Check-Cap Announces Filing of CE Mark Registration for C-Scan®

Management Hosts Conference call at 9:00 a.m. EDT

ISFIYA, Israel and BOSTON, Sept. 27, 2017 /PRNewswire/ --Check-Cap Ltd. (the "Company" or "Check-Cap") (NASDAQ: CHEK) (NASDAQ: CHEKW), a clinical-stage medical diagnostics company engaged in the development c C-Scan®, an ingestible capsule for preparation-free, colorectal cancer screening, today announced that it has filed for the CE Mark registration of C-Scan. Data from the multi-center clinical investigation to support the submission showed safety and encouraging results for detecting patients with polyps in an un-prepped colon.

The objective of the study was to assess safety and the clinical performance of C-Scan in detecting patients with polyps. The three-center trial enrolled 66 patients, with a mean age of 59 years. Following capsule ingestion, subjects swallowed small doses of contrast agent and fiber supplements with each meal throughout capsule passage. Average capsule transit time was 52±32 hours, and the average total X-ray dose was 0.05 mSv (CT colonography effective dose is ~ 6.0 mSv). No bowel preparation, sedation, or change in diet was required. Both confirmatory colonoscopy, performed by an independent investigator, and C-Scan review, performed by a central review group, were blinded to results.

The study demonstrated a 44% sensitivity in the 45 subjects included in the analysis for polyps, with specificity of 89%. Sensitivity strongly correlated (R-squared = 0.98) to the percentage of the colon scanned. Sensitivity was 78% ($p<0.05$) and 100% ($p<0.05$) for subjects where greater than 50% and 70% of the colon was scanned, respectively. Specificity was consistent for all subjects.

Professor Nadir Arber, Principal Investigator and Prof. of Internal Medicine and Gastroenterology and Head of the Health Promotion Center and Integrated Cancer Prevention Center at the Tel-Aviv Sourasky Medical Center, state "These clinical results demonstrate C-Scan's positive safety profile and strong correlation between detection of patients with polyps and capsule scan coverage. Top line accuracy results are rather encouraging as well, as the sensitivity for advanced adenomas by stool testing, the primary colorectal cancer screening test in EU, demonstrates sensitivity ranges of 22% to 40%." Prof. Arber continued, "Despite evidence suggesting that polyp detection and removal can decrease CRC incidence and mortality, screening adherence remains disappointingly low. Many patients are unwilling to choose standard tests due to unpleasant bowel preparation requirements or stool collection. The promise of C-Scan is to provide a more patient-friendly option which could potentially increase screening rates. We look forward to additional research evaluating C-Scan for colonic polyp detection."

Colorectal cancer is the second leading cause of cancer death in the U.S., with an estimated 135,000 diagnoses and 50,000 deaths in 2017. Despite compelling evidence that screening can detect colorectal cancer and precancerous polyps, nearly one-third of the recommended adult population has never been screened. The C-Scan® system is designed to improve the patient experience with screening by eliminating many unattractive requirements, such as bowel preparation, fasting, and sedation.

Bill Densel, CEO of Check-Cap, commented: "Submission of the CE Mark application marks an important milestone for Check-Cap, and we are pleased with the achievements made in the clinical performance of C-Scan, as demonstrated in the multi-center, comparative trial. Our system was shown to be safe and capable of identifying polyps for removal in patients with no bowel preparation. We are underway with the clinical evaluation of our advanced C-Scan version, incorporating improvements to software algorithms." Mr. Densel concluded, "We are committed to developing an alternative to today's invasive and preparation-intensive approaches to colorectal cancer prevention. We look forward to EU post market initiation and US pilot trial, expected to begin in the first ha of 2018."

Conference Call and Webcast Information

Check-cap will host a management conference call today at 9:00 a.m. EDT. To access the conference call, please dial 1-877-317-6789 from the U.S. or 1-412-317-6789 internationally. The call will also be available via webcast a can be accessed through the Investor Relations page of Check-cap's website. Please allow extra time prior to the call to visit the site and download any necessary software to listen to the live broadcast.

A replay of the conference call will be available approximately one hour after completion of the live conference ca at the Investor Relations page of Check-cap's website. A dial-in replay of the call will be available until October 11, 2017; please dial 1-877-344-7529 from the U.S. or 1-412-317-0088 internationally and use the access code: 10112630.

About Check-Cap

Check-Cap is a clinical-stage medical diagnostics company developing C-Scan®, the first capsule-based system fc preparation-free colorectal cancer screening.

Utilizing innovative ultra-low dose X-ray and wireless communication technologies, the capsule generates information on the contours of the inside of the colon as it passes naturally. This information is used to create a 3D map of the colon, which allows physicians to look for polyps and other abnormalities. Designed to improve the patient experience and increase the willingness of individuals to participate in recommended colorectal cancer screening, C-Scan removes many frequently-cited barriers, such as laxative bowel preparation, invasiveness and sedation. The C-Scan system is currently not cleared for marketing in any jurisdiction.

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 the "Special Note On Forward-looking Statements" and "Risk Factors" in the Company's Annual Report on Form 20-F 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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