



Celsion Provides Update on Progress of ThermoDox(R) Phase III Study for Primary Liver Cancer

Eleven Countries Including China Now Enrolling Patients, Enrollment to Be Complete in Mid 2010

COLUMBIA, Md., Dec 03, 2009 (BUSINESS WIRE) -- Celsion Corporation (NASDAQ:CLSN), a leading oncology drug development company, today provided an update on the progress of its pivotal ThermoDox(R) Phase III "HEAT" trial for the treatment of hepatocellular carcinoma (HCC), the most common form of primary liver cancer. Following recent regulatory approvals in China, Malaysia, Thailand and the Philippines, the study is now enrolling patients in eleven countries, with the majority of clinical sites located in the Asia Pacific region where HCC is most prevalent.

Enrollment in this 600 patient study continues to accelerate and Celsion expects to meet its objective of completing enrollment by the middle of 2010. A pre-planned, un-blinded interim efficacy analysis will be performed by an independent Data Management Committee when 50% of the endpoint events, tumor recurrence, are realized in the study population. Based on an historical review of RFA cases, Celsion expects the study could be completed by the middle of 2011, and pending positive data, a NDA would be submitted to the FDA before the end of 2011.

Michael H. Tardugno, President and Chief Executive Officer of Celsion stated, "We are pleased with the progress of patient enrollment and expect this trend to continue, based on the rapid start-up of additional clinical sites in China and other Asia Pacific countries. By year end, we expect to have sixty sites enrolling patients, with the majority of patients in countries such as China, Korea, Taiwan and Japan, where HCC is endemic. We have capital sufficient to complete enrollment and should the study show a benefit consistent with its primary endpoint, we would expedite filing for regulatory approvals in the U.S. and other countries where the trial is being conducted."

Celsion's global ThermoDox Phase III study for primary liver cancer is being conducted under a FDA Special Protocol Assessment (SPA). The study is designed to evaluate the efficacy of ThermoDox in combination with radiofrequency ablation (RFA) when compared to patients who receive RFA alone as the control. The primary endpoint is progression free survival with a secondary confirmatory endpoint of overall survival. Additional information on the ThermoDox Phase III clinical study may be found at <http://www.clinicaltrials.gov>.

About Primary Liver Cancer

Primary liver cancer is a type of cancer that begins in the cells of the liver and is not typically detected early, often resulting in a poor patient prognosis. 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. There are few non-surgical therapeutic treatment options available as radiation and chemotherapy are largely ineffective in the treatment of primary liver cancer. The standard first line treatment for liver cancer is surgery, either resection or liver transplantation, but 70% to 80% of patients are ineligible for surgery. Radio frequency ablation (RFA), with limitations, has shown to be effective and has increasingly become the standard of care for non-resectable liver disease. Celsion is evaluating its lead drug, ThermoDox, in combination with RFA to improve the range and efficacy of the RFA procedure to treat this difficult disease.

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, an approved and frequently 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 demonstrated evidence of efficacy in a Phase I study for primary liver cancer and the FDA has granted Orphan Drug designation for this indication. For recurrent chest wall breast cancer, ThermoDox 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.

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.

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