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Celsion Announces Drug Safety Monitoring Board Recommends Advancing DIGNITY Study of ThermoDox(R) in Recurrent Chest Wall Breast Cancer Into Phase II

Safety Data Review Establishes 50 mg/m2 as Phase II Dose

COLUMBIA, MD -- (MARKET WIRE) -- 06/08/11 -- Celsion Corporation (NASDAQ: CLSN), a leading oncology drug development company, today announced that after reviewing safety data from the Company's recently completed Phase I portion of the DIGNITY Phase I/II study of ThermoDox® and hyperthermia in recurrent chest wall (RCW) breast cancer (the DIGNITY Study), an independent Drug Safety Monitoring Board (DSMB) has recommended advancing from Phase I to Phase II at 50 mg/m2 of ThermoDox®.

The DIGNITY Study is a multicenter, single-arm, open-label, potentially registrational trial enrolling up to 109 patients with RCW breast cancer. The study is designed to evaluate the potential for ThermoDox® in combination with hyperthermia to provide local control of superficial breast cancer recurrence. The primary endpoint is durable complete local response. The DIGNITY Study builds upon promising data from a Phase I dose escalation study conducted at the Duke University Medical Center, in which patients (n=16) demonstrated evidence of clinical activity, either stable disease, partial response or complete response. Toxicities are consistent with doxorubicin, the active agent in ThermoDox® and a widely used chemotherapeutic with a well established safety profile.

"Breast cancer recurrence at the chest wall presents a significant treatment challenge, often resisting surgical, radiologic or chemotherapeutic intervention," noted Nicholas Borys, MD, Celsion's Chief Medical Officer. "ThermoDox®, which releases high concentrations of doxorubicin when RCW tumors are heated, has demonstrated that it can be safely administered at a 50 mg/m2 dose up to 6 cycles. We look forward to initiating the DIGNITY Study in the larger Phase II population with a possible expanded inclusion to other superficial cancers."

"ThermoDox's treatment profile holds promise in a wide variety of indications where heat-based therapy has demonstrated efficacy, giving it potential as a pipeline within a product," said Michael H. Tardugno, President and Chief Executive Officer of Celsion. "As we complete enrollment in our Phase III HEAT Study of ThermoDox® in primary liver cancer, we will look to aggressive enrollment strategies, including expansion of the DIGNITY Study's inclusion criteria, with the goal of having clinical data in two indications as ThermoDox® approaches registration."

The DIGNITY Study recruited patients at nine clinical sites within the United States. Additional information on the study may be found at www.clinicaltrials.gov.

About Breast Cancer Recurrence at the Chest Wall

Depending on risk factors, up to 40% of women with mastectomies may experience breast cancer recurrence at the chest wall. The disease is a highly aggressive form of cancer and is generally defined as the recurrence of tumor to the area of the initial definitive treatment such as mastectomy. There are a significant number of women diagnosed with breast cancer recurrence at the chest wall that have exhausted all treatment options and cannot be treated with further surgical resection, radiation, or existing chemotherapy.

About ThermoDox®

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 including breast cancer. ThermoDox® is administered intravenously and in combination with hyperthermia. Localized mild hyperthermia (39.5-42 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.

ThermoDox® has already demonstrated remarkable evidence of clinical activity in Phase I studies for primary liver cancer and recurrent chest wall breast cancer. For the primary liver cancer indication, Celsion has been granted FDA Orphan Drug designation. For recurrent chest wall breast cancer, ThermoDox® 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.

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 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, Mayo Clinic, the University of Pisa, 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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