



March 30, 2009

## **Celsion Announces Promising ThermoDox<sup>®</sup> Clinical Results in Primary Liver Cancer Were Published in Expert Opinion**

COLUMBIA, Md., Mar 30, 2009 (BUSINESS WIRE) -- Celsion Corporation (NASDAQ:CLSN), a leading oncology drug development company, announced that promising Phase 1 ThermoDox clinical results in hepatocellular carcinoma (HCC) or primary liver cancer have been published in the peer-reviewed medical journal Expert Opinion on Pharmacology. The review article titled "Lyso-thermosensitive liposomal doxorubicin: a novel approach to enhance efficacy of thermal ablation of liver cancer" was published in the February issue (Expert Opin. pharmacother. (2009)10(2):333-343).

ThermoDox is a proprietary formulation of lyso-thermosensitive liposomal doxorubicin (LTLD) used in combination with radiofrequency ablation (RFA) to provide local tumor control. The primary author of the study, Professor Ronnie TP Poon, M.D., University of Hong Kong, Queen Mary Hospital, Department of Surgery, Hong Kong, China, concluded that among Child-Pugh class A-B patients with medium or large tumors, ThermoDox is safe and demonstrates a statistically significant dose-response effect.

In the Phase 1 dose finding study, 24 patients (9 with HCC and 15 with liver tumors metastatic from 9 other primary sites) were treated with a single 30-min IV infusion of LTLD at 20, 30, 40, 50 or 60 mg/m<sup>2</sup>, starting 15 minutes before RFA. Dr. Poon reports, "There was a statistically significant (p=0.0380) LTLD dose response effect: median time to treatment failure for patients receiving at least the maximum tolerated dose of 50 mg/m<sup>2</sup> was 374 days while that for patients receiving less than 50 mg/m<sup>2</sup> was 80 days. This is consistent with the hypothesis that LTLD significantly increases RFA efficacy."

"The study results featured in this publication support our strategy for developing ThermoDox," commented Mr. Michael H. Tardugno, Celsion's President and Chief Executive Officer. "Based on these encouraging Phase I results, we initiated a pivotal Phase 3 registration trial under a special protocol assessment with the FDA in 600 patients with unresectable HCC. We hope to complete enrollment in this trial by the end of the first quarter of next year. "

### **About ThermoDox<sup>®</sup>**

ThermoDox<sup>®</sup> in combination with hyperthermia has the potential to provide local tumor control and improve quality of life. ThermoDox<sup>®</sup> 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<sup>®</sup> is being evaluated in a 600 patient global Phase III study at 40 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 in the first quarter of 2010. For recurrent chest wall breast cancer, ThermoDox<sup>®</sup> 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 2010. Additional information on these ThermoDox<sup>®</sup> clinical studies 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. 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 increasingly 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 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.*

SOURCE: Celsion Corporation

### Investors:

Celsion Corporation  
Sean Moran, 410-290-5390  
Senior Vice President and Chief Financial Officer  
[smoran@celsion.com](mailto:smoran@celsion.com)

or

The Trout Group  
Marcy Nanus, 646-378-2927  
[mnanus@troutgroup.com](mailto:mnanus@troutgroup.com)

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