prevent colorectal cancer. However, the acceptance of the colonoscopy procedure is low, in part due to the invasiveness of the procedure and bowel cleansing. We believe Check-Cap has the potential to reach those who are deterred by colonoscopy ar to help improve colon cancer screening through a patient-friendly solution without the need of bowel cleaning, sedation, and fasting."

About the Pivotal Trial:
The U.S. pivotal study (NCT05271656) is designed to obtain FDA clearance for C-Scan® in the U.S. The study is a two-part open label trial to evaluate the accuracy of C-Scan to identify subjects who are at elevated risk for colon polyps. It is expected to enroll approximately 1,000 subjects ages 50-75 and will be conducted at up to 15 clinica sites in the U.S. The first part of the trial is designed to enable further calibration of C-Scan for the average risk U.S. population and will enroll up to 200 subjects. The second part consists of a statistically powered, randomizec study which will compare the performance of C-Scan to traditional colonoscopy, using sensitivity and specificity measures and will enroll approximately 800 subjects. Additional information about the trial (NCT05271656) can b found here.

About Colorectal Cancer
Colorectal cancer is the third most commonly diagnosed cancer, with more than 1.9 million new cases identified every year globally. Over 935,000 deaths occur annually worldwide as a result of CRC, with a 64% survival rate a 5 years. While 0.5% of the average-risk screening population presents cancerous polyps in the colon and rectum, approximately 25% of the same population presents benign polyps with the potential to turn into cancer over time. It can take as many as 10 to 15 years before a pre-cancerous polyp develops into invasive cancer. As such, there is a crucial detection window for the prevention of colorectal cancer, through the detection of these benign polyps with potential future malignancy.

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, 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.

Investor Contacts
Irina Koffler
LifeSci Advisors, LLC
646.970.4681
ikoffler@lifesciadvisors.com

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

Media Contact
Mónica Rouco Molina, Ph.D.
Account Supervisor - Europe
LifeSci Communications
mroucomolina@lifescicomms.com

SOURCE Check-Cap Ltd.

Additional assets available online: Photos (1)