Check-Cap Announces IDE Submission to FDA for Its C-Scan® System

If Approved, U.S. Pilot Study Anticipated to Commence in 4Q 2018

ISFIYA, Israel, Oct. 9, 2018 /PRNewswire/ -- Check-Cap Ltd. (the "Company" or "Check-Cap") (NASDAQ: CHEK) (NASDAQ: CHEKW) (NASDAQ: CHEKZ), a clinical-stage medical diagnostics company engaged in the development of C-Scan®, a preparation free screening method for the prevention of colorectal cancer through the detection of precancerous polyps, today announced that it has submitted an Investigational Device Exemption (IDE) to the U.S. Food and Drug Administration (FDA) to advance studies of C-Scan®. If approved, the Company plans to initiate a U.S. pilot study during the fourth quarter of 2018.

Alex Ovadia, Chief Executive Officer of Check-Cap, commented: "We are pleased to announce IDE submission for our C-Scan® System. More than 700,000 deaths occur every year as a result of colorectal cancer and more than 1.3 million new colorectal cancer incidents are identified each year. Despite evidence that colorectal cancer screening can reduce associated mortality, adherence remains low due to the required preparation, invasiveness, and limited access in some communities to the current screening methods. We look forward to completing our U.S regulatory path approval process, commencing our U.S. pilot study later this year, and eventually bringing the C-Scan® System to people in need. This schedule aligns with our near-term goals for the remainder of 2018, as we continue to execute on our clinical and commercial plans toward 2019."

About Check-Cap

Check-Cap is a clinical-stage medical diagnostics company developing C-Scan®, an ingestible capsule-based device for 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 3 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.

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 forward 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 for the year ended December 31, 2017 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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