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Data Safety Monitoring Board Recommends Continuation of Celsion's Phase III ThermoDox(R) Study for Primary Liver Cancer

COLUMBIA, Md., Sep 21, 2009 (BUSINESS WIRE) -- Celsion Corporation (NASDAQ:CLSN) announced today the Data Safety Monitoring Board ("DSMB") has reviewed the safety data from the first group of patients enrolled in its pivotal ThermoDox(R) Phase III clinical trial for primary liver cancer ("HEAT study") and has recommended that Celsion continue to enroll patients in the trial.

The DSMB for the ThermoDox HEAT study is comprised of an independent group of medical and scientific experts who are responsible for reviewing and evaluating patient safety and efficacy data. The DSMB reviews safety data at regular intervals and its charter is to ensure patient safety and monitor the quality and overall conduct of the study. The study design and statistical plan for the Phase III ThermoDox trial also incorporates a pre-planned interim efficacy analysis by the DSMB after patient enrollment is complete with the intent to stop the study if there is overwhelming evidence of treatment benefit or an extremely low probability of treatment success.

Michael H. Tardugno, President and Chief Executive Officer of Celsion stated, "We are pleased that the DSMB has recommended continuing the study based on its review of the safety data. We expect patient enrollment to continue to accelerate, as the trial was recently expanded to Japan in coordination with our exclusive Japanese license partner Yakult. We note that under our partnership, Yakult will bear all costs associated with the Japanese cohort. Additionally, Celsion anticipates that regulatory approval for new clinical sites in China is imminent. Together with the expected activation of sites in Malaysia, the Philippines, and Thailand, the Company projects 60 sites by year end. We expect to complete enrollment in the spring of 2010."

Celsion's global Phase III ThermoDox study for primary liver cancer is enrolling 600 patients and is being conducted under a FDA Special Protocol Assessment (SPA). The study is designed to evaluate the efficacy of ThermoDox in combination with RFA when compared to patients who receive RFA alone as the control. The primary endpoint for the study is progression-free 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 one of the most deadly forms of cancer and ranks as the fifth most common solid tumor cancer. The incidence of primary liver cancer is approximately 20,000 cases per year in the United States and is rapidly growing worldwide at approximately 1,000,000 cases per year, due to the high prevalence of Hepatitis B and C in developing countries. Among the standard treatment options for liver cancer is surgical resection of the tumor; however 80% to 90% of patients are ineligible for surgery. Radio frequency ablation (RFA) has increasingly become the standard of care for non-resectable liver tumors, but the treatment becomes less effective for larger tumors.

About ThermoDox(R)

ThermoDox(R) 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. ThermoDox(R) is administered intravenously and in combination with hyperthermia has the potential to provide local tumor control and improve quality of life. Localized mild hyperthermia (39.5-42 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 already demonstrated remarkable evidence of clinical activity in Phase I studies for primary liver cancer and recurrent chest wall breast cancer. For the primary liver cancer indication, Celsion has been granted FDA Orphan Drug designation. 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

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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