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Celsion Receives Fast Track Designation for ThermoDox(R) Development Program to Treat Primary Liver Cancer

Supplements Special Protocol Assessment for Global Phase III HEAT Study

COLUMBIA, Md., Aug 24, 2010 /PRNewswire via COMTEX News Network/ -- Celsion Corporation (Nasdaq: CLSN), a leading oncology drug development company, today announced that the U.S. Food and Drug Administration (FDA) has designated the HEAT Study of its investigational drug, ThermoDox(R), in combination with radiofrequency ablation (RFA), as a Fast Track Development Program. ThermoDox, a proprietary heat-activated liposomal encapsulation of doxorubicin, is currently being evaluated under a Special Protocol Assessment (SPA) agreement with the FDA in a 600 patient global Phase III trial in patients with non-resectable hepatocellular carcinoma (HCC), commonly referred to as primary liver cancer. With nearly 70% of patients enrolled in the trial, Celsion is targeting to complete patient enrollment by year end 2010.

"We are very pleased to receive the Agency's Fast Track Designation for ThermoDox," stated Mr. Michael H. Tardugno, Celsion's President and Chief Executive Officer. "Fast Track Designation is an acknowledgement that HCC is a significant unmet medical need representing a life threatening disorder. It also recognizes the challenges facing pharmaceutical companies to develop effective new treatments for this difficult disease. Together with the FDA's SPA agreement, granting accelerated review for the HEAT Study, the Fast Track status provides Celsion with the shortest time to approval. Supported further by the National Cancer Institute's recent designation of the HEAT Study as a Priority Clinical Trial, it is clear that the major U.S. healthcare agencies and the liver cancer medical community recognize the potential of ThermoDox. We look forward to working with the FDA and other regulatory agencies around the world to make ThermoDox available to patients as soon as possible."

The FDA's Fast Track Development Program provides for expedited regulatory review for new drugs that treat serious or life threatening diseases which are not satisfactorily treated by existing therapies, or for drugs that provide a significant advantage over existing therapies for serious diseases. Under the Fast Track Designation, Celsion is now eligible to submit a U.S. New Drug Application (NDA) on a rolling basis. This permits the FDA to review sections of the NDA in advance of receiving the complete submission.

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. The standard first line treatment for liver cancer is surgical resection of the tumor; however 80% to 90% of patients are ineligible for surgery. Radio frequency ablation (RFA) has increasing become the standard of care for non-resectable liver tumors, but the treatment becomes less effective for larger 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.

About ThermoDox(R)

ThermoDox(R) in combination with hyperthermia has the potential to provide local tumor control and improve quality of life. 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. 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.

For primary liver cancer, ThermoDox(R) is being evaluated in a 600 patient global Phase III study at 75 clinical sites under an FDA Special Protocol Assessment. 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 and enrollment is expected to be completed by year end 2010. 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 across the United States and to

complete the study by the first half of 2011. Additional information on the Company's ThermoDox(R) clinical studies may be found at http://www.clinicaltrials.gov

About Celsion

Celsion is a leading oncology company dedicated to the development and commercialization of innovative cancer drugs including tumor-targeting treatments using focused heat energy in combination with heat-activated drug delivery systems. 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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