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Press Release

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Medicsight PLC

("Medicsight" or "the Company")

FDA 510(k) Clearance to market ColonCAD™ API in the United States

Sales and commercialisation channels for ColonCAD now open

Medicsight PLC (AIM: MDST), an industry leader in the development of Computer-Aided Detection (CAD) and medical image analysis software is pleased to announce that the Medicsight ColonCAD™ API has received clearance from the U.S. Food and Drug Administration (FDA). The clearance enables Medicsight to implement its US sales and marketing strategy, a primary objective in the development of the business since flotation.

Medicsight's ColonCAD is designed to assist radiologists during their review of CT colonography (CTC – also known as "Virtual Colonoscopy") images by automatically highlighting potential colorectal polyps (possible precursors to colorectal cancer) on the CT image. The FDA clearance was supported by a large clinical trial involving 15 radiologist readers who each reviewed 112 patient CT colonography cases both unassisted and assisted by ColonCAD. ColonCAD was used to support their evaluation after they had made an initial review of all the CTC image data. Cases were from a mixture of symptomatic and asymptomatic patients. The clinical trial results demonstrated that, when assisted by ColonCAD, radiologists' accuracy for detecting polyps of all sizes was significantly improved compared with unassisted reading.

Professor Steve Halligan of University College Hospital in London, the Principal Investigator for the trial, commented "The supporting clinical study clearly demonstrates the positive effect of Medicsight's ColonCAD on the performance of radiologists, and I believe that the results show the true potential of computer aided detection as a tool which will provide significant benefit in clinical practice around the world."

Allan Rowley, CEO of Medicsight, said “We are absolutely delighted to have reached this important milestone for Medicsight and are excited about receiving FDA clearance for ColonCAD™ API at a time when we anticipate that the demand for Virtual Colonoscopy and CAD will rapidly increase. We look forward to the commercialisation of Medicsight ColonCAD in the United States through our network of advanced visualisation partners who are ready to deliver the ColonCAD solution to end users. I would also like to thank the whole Medicsight team for their commitment to the project, and bringing us to this key juncture.”

Professor Perry Pickhardt from the University of Wisconsin School of Medicine & Public Health, said “Having experienced the potential of Medicsight’s ColonCAD in a research environment I am very excited that the product will now be available for clinical use in the US. I believe that ColonCAD will provide a real benefit and have a positive impact on radiologists’ review of virtual colonoscopy images.”

CT colonography is a minimally invasive examination that captures digital images of the patient’s colon and generates detailed three-dimensional digital images of the entire colorectum - enabling radiologists to thoroughly review the entire colon area. Virtual Colonoscopy can be used for colon screening and also for the investigation of symptoms of colonic disease.

In comparison to an optical colonoscopy examination, a Virtual Colonoscopy has the benefits of: (a) being much less invasive; (b) has no requirement for intravenous sedation or pain medication; and (c) requires no recovery time. With only half of the 100 million qualifying Americans aged fifty and over undergoing a colon cancer screening test, the availability of tests that improve patient compliance is of vital importance, and tools like Virtual Colonoscopy with Medicsight’s ColonCAD that improve test performance, are likely to be of significant benefit to patient care and helping reduce colorectal cancer.

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Notes to editors

Medicsight plc is a UK-headquartered, research driven, leading developer of computer-aided detection (CAD) and image analysis software for the medical imaging market. The CAD software automatically highlights suspicious areas on computerised tomography (CT) scans of the colon, helping radiologists to identify, measure and analyse potential disease and early indicators of disease. Medicsight's CAD software has been developed using a large and population diverse database of verified patient CT scan data. Medicsight's ColonCAD™ software products are seamlessly integrated with the advanced 3D visualisation workstations of several industry-leading imaging equipment partners.

About Computer-Aided Detection

With increasingly sophisticated radiological imaging hardware such as Multi-Detector CT scanners, radiologists are facing a growing challenge in the amount of detailed patient image data that they must review for each patient examination. Some CT scan examinations generate as many as 2000 images per patient. Review of this data by the radiologist is not only time-consuming but also prone to error due to reader fatigue. CAD software can help the reviewing radiologist by analysing the image data and automatically highlighting suspicious regions of interest for closer inspection. Without CAD software some potential abnormalities or areas of disease may be overlooked. This can be critical for diagnosis and the management of patient outcomes as early detection of disease greatly increases the probability of successful treatment and a positive therapeutic outcome. In addition to supporting individual radiologists CAD also has the potential to help standardise CT interpretation across both individuals and institutions thereby supporting population based screening programmes.

About Medicsight's CAD software

Medicsight's ColonCAD™ software uses an advanced CAD algorithm to analyse CT scans of the colon and automatically highlight suspicious areas that may be indicators of disease. CAD may highlight areas easily overlooked by the reviewing radiologist, such as small lesions or regions that are hidden from view behind folds in the colon.

ColonCAD can be seamlessly integrated with advanced 3D visualisation platforms of industry-leading imaging equipment partners. The integrated systems provide sophisticated image viewing capabilities, including 3D reconstructed image data, with the added advantage of demonstrating automatic CAD findings to assist clinical end users in the detection and analysis of disease.

Since inception, Medicsight has developed close and lasting relationships with some of the world's foremost clinicians in product related areas. This provides the Company with a wealth of clinical expertise and dedicated clinical research to support ongoing product development. Medicsight also collaborates with a number of leading academic institutions and clinical research programmes worldwide to develop the Company's comprehensive database of population diverse verified patient CT scan data, thus allowing Medicsight's products to be validated to the highest possible standards.

About colorectal cancer

According to the American Cancer Society, colorectal cancer is one of the leading causes of cancer-related deaths in the United States with an estimated 49,000 colorectal cancer deaths expected during 2011. However regular screening (where polyps can be detected at an early stage before they have developed into cancer) is one of the most powerful methods of colorectal cancer prevention. Screening for colorectal polyps increases the probability of more colorectal cancers being detected earlier - when the disease is easier to cure.