



Video: Celsion Corporation Initiates Enrollment Awareness Program for Pivotal Phase I/II DIGNITY Trial of ThermoDox(R) in Patients with Recurrent Chest Wall (RCW) Breast Cancer

COLUMBIA, Md., Sept 28, 2009 /PRNewswire-FirstCall via COMTEX News Network/ -- -- Celsion Corporation (Nasdaq: CLSN) announced today initiation of a nationwide enrollment program in its pivotal Phase I/II DIGNITY clinical trial evaluating the use of ThermoDox(R) in combination with hyperthermia for the treatment of Recurrent Chest Wall (RCW) Breast Cancer. In early studies, conducted at Duke University Medical Center, investigators report that ThermoDox(R) has demonstrated significant promise in treating this highly aggressive disease.

To view the Multimedia News Release, go to: <http://www.prnewswire.com/mnr/celsion/39944/>

In connection with October's designation as Breast Cancer Awareness Month, Celsion has initiated a multi-faceted program aimed at creating awareness for its clinical study. The campaign provides outreach to patients, family members, physicians and caregivers highlighting the trial and enrolling sites. Interested individuals can find more information about the DIGNITY trial and enrollment at www.clinicaltrials.gov.

According to the American Cancer Society, 1 in 8 women will get breast cancer in their lifetime and 192,370 women are diagnosed with the disease each year. It is estimated that up to 40% of women who undergo a mastectomy will experience a local recurrence, or RCW breast cancer. This condition affects about 15,000 to 20,000 patients annually in the US. The prognosis for these patients is poor, with most going on to develop metastatic disease, and there are limited treatment options available.

Dr. Brigid M. O'Connor, Principal Investigator and Radiation Oncologist at Rhode Island Hospital, has been working to evaluate the potential of ThermoDox(R) through the DIGNITY trial. "The DIGNITY trial may be a promising new option for patients who present with RCW Breast Cancer," said Dr. O'Connor. "Unfortunately, current treatment options are limited, especially for those who have already undergone chemotherapy or radiation in the past. I am pleased to be a part of this study that aims to provide treatment options for these patients to improve their quality of life."

Celsion initiated its Phase I/II trial after receiving written support from the US Food and Drug Administration (FDA) that the study may be considered pivotal pending a robust objective complete response rate. The study is being conducted at 7 sites across the country, including: Rhode Island Hospital, Providence, RI; Florida Cancer Institute, Hudson, FL; New York University Hospital, New York, NY; Saint Barnabas Medical Center, Livingston, NJ; Duke University Health System, Durham, NC; Virginia Commonwealth University -- Medical Center, Richmond, VA; and Cancer Treatment Center of America, Tulsa, OK.

"Recurrent Chest Wall Cancer is a devastating disease with debilitating complications, and because there is no effective therapeutic approach to locally controlling its progression, many of these patients live with difficult medical problems for their remaining years," said Michael H. Tardugno, President and Chief Executive Officer of Celsion Corporation. "Celsion is dedicated to the development and commercialization of innovative, comparatively low-risk oncology drugs addressing indications with unmet medical needs."

About the DIGNITY Clinical Trial

The DIGNITY clinical trial is a Phase I/II open label, dose escalating trial to evaluate the safety and efficacy of ThermoDox(R) with hyperthermia for the treatment of Recurrent Chest Wall (RCW) Breast Cancer, an aggressive form of cancer with a poor prognosis and limited treatment options. The primary endpoint in the DIGNITY trial is durable complete local response at the tumor site. Celsion intends to enroll 100 patients in the United States within the calendar year 2010. The results from the DIGNITY trial are expected to build on the promising data from the Phase I dose escalation study currently being conducted at Duke University Medical Center.

About ThermoDox(R)

ThermoDox(R) 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(R) is administered intravenously and in combination with hyperthermia has the potential to provide local tumor control and improve quality of life. 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(R) has also demonstrated evidence of efficacy in a Phase I study for primary liver cancer. Celsion has been granted FDA Orphan Drug designation for ThermoDox(R) and is conducting a pivotal 600 patient global Phase III study in primary liver cancer under a FDA Special Protocol Assessment.

Additional information on ThermoDox(R) clinical studies for RCW breast cancer and primary liver cancer can be found at: www.clinicaltrials.gov.

ThermoDox(R) is a registered trademark of Celsion Corporation.

About Celsion

Celsion is dedicated to the development and commercialization of innovative oncology drugs including tumor-targeting treatments using focused heat energy in combination with heat-activated drug delivery systems. Celsion has licensed ThermoDox(R) to Yakult-Honsha for the Japanese market and has a partnership agreement with Phillips Medical to jointly develop its heat activated liposomal technology in combination with high intensity focused ultrasound to treat difficult cancers. 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.

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