



October 1, 2012

## **Celsion Announces DIGNITY Study Data Presented at 2012 Congress for European Society of Medical Oncology**

### **Updated Safety and Efficacy Results With ThermoDox(R) Plus Hyperthermia for Breast Cancer at the Chest Wall**

LAWRENCEVILLE, NJ -- (Marketwire) -- 10/01/12 -- Celsion Corporation (NASDAQ: CLSN), a leading oncology drug development company, today announced the presentation of Phase I results from the Company's Phase I/II DIGNITY study of ThermoDox® in Breast Cancer Recurrences at the Chest Wall at the ESMO 2012 Congress, the annual conference for the European Society of Medical Oncology held in Vienna, Austria September 28 to October 2, 2012. The presentation, titled "Breast Cancer Recurrences at the Chest Wall (BCRCW) When Standard Treatments (Tx) Have Failed: Lyso-thermosensitive liposomal doxorubicin (LTLTD) + Mild Local Hyperthermia (MLH)," was delivered by Professor Hope S. Rugo, MD, from the UCSF School of Medicine, and provided a clinical update of the Phase I/II DIGNITY trial studying ThermoDox® for breast cancer. A copy of the poster presentation is available at [www.celsion.com/docs/pipeline\\_presentations](http://www.celsion.com/docs/pipeline_presentations).

In the Phase I portion of the DIGNITY study, a highly treatment-refractory BCRCW patient population was treated using ThermoDox® in combination with MLH for superficial lesions < 3cm depth that have failed standard treatment. The study was designed to determine the Maximum Tolerated Dose (MTD) or confirm 50 mg/m<sup>2</sup> as acceptable, evaluate safety, Sparse PK sampling, and determine early effects of ThermoDox® in combination with MLH. A total of 11 subjects were treated. Drug Related Adverse Events were consistent with the known safety profile of doxorubicin including myelosuppression, alopecia, fatigue, and nausea. Reversible myelosuppression was the most frequently observed effect, effectively managed with ASCO g-CSF treatment recommendations. Clinically meaningful responses were observed, including a target lesion response rate of 45% without local progression (complete response 9.1%, n=1/11, partial response 36.4%, n=4/11). The study found that 50 mg/m<sup>2</sup> is the acceptable Phase 2 dose, as determined by independent review. Based on these results, Celsion is continuing into a Phase 2 study, to include additional clinical research sites.

Professor Rugo commented, "BCRCW patients, who in this study had an average of over four prior regimens, often have limited or no treatment options, underscoring a significant unmet medical need in this population. The initial experience with hyperthermia and ThermoDox® demonstrates the tolerability of the regimen in these patients as well as early efficacy signals, providing strong support for moving into a larger study."

"Breast cancer recurrence at the chest wall has a poor prognosis, is difficult to treat and is characterized by disfigurement, pain, and restriction of movement. These results, therefore, particularly in such highly refractory patients, are encouraging," said Nicholas Borys, Celsion's Vice President and Chief Medical Officer. "These data are further evidence of ThermoDox®'s broad potential clinical value across different cancers, including the ability to provide a new tool against aggressive, superficial tumors. We look forward to rapidly recruiting patients for the Phase 2 portion of DIGNITY as results from our Phase 3 HEAT study of ThermoDox® in primary liver cancer become available."

#### *National Breast Cancer Awareness Month*

Professor Rugo's presentation of data from the DIGNITY Study comes at a very poignant time for BCRCW patients. Celsion notes that October is National Breast Cancer Awareness Month, and urges the breast cancer research community to make the public aware of our promising trial in this difficult to treat form of cancer.

#### *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.

#### Investor Contact

David Pitts

Argot Partners

212-600-1902

#### Email Contact

Source: Celsion Corporation

News Provided by Acquire Media