



Check-Cap Announces Publication of Peer-Reviewed Article Highlighting Safety and Patient Satisfaction Data for its Colorectal Screening Test, C-Scan®

Patients who underwent the procedure, as part of the 2019 U.S. pilot study, were significantly more likely to recommend C-Scan test compared to colonoscopy

ISFIYA, Israel, Nov. 22, 2021 /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, preparation-free screening test to detect polyps before they may transform into colorectal cancer (CRC), today announced the publication of research titled "[Colorectal cancer and polyp detection using a new preparation-free colon-scan capsule: A pilot study of safety and patient satisfaction](#)" in the peer-reviewed journal *Digestive Diseases and Sciences*, which further validates C-Scan's safety and patient satisfaction based on data from its 2019 previously completed U.S. pilot study.

In this study there were no serious adverse events or occurrences of capsule retention out of the 40 patients who underwent the study procedure. Of the 87% of patients who completed the satisfaction questionnaires, patients were significantly more likely to recommend the C-Scan capsule, with an average score of 4.1 out of 5 versus a 2.0 out of 5 score for colonoscopy ($p=0.001$).

"Screening for the detection of precancerous colorectal polyps is a key approach for cancer prevention. Yet, a known barrier for some patients is the required bowel cleansing for colonoscopy and invasiveness of the procedure. Less invasive alternatives are needed to engage a percentage of the population that avoids regular screening," said Seth A. Gross, M.D., principal investigator of the study, gastroenterologist and associate professor of medicine at NYU Langone Health.

Elizabeth Rajan, M.D., principal investigator of the study, gastroenterologist and professor of medicine, Mayo Clinic Rochester stated, "Our prospective single-arm pilot study demonstrated positive safety results and high patient satisfaction with a new and unique preparation-free colon capsule system intended for detection of colorectal polyps and masses. This study represents a step forward to a prepless approach for CRC screening that may overcome one of the most important deterrents to screening. A multicenter pivotal study is planned in the U.S. to further validate the performance of this technology."

Alex Ovadia, chief executive officer of Check-Cap, commented, "We continue to make progress in preparation for initiation of our upcoming U.S. pivotal study, to further validate the performance, safety, and accuracy of polyp detection using C-Scan. We look forward to making this disruptive screening modality available to the many patients in need of patient-friendly screening tests."

Check-Cap's U.S. pilot study was a prospective open label, single arm study that examined C-Scan's safety, usability and subject compliance and evaluated patient satisfaction compared to colonoscopy. The study was conducted at two U.S. sites, the NYU Grossman School of Medicine and Mayo Clinic, Rochester in 2019. 80% of patients were of average risk for colorectal cancer and the mean age was 52.9. Each patient ingested a C-Scan capsule and underwent a comparative colonoscopy, which was performed by an independent gastroenterologist who was blinded to the corresponding test results.

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.

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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, 2020 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

Media Contact

Mónica Rouco Molina
Senior Account Executive
LifeSci Communications
mroucomolina@lifescicomms.com

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