



January 31, 2013

## **Celsion Announces Results of Phase III HEAT Study of ThermoDox® in Primary Liver Cancer**

### **Company to Host Conference Call at 8:00 AM EST Today**

LAWRENCEVILLE, N.J., Jan. 31, 2013 /PRNewswire/ -- Celsion Corporation (NASDAQ: CLSN), a leading oncology drug development company, today announced that ThermoDox® in combination with radiofrequency ablation (RFA) did not meet the primary endpoint of the Phase III HEAT Study in patients with hepatocellular carcinoma (HCC), also known as primary liver cancer.

Specifically, Celsion has determined, after conferring with its independent Data Monitoring Committee (DMC) that the HEAT Study did not meet the goal of demonstrating persuasive evidence of clinical effectiveness that could form the basis for regulatory approval in the population chosen for study. The HEAT Study was designed to show a 33% improvement in PFS with 80% power and a p-value = 0.05. In the trial, ThermoDox® was well-tolerated with no unexpected serious adverse events. The HEAT Study was conducted under a Special Protocol Assessment agreed to with the U.S. Food and Drug Administration (FDA).

"We are disappointed that the HEAT Study did not provide sufficient evidence of clinical effectiveness of ThermoDox® as measured by the trial's primary endpoint," said Michael H. Tardugno, Celsion's President and Chief Executive Officer. "We will consider following the patients currently enrolled in the HEAT Study to the secondary endpoint, Overall Survival (OS), and are conducting additional analyses of the data from the trial in order to assess the future strategic value of ThermoDox. We expect that the results will be presented in the future at appropriate medical meetings. We wish to acknowledge and thank the patients and investigators who participated in the trial."

Celsion ended 2012 with a strong balance sheet that provides the Company the opportunity to evaluate its future development plans. The Company projects its unaudited cash and investment balance to be approximately \$23 million as of December 31, 2012 and approximately \$27 million as of January 31, 2013.

### **Conference Call**

The Company is hosting a conference call to discuss the Phase III HEAT Study results at 8:00 a.m. EST today. To participate in the call, interested parties may dial 1-888-466-4462 (Toll-Free/North America) or 1-719-457-2627 (International/Toll) and ask for the Celsion Corporation Phase III HEAT Study Conference Call approximately 10 minutes before the call is scheduled to begin. The call will also be broadcast live on the internet at <http://www.celsion.com>.

The call will be archived for replay at 2 p.m. EST on January 31, 2013, and will remain available until February 14, 2013. The replay can be accessed at 1-877-870-5176 (Toll-Free/North America) or 1-858-384-5517 (International/Toll) using Conference ID: 4540212. An audio replay of the call will also be available on the Company's website, <http://www.celsion.com>, for 30 days after 2p.m. EST on Thursday, January 31, 2013.

### **About the HEAT Study**

HEAT (**H**epatocellular Carcinoma Study of **R**FA and **T**hermoDox®) was an international, multi-center, randomized, placebo-controlled study that randomized 701 patients with intermediate (tumor size 3 cm to 7 cm), unresectable HCC to 50mg/m<sup>2</sup> ThermoDox® plus RFA or RFA alone. The primary endpoint of the study was progression-free survival, as defined by the Special Protocol Assessment agreed to with the U.S. FDA. Safety and tolerability were also evaluated.

The HEAT Study, the largest clinical trial to date in patients with intermediate HCC, was conducted at 79 clinical sites around the world, including the United States, Canada, Italy, China, Taiwan, Hong Kong, Korea, Thailand, Malaysia and the Philippines.

### **About Hepatocellular Carcinoma**

Hepatocellular carcinoma (HCC), also known as primary liver cancer, is currently one of the most common and deadly forms of cancer worldwide. With few approved treatment options, it is estimated that up to 90 percent of unresectable (inoperable) liver cancer patients will die within five years of diagnosis. HCC is the fourth leading cause of death from cancer and the third most common in males. There are approximately 26,000 new cases per year in the US and approximately 40,000 cases per year in Europe. However, HCC is rapidly growing worldwide at approximately 750,000 cases per year, due to the high prevalence of Hepatitis B and C in developing countries - more than 50 percent of these new cases will be in China . HCC currently is the world's fifth largest cancer and the World Health Organization estimates that HCC may become the number one cancer worldwide by 2020, surpassing lung cancer.

### **About ThermoDox®**

ThermoDox® is an investigational, proprietary heat-activated formulation of liposomal doxorubicin, an approved and frequently used oncology drug for the treatment of a wide range of cancers, and is currently being investigated in clinical trials for its potential to treat patients with intermediate (tumor size 3 to 7 cm), unresectable (inoperable) HCC.Â ThermoDox® is an investigational treatment and is not approved by the FDA, EMA or other health authorities.Â Â

ThermoDox® enhances the efficacy of doxorubicin by encapsulating it with Celsion's proprietary lysolipid thermally sensitive liposomes (LTSL).Â These heat-sensitive liposomes change structure when heated to a specific temperature (via a heat source like RFA), creating openings in the liposome that release doxorubicin directly into the targeted tumor and surrounding tissue. While the RFA targets the tumor, ThermoDox® delivers higher concentrations of chemotherapy directly to the tumor site, capturing micrometastases (tumors too miniscule to be detected) outside of the RFA ablation zone, which are most commonly responsible for post-treatment disease recurrence.Â In animal models, ThermoDox® has been shown to deliver 25 times more doxorubicin into tumors than intravenous doxorubicin, and five times more doxorubicin than standard liposomal formulations of the drug. Additionally, ThermoDox® is less permeable across normal blood vessels than free doxorubicin, minimizing systemic toxicity.Â

### **About Celsion Corporation**

Celsion is a leading oncology company dedicated to the development and commercialization of innovative cancer drugs. The company is focused on advancing its heat-mediated, tumor-targeting drug delivery platform to address difficult-to-treat cancers. 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.Â 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.Â 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; the need for Celsion to analyze the results of the HEAT Study further; the need for Celsion to evaluateÂ its future development plans; cash projections are unaudited; 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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