

## **Given Imaging Submits PillCam COLON 2 Application to FDA for U.S. Regulatory Clearance**

Given Imaging

Given Imaging Ltd., a world leader in GI medical devices and pioneer of capsule endoscopy, today announced that it has filed a U.S. Food and Drug Administration (FDA) application seeking regulatory clearance to market its PillCam® COLON 2 for visualization of the lower gastrointestinal tract.

“Filing for FDA clearance is another important milestone for Given Imaging in advancing our efforts to commercialize PillCam COLON 2. We believe that PillCam COLON 2 meets a significant unmet need for a non-invasive imaging tool for visualization of the lower GI Tract for physicians and their patients who are unable to undergo colonoscopy or in cases of an incomplete colonoscopy,” said Homi Shamir, president and CEO, Given Imaging.

The PillCam COLON 2 capsule endoscopy system is complementary to colonoscopy and the proposed indication for use meets an unmet need and makes it an attractive imaging tool for patients who are at a higher risk for complications from colonoscopy as well as for patients who received an incomplete optical colonoscopy. The diagnostic use of PillCam COLON 2 may improve the standard of care for patients who are currently unable to undergo an exam, while minimizing potential adverse events, and reducing the risks associated with radiation-based alternative procedures such as CT colonography or double-contrast barium enema.

Based on guidance provided by the FDA, Given Imaging has submitted its PillCam COLON 2 application through a direct de novo pathway. Under new guidelines specified by the FDA Safety and Innovation Act (FDASIA) of 2012, the Company believes that the direct de novo pathway may expedite the regulatory approval process by a few months.

### **About Colorectal Polyps**

There are two common types of colorectal polyps: adenomatous, which can develop into cancer, and hyperplastic, which are rarely more than 5 mm in size and are infrequently cancerous.<sup>1</sup> For adenomas, the potential for malignancy is related to polyp size.<sup>2</sup> Larger polyps are more likely to develop into cancer, and polyps that are over 2 cm in size may potentially contain cancer.<sup>3</sup>

### **About Colon Cancer**

Colon cancer involves the large intestine (colon), the lower part of the digestive tract, while rectal cancer specifically involves the last 6 inches of the colon. Together, they're often referred to as colorectal cancers. Colon and rectal cancers begin in the digestive tract and occur when cells that line the colon or the rectum become abnormal and grow uncontrollably. Despite widespread public education efforts, colorectal cancer screening compliance rates remain low, with just 50% of

the eligible US population undergoing a colonoscopy.<sup>4</sup> About 147,000 people in the U.S. are diagnosed with colorectal cancer annually, according to the National Cancer Institute.<sup>5</sup> Worldwide, the disease causes one million cases and 600,000 deaths every year, with lower CRC screening compliance in Europe and Japan.

## About PillCam COLON 2

The PillCam COLON 2 capsule is equipped with two miniature color video cameras (one on each end), a battery and an LED light source; it measures 11 mm X 31 mm. PillCam® COLON 2 is designed to be ingested by the patient and transmit up to 35 frames per second for approximately 10 hours to a recording device worn by the patient. Data are transferred from the device to a computer that uses RAPID® software to compile the video data and enable the physician to review and report the results of the PillCam study.

The risks of PillCam capsule endoscopy include capsule retention, aspiration, or skin irritation. PillCam COLON capsule endoscopy presents additional risks, including risks associated with drug products used to prepare the patient for the procedure, which are currently used for colonoscopy, including allergies or other known contraindications to any preparation agents or medications used for the PillCam COLON regimen, according to laxative medication labeling and per physician discretion. Medical, endoscopic, or surgical intervention may be necessary to address any of these complications, should they occur.

## About Given Imaging Ltd.

Since pioneering the field of capsule endoscopy in 2001, Given Imaging has become a world leader in GI medical devices, offering health care providers a range of innovative options for visualizing, diagnosing and monitoring the digestive system. The company offers a broad product portfolio including PillCam® capsule endoscope for the small bowel, esophagus and colon. The company also offers industry-leading GI functional diagnostic solutions including ManoScan™ high-resolution manometry, Bravo® capsule-based pH monitoring, and Digitrapper® pH-Z impedance, and the SmartPill GI monitoring systems. Given Imaging is committed to delivering breakthrough innovations to the GI community and supporting its ongoing clinical needs. Given Imaging's headquarters are located in Yoqneam, Israel, with operating subsidiaries in the United States, Germany, France, Japan, Australia, Vietnam, Hong Kong and Brazil. For more information, please visit [www.givenimaging.com](http://www.givenimaging.com) [1].

[1] <http://www.mayoclinic.com/health/colon-polyps/DS00511/DSECTION=causes> [2]

[2] <http://emedicine.medscape.com/article/367452-overview> [3]

[3] <http://www.asge.org/PatientInfoIndex.aspx?id=396> [4]

[4] [http://www.cdc.gov/cancer/colorectal/statistics/screening\\_rates.htm](http://www.cdc.gov/cancer/colorectal/statistics/screening_rates.htm) [5]

[5] <http://seer.cancer.gov/statfacts/html/colorect.html> [6]

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## Links:

[1] <http://www.givenimaging.com>

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[6] <http://seer.cancer.gov/statfacts/html/colorect.html>