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ASIA EDITION

Check-Cap, GE Healthcare announce updates on C-Scan System

20 August 2019 | News | By Sonali Wankhade

The C-Scan System has received CE marking for marketing in Europe and approval from the Israeli Ministry of Health, the Medical Device Division (AMAR) for marketing in Israel

Israel based Check-Cap Ltd., 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, and GE Healthcare, have announced the completion of manufacturing line transfer implementation and qualification for the C-Scan System.

This collaboration between Check-Cap and GE Healthcare was primarily initiated to enable the manufacture of C-Scan Systems for U.S. clinical trials. Upon the successful completion of this current clinical trial phase, both companies intend to explore collaboration expansion opportunities.

"Our collaboration with GE Healthcare, a global leader in medical technology manufacturing, has established a solid manufacturing infrastructure for the C-Scan System," said Alex Ovadia, chief executive officer of Check-Cap. "We are confident in GE's ability to scale up production and intend to explore other possible collaboration opportunities, primarily in the U.S., while adhering to regulatory and safety standards in various markets worldwide, as we advance our pilot clinical trial in the U.S."

"We have worked closely with the experienced Check-Cap team to transfer and qualify the manufacturing process of the C-Scan System to GE Healthcare," said Marco Campione, General Manager, Americas Pharmaceutical Diagnostics, GE Healthcare. "This partnership reflects our commitment to helping Check-Cap increase capacity, improve productivity and potentially leverage our global infrastructure to improve people's lives."

Check-Cap is currently conducting a pilot clinical trial 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 clinical trial results, the Company plans to file with the U.S. FDA for approval of a pivotal clinical trial, to be initiated in-2020. The C-Scan System has received CE marking for marketing in Europe and approval from the Israeli Ministry of Health, the Medical Device Division (AMAR) for marketing in Israel.