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## **Celsion Announces Phase III HEAT Study of ThermoDox(R) in Primary Liver Cancer Reaches Target Number of Events for Unblinding**

### **Company Begins Data Collection, Expects to Report Top Line Data in January 2013; Reiterates Strong Balance Sheet Position**

LAWRENCEVILLE, NJ -- (Marketwire) -- 11/09/12 -- Celsion Corporation (NASDAQ: CLSN), a leading oncology drug development company, today announced that it projects that a minimum of 380 events of progression have been realized in the Company's pivotal, Phase III HEAT Study, a multinational, double-blind, placebo-controlled, pivotal study of ThermoDox® in combination with radiofrequency ablation (RFA) for the treatment of hepatocellular carcinoma (HCC), also known as primary liver cancer. According to protocol, 380 events of progression, subject to confirmation by the Study's independent Data Monitoring Committee (DMC), trigger the data collection process, unblinding and final analysis of the results by the DMC. Progression Free Survival (PFS) is the HEAT Study's primary endpoint. The HEAT Study has been granted Special Protocol Assessment by the FDA. Following DMC review, the Company plans to disclose top line results, an announcement that is expected to occur in January 2013.

"The HEAT Study addresses a significant and growing global unmet medical need in oncology, primary liver cancer. With a positive outcome, ThermoDox® will become the most important 1st line therapy for patients with non-resectable disease," said Michael H. Tardugno, Celsion's President and Chief Executive Officer. "The positive implications of this study, for patients and their families, the healthcare community, our investors and employees, cannot be overestimated."

Mr. Tardugno added: "We enter this transformative period from a position of financial strength, having taken ThermoDox® through to pivotal data while maintaining full worldwide rights outside of Japan, a minimal number of shares outstanding and a strong balance sheet." The Company ended the second quarter of 2012 with \$24 million in cash, subsequently supplemented by \$4.7 million in option and warrant exercises. Celsion also has available to draw an additional \$5 million from a \$10 million loan facility with Oxford Finance LLC and Horizon Technology Finance Corporation, pending positive data from the Phase III HEAT Study. "Consistent with our previous guidance, we have no plans to raise additional capital before disclosing top line data from the HEAT Study which, if positive, will vastly expand the Company's strategic and financing options."

The HEAT Study, which has enrolled a total of 701 patients, has been designated as a Priority Trial for liver cancer by the National Institutes of Health, has received Fast Track Designation from the FDA and has received Orphan Drug Designation in both the U.S. and Europe. ThermoDox® is also being evaluated in two Phase II trials for patients with recurrent chest wall breast cancer and colorectal liver metastases.

#### *About ThermoDox® and the Phase III HEAT Study*

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. In the HEAT Study, ThermoDox® is administered intravenously in combination with Radio Frequency Ablation (RFA). Localized mild hyperthermia (39.5 - 42 degrees Celsius) created by the RFA 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® is being evaluated in a global, multi-center, randomized, pivotal Phase III HEAT Study at 79 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 with a secondary confirmatory endpoint of overall survival. Additional information on the Company's ThermoDox® clinical studies may be found at [www.clinicaltrials.gov](http://www.clinicaltrials.gov).

#### *About Celsion Corporation*

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 liposomal drug technology. Celsion has research, license, or commercialization agreements with leading institutions including the National

Institutes of Health, Duke University Medical Center, University of Hong Kong, the University of Pisa, the UCLA Department of Medicine, the Kyungpook National University Hospital, the Beijing Cancer Hospital and the University of Oxford.

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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