



Check-Cap Announces New Data Demonstrating Safety and Detection of Polyps in Clinical Study Evaluating Preparation-Free Colorectal Cancer Screening Capsule

- Data to be presented at the American College of Gastroenterology Annual Scientific Meeting and the United European Gastroenterology Week -

ISFIYA, Israel, Oct. 20, 2015 [/PRNewswire/](#) -- Check-Cap Ltd. (Nasdaq: CHEK, CHEKW), a clinical stage medical diagnostics company engaged in the development of an ingestible capsule for preparation-free, colorectal cancer screening, today announced new data demonstrating safety and polyp detection from a clinical study evaluating the company's non-invasive system for preparation-free examination of the colon. Results will be presented at the American College of Gastroenterology (ACG) Annual Scientific Meeting taking place October 16-21, 2015 and the United European Gastroenterology Week (UEGW) taking place October 24-28, 2015.

"Despite a compelling body of clinical evidence demonstrating that routine colonoscopies are effective in the early detection of colorectal cancer, studies suggest that only approximately 65 percent of patients in the target population adhere to current screening guidelines. Colorectal cancer is highly preventable as it can exist in the colon in a precancerous state for as many as 10 years before developing into cancer," said presenter Seth A. Gross, MD Associate Professor and Chief, Gastroenterology at Tisch Hospital, NYU Langone Medical Center. "Early screening for colorectal cancer is the best way to prevent disease progression and mortality. These data suggest that a non-invasive, preparation-free alternative may be a feasible alternative modality to help address this significant unmet medical need."

The study evaluated data from 49 volunteers and tracked the entire passage of the capsule through the alimentary tract using radio frequency telemetry and Check-Cap's proprietary capsule position tracking system. All capsules were swallowed naturally without adverse events, and there was a 100% capsule excretion rate after an average transit time of 68 +/- 31 hours. Enrolled subjects were exposed to ultra-low doses of radiation with an average total exposure of 0.03 +/- 0.007 mSv (approximately equivalent to a single chest x-ray). Quantitative ultra-low dose x-ray 3D imaging was achieved in the colon of human subjects, and the system successfully generated multiple reconstructions of colon segments with polyps. While colonic polyps were clearly demonstrated by the system, in order to get statistically significant results, the efficacy of this colon screening modality will need to be validated in a larger multi-center study.

These study results represent a preliminary analysis of the first patients evaluated in Check-Cap's ongoing multi-center clinical evaluation. The study aims to further evaluate the clinical efficacy of the Check-Cap system for the detection of pre-cancerous polyps. Check-Cap anticipates submitting data from this study for CE Mark in the first quarter of 2016 and initiating a U.S. pivotal trial in the second half of 2016.

"We are very encouraged by these preliminary data, which further demonstrate the safety and performance capabilities of the Check-Cap system," said Bill Densel, CEO of Check-Cap. "Without the requirement of traditional bowel preparation and lifestyle modifications or the compromise of privacy, Check-Cap is designed to detect pre-cancerous polyps and cancerous lesions and address the most significant barriers to patient adherence to colorectal cancer screening guidelines."

About Check-Cap

Check-Cap is a clinical stage medical diagnostics company developing the first non-invasive system for preparation-free imaging of the colon to identify precancerous polyps and cancers. The Company is developing an ingestible capsule that utilizes proprietary, ultra-low-energy X-ray-based technology to safely generate high-resolution, 3-dimensional imagery of the interior of the colon. Without requiring traditional bowel cleansing or diet and activity modifications, Check-Cap's system is designed to increase patient acceptance and adherence to colorectal cancer screening recommendations. The Check-Cap system is currently not cleared for marketing in any jurisdiction.

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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

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