ActiViews, Inc. Announces FDA 510(k) Clearance of CT-GuideT Needle Guidance System for Liver Interventions

The Associated Press

WAKEFIELD, Mass.--(BUSINESS WIRE)--Apr 23, 2012-- ActiViews, Inc, a company pioneering the development of simple, accurate, and cost-effective surgical navigation solutions, announced today that it has received U.S. Food and Drug Administration (FDA) 510(k) clearance to market its flagship product, CT-Guide(TM) Needle Guidance System, for liver interventions.

CT-Guide(TM) navigation is designed to assist physicians during CT-guided interventional diagnostic and therapeutic procedures such as percutaneous biopsies, ablations, and marker placements in the lung and liver. The system enables physicians to locate interventional instruments in relation to pre-acquired CT images, which is analogous to the way a GPS locates a car using stored roadmaps. CT-Guide(TM) navigation features a single-use miniature video camera that is easily affixed onto standard interventional instruments, a patented sterile registration sticker, and proprietary 3D software that is viewed on a HD flat panel monitor mounted on a mobile workstation. CT-Guide(TM) navigation allows physicians to determine the location of the navigated instrument in relation to the 3D space of the CT images and the desired target, continuously displaying the location of the instrument and its planned path on the CT image of the patient's anatomy.

"With today's announcement, ActiViews further cements our commitment to become a leading provider of minimally invasive thoracic and abdominal surgical oncology solutions," commented Christopher von Jako, President of ActiViews, Inc. "With now our second successful clinical trial for the FDA with CT-Guide(TM) navigation, we are able to offer our customers an expanded indication from lung into liver and further clinical evidence of the efficacy of our unique and simple tool in these critical applications." In support of its FDA medical device submission for liver interventions, ActiViews concluded a safety and effectiveness clinical trial in December at two hospitals affiliated with McGill University Health Center in Montreal, Canada. The clinical study yielded 100% success in the primary end point of targeting accuracy with CT-Guide(TM) navigation used in biopsy and radiofrequency and microwave ablation procedures, and there were no device related adverse events. These confirmed the safety and effectiveness of CT-Guide(TM) navigation for the liver indication.

"With our experience in over 150 procedures performed at our institution, we demonstrated that CT-Guide(TM) navigation is an ideal tool for various CT-guided interventional oncology applications. By being very easy-to-use and simple to learn, the ActiViews device enables even less experienced users to perform the procedures with the effectiveness and confidence of more advanced users, further

enhancing the benefits of minimally invasive interventions to a wider range of patients." said Dr. David Valenti, Assistant Professor and Head of the Division of Interventional Radiology, McGill University Health Center, and Principle Investigator in the liver study.

"The simplicity and accuracy of the ActiViews system in guiding complex, deep and double angled needle approaches has been key in our adoption and repetitive usage in our minimally invasive interventional oncology procedures at McGill. Further, by eliminating most of the trial and error cycles involved in free hand guidance, the system has shown in some of our other preliminary comparative studies to shorten procedure time and reduce patient radiation exposure during the procedure," said Dr. Tatiana Cabrera, Assistant Professor, Radiology, McGill University Health Center.

About Liver Cancer: Liver cancer is one of the most common forms of cancer. Recent estimates indicate that over 700,000 new patients will be diagnosed worldwide each year with primary liver cancer. Liver cancer is also a leading cause of cancer deaths worldwide, accounting for more than 600,000 deaths each year. According to the American Cancer Society, liver cancer incidence rates increased by over 3% per year from 2004 to 2008, trends that have persisted in the US since 1992. In addition, the liver is the second most common organ affected by metastatic disease. For example, each year in the US, nearly 50% of the about 150,000 new primary colorectal cancer patients will either have a cancer that has already spread or will spread to the liver. More information on liver cancer can be found at www.cancer.com.

About ActiViews: ActiViews is a privately held high-tech medical device company that develops, manufactures, and markets novel surgical navigation solutions. The company's mission is to become the leading provider of simple, accurate, and affordable navigation solutions in order to enhance physician confidence in performing minimally invasive thoracic and abdominal surgical oncology procedures. The U.S. Patent and Trademark Office has approved the core technology platform patent with other ancillary patents currently pending. CT-Guide(TM) navigation is the first and only commercially available system for CT-guided interventions for both lung and liver applications. ActiViews, Inc. is located in the metro-Boston area with Research and Development facilities in Haifa, Israel. For further information visit the website at www.activiews.com. ActiViews, Navigate with Confidence(TM).

Photos/Multimedia Gallery Available: http://www.businesswire.com/cgi-bin/mmg.cgi?eid50246600&langen CONTACT: ActiViews, Inc.

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