BioSpectrum the business of Bio & Health Sciences ASIA EDITION

Given Imaging's Colon PillCam cleared in Japan

July 18, 2013 | News | By BioSpectrum Bureau



Singapore: Israel-based Given Imaging, a world leader in gastrointestinal medical devices and pioneer of capsule endoscopy, announced that PillCam Colon has been cleared by Japan's Pharmaceuticals and Medical Devices Agency (PMDA) for diagnosis of colonic disease when colonoscopy is required but difficult to conduct, including patients unwilling or unable to undergo colonoscopy.

"We thank the PMDA for its very efficient review process and for granting a broad indication for PillCam Colon," said Mr Homi Shamir, president and CEO, Given Imaging. "The clearance of PillCam Colon in Japan, the world's second largest healthcare market, represents an important accomplishment for Given Imaging. The decision could expand our potential customer base in Japan from approximately 1,000 today to potentially 10,000 and will help in enhancing adherence to screening guidelines for over 1,000,000 potential patients," he added.

Screening guidelines in Japan call for everyone over 40 to undergo a fecal occult blood test (FOBT). Compliance with screening remains low and only approximately 25 percent of the population actually get tested. After a physician identifies blood in a patient's feces (which can be a strong indication of colon cancer or other diseases), only 54.7 percent of these patients proceed to have a recommended colonoscopy to confirm the diagnosis due to a variety of reasons. PillCam Colon's ease of use and minimally-invasive profile could appeal to those patients.

"The number of deaths due to colorectal cancer in Japan continues to increase at an alarming rate," said Dr Akira Terano, MD, PhD, Emeritus president, Dokkyo Medical University, president, Japanese Association for Capsule Endoscopy (JACE). "Colorectal cancer is now the leading cause of cancer death in women in Japan and the incidence rate for colorectal cancer in men and women is expected to be at the top of the list in the population of Japan by 2020. PillCam Colon is a less invasive medical device which would be able to drive higher compliance. I believe that PillCam Colon would make a huge contribution for early detection and treatment of colon cancer by applying it in the clinical setting. JACE would undertake the central role in research, education and the upgrading of the medical system for the capsule endoscopy of the colon. I believe PillCam Colon will be widely accepted into the clinical practice for patients who are not able or unwilling to undergo a colonoscopy due to physical or psychological reasons or who do not have a convenient access to a medical (colonoscopy) facility near their place

of residence."

"Our top priority is to provide physicians and patients with an alternative colorectal exam option to ensure every patient, including those who are unable or unwilling to get a colonoscopy, has the opportunity to undergo a colorectal exam," Mr Shamir said. "Meaningful sales of PillCam Colon capsule will commence immediately after obtaining reimbursement," he added.