



Investigator Meetings Completed in Japan and China for Celsion's Global Phase III ThermoDox(R) Trial for Primary Liver Cancer

Celsion rapidly initiates sites in two major countries to ensure timely study enrollment

COLUMBIA, Md., Oct 20, 2009 (BUSINESS WIRE) -- Celsion Corporation (NASDAQ: CLSN) announced today that it has completed a critical regulatory step in the countries of China and Japan to rapidly enroll patients in its global Phase III ThermoDox trial for the treatment of Hepatocellular Carcinoma (HCC), also known as primary liver cancer. The two instructional and educational meetings with principal investigators and institutional staffs were conducted in Tokyo and Beijing over the past ten days and were attended by over 60 physicians and surgeons who specialize in treating nonresectable liver cancer patients with radiofrequency ablation.

Celsion's global Phase III HEAT trial is evaluating the efficacy and safety of ThermoDox in combination with RFA when compared to RFA alone. The trial will enroll up to six hundred patients and is currently being conducted in the United States, Canada, China, Japan, Hong Kong, Korea, Taiwan and Italy. Celsion has recently announced that its clinical trial applications (CTA) have been agreed to by regulatory authorities in the Philippines and Malaysia and will be initiating its trial in Southeast Asia shortly. Celsion expects to have more than sixty sites fully activated and enrolling patients by the end of the year. Completion of patient enrollment is expected to occur in the first half of 2010.

"Getting these new sites initiated, trained and ready to enroll patients in both Japan and China is representative of the importance of these two major markets and is consistent with Celsion's objective to bringing the promise of ThermoDox to a needy global patient population as soon as possible," stated Michael H. Tardugno, Celsion's President and Chief Executive Officer. "The incidence of HCC is growing at a reported 5% annually and is projected by the World Health Organization to be the world's number one cancer by 2020. As RFA emerges globally as the first-line treatment for early stage HCC, ThermoDox is being evaluated for its potential to improve the efficacy of this cost effective procedure. The US FDA agreed to a Special Protocol Assessment (SPA) for this study with progression free survival as the primary and accelerated endpoint. Should the study hit the primary end point, Celsion is committed to filing for marketing approval in those countries where it is conducting the trial."

About Primary Liver Cancer

Mortality among primary liver cancer patients is one of the world's highest and ranks as the fifth most common solid tumor cancer. The incidence of primary liver cancer in the USA is approximately 20,000 cases per year and is rapidly growing worldwide. Globally there are approximately 660,000 cases per year, with the major risk factor being Hepatitis B and C in high prevalence in developing countries. The standard first line treatment for liver cancer is surgical resection of the tumor, but 70% to 80% of patients are ineligible for surgery. Radio frequency ablation (RFA) has increasingly become the standard of care for non-resectable liver tumors. There are few non-surgical therapeutic treatment options available as radiation therapy and chemotherapy are largely ineffective in the treatment of primary liver cancer. Celsion is evaluating its lead drug, ThermoDox, in combination with RFA to improve the outcomes of patients with non-resectable HCC.

About ThermoDox

ThermoDox in combination with hyperthermia has the potential to provide local tumor control and improve quality of life. ThermoDox is a proprietary heat-activated liposomal encapsulation of doxorubicin, a commonly used oncology drug for the treatment of a wide range of cancers including breast cancer. Localized mild hyperthermia (40-42 degrees Celsius) releases the entrapped doxorubicin from the liposome. This delivery technology enables high concentrations of doxorubicin to be deposited preferentially in a targeted tumor.

ThermoDox has also demonstrated evidence of efficacy in a Phase I study for primary liver cancer. Celsion has been granted FDA Orphan Drug designation for ThermoDox and is conducting a pivotal global Phase III study in primary liver cancer under a FDA Special Protocol Assessment. For recurrent chest wall breast cancer, ThermoDox(R) is being evaluated in a pivotal Phase I/II open-label, dose-escalating trial that is designed to measure durable local complete response at the tumor site. Celsion expects to enroll approximately 100 patients in the U.S. within calendar year 2010

ThermoDox(R) is a registered trademark of Celsion Corporation

About Celsion

Celsion is dedicated to the development and commercialization of innovative oncology drugs including tumor-targeting treatments using focused heat energy in combination with heat-activated drug delivery systems. Celsion has licensed ThermoDox(R) to Yakult-Honsha for the Japanese market and has a partnership agreement with Phillips Medical to jointly develop its heat activated liposomal technology in combination with high intensity focused ultrasound to treat difficult cancers. Celsion has research, license, or commercialization agreements with leading institutions such as the National Institutes of Health, Duke University Medical Center, University of Hong Kong, Cleveland Clinic, and the North Shore Long Island Jewish Health System.

For more information on Celsion, visit our website: <http://www.celsion.com>

Celsion wishes to inform readers that forward-looking statements in this release are made pursuant to the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995. Readers are cautioned that such forward-looking statements involve risks and uncertainties including, without limitation, unforeseen changes in the course of research and development activities and in clinical trials by others; possible acquisitions of other technologies, assets or businesses; possible actions by customers, suppliers, competitors, regulatory authorities; and other risks detailed from time to time in the Company's periodic reports filed with the Securities and Exchange Commission.

SOURCE: Celsion Corporation

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