Check-Cap Announces Positive Final Results from Its Post-CE Approval Study of the C-Scan® System

ISFIYA, Israel, July 9, 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 positive final results from its recently completed post-CE approval study evaluating the clinical performance and safety of the C-Scan system.

The multi-center, open label, home monitoring, prospective study was designed to determine the performance characteristics of Check-Cap's capsule-based screening test, the C-Scan system, for detecting pre-cancerous polyps compared with the fecal immunochemical test (FIT), a commonly used non-invasive colorectal cancer screening test; in each case using colonoscopy as the reference method. The study included 90 evaluable patient who either had known polyps or were considered to be of average risk. Each patient ingested a C-Scan capsule ar also underwent a FIT and a comparative colonoscopy performed by independent gastroenterologists, who were blinded to the corresponding test's results. The C-Scan clinical evaluation was obtained using the evaluable patie population implementing a gender-based motility analysis and the results of both C-Scan and FIT were compared to colonoscopy.

The primary efficacy endpoint of the study was sensitivity (ability to correctly identify patients with polyps) and specificity (ability to correctly identify patients with lack of polyps) of the C-Scan system compared to FIT in detecting subjects with polyps ≥10 mm. The results demonstrate that C-Scan achieved a sensitivity of 76% (p=0.0005) in patients with polyps ≥10 mm, while FIT achieved a sensitivity of 29% (p=0.005) in patients with polyps ≥10 mm. C-Scan achieved a specificity of 82% in all patients, while FIT achieved a specificity of 96% in all patients.

In addition, C-Scan detected all 4 patients (100%) with polyps ≥40 mm, while the FIT detected only 1 of the 4 patients (25%) with polyps ≥40mm. Overall, C-Scan achieved a sensitivity of 66% (p=0.01) in all patients, including patients with polyps <10mm, while FIT achieved a sensitivity of 23% (p<0.0001) in all patients, includin patients with polyps <10mm. In total, 142 patients enrolled in the study and after factoring in technical and physiological dropouts and protocol violations, the number of evaluable patients was 90. No serious adverse events were reported, and the adverse events were mild in severity.

Alex Ovadia, chief executive officer of Check-Cap, commented, "We are delighted to share the results from the post-CE approval study which continue to validate the importance and potential of the C-Scan system. Completin this study on a larger sample is an essential milestone in the development and commercialization process of the C Scan system in the U.S. and worldwide, as it provides us with additional insight for a U.S. pivotal study, which we plan to be initiate during 2020."

Nadir Arber, M.D., MSc, MHA, Professor of Internal Medicine and Gastroenterology, and Head of the Health Promotion Center and Integrated Cancer Prevention Center at the Tel-Aviv Sourasky Medical Center, and principa investigator of the study, stated, "The final results from the post-CE approval study confirm the potential clinical value of the C-Scan system. The results also demonstrate an advancement in the detection of larger polyps, generally considered to have higher potential for malignant transformation. There is a great unmet need for a patient-friendly and preparation-free screening option that can detect polyps in the colon before they become cancerous. Although colorectal cancer can be prevented through the detection of precancerous polyps, screening adherence remains low due to the bowel preparation, sedation and invasiveness associated with current screenin methods. I am encouraged by C-Scan's potential to reduce global incidence of colorectal cancer and I look forwar to seeing this 'swallow and forget' product available in clinics worldwide."

Check-Cap is currently conducting a pilot study in the U.S. (NCT03735407) to evaluate the safety, usability and subject compliance of the C-Scan system at the New York University School of Medicine and Mayo Clinic. In addition, Check-Cap intends to continue collecting clinical data in additional studies in preparation for its planned pivotal study. Assuming positive pilot study results, the Company plans to initiate a pivotal study in people of average risk for polyps and colorectal cancer in mid-2020. The C-Scan system has received CE marking and approval from the Israeli Ministry of Health, the Medical Device Division (AMAR) for marketing in Israel.

About Colorectal Cancer
Every year, nearly 881,000 deaths occur as a result of colorectal cancer (CRC) and more than 1.8 million new cases are identified. 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 car 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 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 ar 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 preparatior 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 forwar looking statements, please refer to " 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.

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