Given Imaging Reports Data Showing Greater Role for Capsule Endoscopy in Detecting and Monitoring Crohn's Disease

The Associated Press

Given Imaging Ltd. (NASDAQ: GIVN), a world leader in GI medical devices and pioneer of capsule endoscopy, today announced results of two studies suggesting an increased role for capsule endoscopy in detecting Crohn's lesions in the small bowel. The studies will be presented at the United European Gastroenterology Week (UEGW), Europe's largest gastroenterology conference, taking place in Amsterdam from October 20-24, 2012. Given Imaging is exhibiting at booth #56 from Oct 22-24.

"Capsule endoscopy for the detection of Crohn's disease in the small bowel has been clinically validated by a substantial and growing body of peer-reviewed research," said presenter Roberta Pica, M.D., Department of Clinical Sciences, Gastroenterology Unit at the Sapienza University of Rome. "As physicians, it's important to gather as much information as possible about the structural changes in the lining of the patient's small and large intestines to determine an accurate diagnosis and proper course of treatment. In this new study, early evidence shows that capsule endoscopy, widely considered the gold standard in small bowel visualization, is superior to magnetic resonance enterography (MRE) as a reliable tool to evaluate the type and extent of mucosal lesions associated with small bowel Crohn's disease. This information can lead to a more precise course of treatment with the goal to improve patient outcomes."

Dr. Pica and colleagues presented the results of a prospective study (P1414) comparing use of wireless capsule endoscopy (WCE) to magnetic resonance enterography (MRE) in the small bowel of 16 consecutive patients with confirmed or suspected Crohn's disease. In nine of 10 patients (90%), WCE detected significant lesions as indicated by the presence of erythema, aphthous, ulcers, fissures or mucosal hemorrhages, with four patients showing lesions in both the jejunum and ileum and five only of the terminal ileum. MRE was less accurate than WCE, detecting inflammatory lesions in 11 of 15 patients (73%), with two patients showing lesions in both the jejunum and ileum and nine in only the terminal ileum. In a group of nine patients who were evaluated with both examinations, WCE detected lesions in eight patients (90%), while MRE detected lesions in six (67%). In addition, 2 patients had a false negative on MRE and showed significant lesions in the terminal ileum with capsule endoscopy, and capsule endoscopy was able to exclude a false positive diagnosis of lymphoma suggested by MRE. The authors concluded that both tools are complementary methods for diagnosing small bowel Crohn's disease, noting that WCE represents a reliable tool in the evaluation of mucosal lesions for the direct visualization of the mucosal surface, while MRE

enables physicians to diagnose specific alterations of the bowel wall.

Separately, Efstathios Saprikis, M.D., 2nd Department of Gastroenterology, Evangelismos Hospital, Athens, Greece, presented a poster (P0203) showing that small bowel capsule endoscopy in patients with established Crohn's disease is safe and associated with a low percentage of capsule retention. When capsule retention did occur, the majority of the cases were adequately managed with conservative treatment. Dr. Saprikis and colleagues identified 301 patients who underwent ileocolonoscopy prior to small bowel capsule endoscopy. Among the 301 eligible patients with established Crohn's disease, capsule endoscopy identified signs of Crohn's disease in the small bowel in 196 (65.1%). Capsule retention only occurred in five patients (1.66%). These reported capsule retention rates are in line with previously reported data as well as society guidelines for CE use in patients with suspected Crohn's or established Crohn's disease.

About United European GastroenterologyUEG, or United European Gastroenterology, is a professional non-profit organization combining all the leading European societies concerned with digestive disease. Together, their member societies represent over 22,000 specialists, working across medicine, surgery, pediatrics, GI oncology and endoscopy. This makes UEG the most comprehensive organisation of its kind in the world, and a unique platform for collaboration and the exchange of knowledge.

UEG's mission is continually to improve standards of care in gastroenterology, and promote ever greater understanding of digestive and liver disease -- among the public and medical experts alike. As part of that work, it runs a number of education and training courses facilitated by highly respected experts. UEG also organizes UEG Week -- the largest and most prestigious meeting of its kind in Europe. UEG Week has been running since 1992, in a variety of major cities, and now attracts more than 14,000 people from across the world. For more information, please visit www.ueg.eu [1].

About PillCam® SB The PillCam®SB video capsule is a minimally invasive procedure to visualize and monitor lesions associated with inflammatory bowel disease (IBD), Crohn's disease and obscure GI bleeding (OGIB). The PillCam measures 11 mm x 26 mm and weighs less than four grams. Now in its second generation, PillCam SB 2 contains an imaging device and light source and transmits images at a rate of two images per second generating more than 50,000 pictures during the course of the procedure. Initially cleared by the U.S. Food and Drug Administration in 2001, PillCam SB is clinically validated by more than 1,500 peer-reviewed studies. It is an accurate, patient-friendly tool used in patients two years and older by physicians to visualize the small bowel. PillCam SB is the gold standard in small bowel evaluation.

The risks of PillCam® capsule endoscopy include capsule retention, aspiration, or skin irritation. The risks of the PillCam patency capsule include capsule retention and aspiration. Endoscopic placement may present additional risks. 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, 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 [2].

Forward-Looking Statements This press release contains forward-looking statements within the meaning of the "safe harbor" provisions of the U.S. Private Securities Litigation Reform Act of 1995. These forward-looking statements include, but are not limited to, projections about our business and our future revenues, expenses and profitability. Forward-looking statements may be, but are not necessarily, identified by the use of forward-looking terminology such as "may," "anticipates," "estimates," "expects," "intends," "plans," "believes," and words and terms of similar substance. Forward-looking statements involve known and unknown risks, uncertainties and other factors which may cause the actual events, results, performance, circumstances or achievements of the Company to be materially different from any future events, results, performance, circumstances or achievements expressed or implied by such forward-looking statements. Such forward-looking statements include statements relating to the Company exploring strategic alternatives and considering possible strategic transactions involving the Company. Factors that could cause actual events, results, performance, circumstances or achievements to differ from such forward-looking statements include, but are not limited to, the ability of the Company to reach agreement on any strategic alternative and/or to complete any such alternative, as well as the following: (1) our ability to develop and bring to market new products, (2) our ability to successfully complete any necessary or required clinical studies with our products, (3) our ability to receive regulatory clearance or approval to market our products or changes in regulatory environment, (4) our success in implementing our sales, marketing and manufacturing plans, (5) the level of adoption of our products by medical practitioners, (6) the emergence of other products that may make our products obsolete, (7) lack of an appropriate bowel preparation materials to be used with our PillCam COLON capsule, (8) protection and validity of patents and other intellectual property rights, (9) the impact of currency exchange rates, (10) the effect of competition by other companies, (11) the outcome of significant litigation, (12) our ability to obtain reimbursement for our product from government and commercial payors, (13) quarterly variations in operating results, (14) the possibility of armed conflict or civil or military unrest in Israel, (15) the impact of global economic conditions, (16) our ability to successfully integrate acquired businesses, (17) changes and reforms in applicable healthcare laws and regulations, (18) quality issues and adverse events related to our products, such as capsule retention,

aspiration and failure to attach or detach, bleeding or perforation that could require us to recall products and impact our sales and net income, and (19) other risks and factors disclosed in our filings with the U.S. Securities and Exchange Commission, including, but not limited to, risks and factors identified under such headings as "Risk Factors," "Cautionary Language Regarding Forward-Looking Statements" and "Operating Results and Financial Review and Prospects" in the Company's Annual Report on Form 20-F for the year ended December 31, 2011. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this press release. Except to the extent expressly required under applicable law, the Company undertakes no obligation to release publicly any revisions to any forward-looking statements, to report events or to report the occurrence of unanticipated events.

Source URL (retrieved on *12/08/2013 - 8:55pm*):
http://www.mdtmag.com/news/2012/10/given-imaging-reports-data-showing-greater-role-capsule-endoscopy-detecting-and-monitoring-crohns-disease?qt-video_of_the_day=0

Links:
[1] http://www.ueg.eu
[2] http://www.givenimaging.com