Check-Cap Announces Positive Results from U.S. Pilot Study of C-Scan® System

Advancing towards IDE submission to the FDA, targeting initiation of U.S. pivotal study in late 2020

ISFIYA, Israel, Dec. 30, 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 the C-Scan® System, the first and only preparation-free ingestible scanning capsule based system for the prevention of colorectal cancer through the detection of precancerous polyps, today announced positive results from the Company's pilot study of the C-Scan® System in the U.S.

The prospective, multi-center, open label, single arm study was designed to evaluate the safety, usability and subject compliance of the C-Scan System. The study included 28 evaluable patients, more than two thirds of who were considered to be of average risk for colorectal cancer. Each patient ingested a C-Scan capsule and also underwent a fecal immunochemical test (FIT) as well as a comparative colonoscopy, which was performed by an independent gastroenterologist who was blinded to the corresponding test results.

The study was performed at two sites, the NYU Grossman School of Medicine and Mayo Clinic, Rochester. The primary endpoint of the study was to evaluate the incidence of device or procedure related serious adverse event Secondary endpoints included patient compliance, subject satisfaction and device and procedure related performance. Due to sample size, the study was not designed to be powered for statistical significance.

No device or procedure related serious adverse events (SAEs) were reported and all device or procedure related adverse events were mild in severity. In total, 45 patients enrolled in the study, of which 40 patients underwent t study procedure. All 40 patients complied with the procedure and completed a questionnaire following the procedure and reported higher satisfaction with the C-Scan System procedure compared to colonoscopy. A total o 28 patients were evaluable after factoring in technical and physiological dropouts and protocol violations. Analysi of the evaluable patient results revealed agreement between C-Scan and colonoscopy in detection of polyps was consistent with data from the post-CE approval study.

"The results of the study are promising, both in terms of safety and patient compliance of the procedure," said Se A. Gross, M.D., principal investigator of the study, gastroenterologist and associate professor of medicine at NYU Langone Health. "Most non-invasive colorectal cancer screening options currently available have modest efficacy detecting pre-cancerous polyps. We are excited about the potential of the C-Scan System offering a patient-friendly screening option that could detect pre-cancerous polyps before they become malignant, and we look forward to seeing the C-Scan System advancing into the U.S. pivotal study in the future."

Elizabeth Rajan, M.D., principal investigator of the study, gastroenterologist and professor of medicine, Mayo Clini Rochester stated, "The availability of preparation-free options for colorectal cancer screening are appealing to patients and may indeed increase screening rates. Initial results from the pilot study are promising with a US pivotal study planned for 2020".

Alex Ovadia, chief executive officer of Check-Cap, commented, "We are pleased with the positive results from this U.S. pilot study. Completing our first study in the U.S. constitutes an important milestone for our company as we work towards the initiation of a U.S. pivotal study in late 2020. We are now focused on preparing our IDE submission to the FDA and collecting additional clinical data utilizing a new version of our C-Scan System, while a the same time continuing to build out our global operational infrastructure. We believe 2020 will be a meaningful year for Check-Cap."

About Check-Cap

Check-Cap is advancing the development of the C-Scan® System, the first and only preparation-free ingestible scanning capsule-based system 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 patients to continue their daily routine with no interruption as the capsule is propelled through the gastrointestinal tract by natural motility.

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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,"

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