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## **Celsion's Phase III ThermoDox(R) HEAT Study Recommended for Continuation by Data Monitoring Committee**

**--Independent Data Monitoring Committee reviewed data from 294 randomized patients --Data from initial Japanese cohort supports continued enrollment in Japan**

COLUMBIA, Md., May 13, 2010 /PRNewswire via COMTEX News Network/ -- Celsion Corporation (Nasdaq: CLSN) announced today that after reviewing data from 294 patients including data from 12 Japanese patients enrolled in the pivotal Phase III ThermoDox(R) clinical study (HEAT Study) for primary liver cancer, the Data Monitoring Committee (DMC) has recommended that Celsion continue to enroll patients in the trial.

The DMC for the 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 DMC reviews study data at regular intervals with the charter 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 DMC after patient enrollment is complete, with the intent to stop the study if there is overwhelming evidence of treatment benefit or a low probability of treatment success.

"We are pleased that the DMC has recommended continuation of the study based on its review of all of the available study data," stated Michael H. Tardugno, President and Chief Executive Officer of Celsion. "The DMC's affirmative review of the 12 Japanese patients enrolled to date is a positive step forward, as it confirms Celsion and Yakult's decision to initiate Phase III trials in Japan. The arrangement, to move directly into Phase III trials was based on previous evidence in primary liver cancer patients, may have shortened our timeline for approval in Japan by two years. With recent acceleration in patient recruitment, and the study now almost 60% enrolled, we are optimistic of a timely completion to enrollment."

Celsion's global Phase III ThermoDox study for primary liver cancer plans to enroll 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 radiofrequency ablation (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 Phase III ThermoDox clinical study may be found at [www.clinicaltrials.gov](http://www.clinicaltrials.gov).

### **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.

*ThermoDox(R) is a registered trademark of Celsion Corporation*

### **About ThermoDox Global Phase III HEAT Study**

Celsion's global ThermoDox Phase III study for HCC, the most common form of primary liver cancer, is being conducted under a Special Protocol Assessment with the U.S. Food and Drug Administration (FDA). The 600 patient 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 is progression free survival with a secondary confirmatory endpoint of overall survival. A pre-planned, un-blinded interim efficacy analysis will be performed by an independent Data Management Committee when 50% of the progression-free survival endpoint events 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 New Drug Application would be submitted to the FDA before the end of 2011. 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 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, but the treatment becomes less effective for larger tumors.

### **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: [www.celsion.com](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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