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Celsion Announces Positive Interim Data from Phase 2 DIGNITY Trial in Breast Cancer

ThermoDox Demonstrates Impressive Response Rate in Refractory Patients

LAWRENCEVILLE, N.J., Feb. 27, 2014 /PRNewswire/ --Â Celsion Corporation (NASDAQ: CLSN) announced today positive interim data from its ongoing open-label Phase 2 DIGNITY Trial of ThermoDox® in Recurrent Chest Wall Breast Cancer (RCWBC).Â The trial will enroll 20 patients at 5 clinical sites in the United States and is evaluating ThermoDox in combination with mild hyperthermia. Based on data available to date, a local response rate of 80% has been observed in the 5 evaluable patients with refractory disease, notably 2 complete responses (CR), 2 partial responses (PR) and 1 patient with stable disease (SD).Â These data are consistent with the previously reported positive Phase 1 data in RCWBC.

"These results are very impressive, especially given the fact that Recurrent Chest Wall Breast Cancer is difficult to treat, has a poor prognosis with a significant impact on quality of life, and that these patients have failed all previous treatment attempts," said Professor Hope S. Rugo, MD, UCSF School of Medicine, the lead investigator for the DIGNITY trial. "I am particularly encouraged by the consistency of the efficacy signals observed in this trial and the earlier Phase 1 studies, which provide further evidence that ThermoDox in combination with hyperthermia may offer a clinically meaningful treatment option for this underserved patient population."

"The data emerging from the Phase 2 DIGNITY program underscore the ThermoDox value proposition and reflect the broad potential for ThermoDox across a range of solid tumor indications," stated Nicholas Borys, M.D., Chief Medical Officer of Celsion. "With the trial now approximately 50% enrolled, we are focused on driving patient recruitment and look forward to continued updates from this trial."

In December, Celsion reported combined clinical data from two Phase I trials, the Company's Phase 1 DIGNITY Study and the Duke University sponsored Phase I trial of ThermoDox® plus hyperthermia in RCWBC. The two similarly designed Phase I studies enrolled patients with highly resistant tumors found on the chest wall and who had progressed on previous therapy including chemotherapy, radiation therapy and hormone therapy.Â ThermoDox® in combination with mild hyperthermia was evaluated in these patients in up to six cycles. Both studies employed an open label 3+3 dose escalation study design to determine the Maximum Tolerated Dose (MTD), evaluate safety and determine early effects of ThermoDox® in combination with mild hyperthermia.Â There were 29 patients treated in the two trials (11 patients in the Company's DIGNITY study and 18 patients in the Duke study).Â Of the 29 patients treated, 23 were eligible for evaluation of efficacy.Â A local response rate of over 60% was reported in 14 of the 23 evaluable patients with 5 complete responses and 9 partial responses.

About Celsion Corporation

Celsion is 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.Â 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 uncertainties of and difficulties in analyzing interim clinical data, particularly in small subgroups that are not statistically significant; FDA and regulatory uncertainties and risks; the significant expense, time, and risk of failure of conducting clinical trials; HEAT Study data is subject to further verification and review by the HEAT Study Data Management Committee; the need for Celsion to evaluate its future development plans; possible acquisitions or licenses of other technologies, assets or businesses or the possible failure to make such acquisitions or licenses; possible actions by customers, suppliers, competitors, regulatory authorities; and other risks detailed from time to time in the Celsion's periodic reports and prospectuses filed with the Securities and Exchange Commission.Â Celsion assumes no obligation to update or supplement forward-looking statements that become untrue because of subsequent events, new information or otherwise.

Celsion Investor Contact
Jeffrey W. Church
Sr. Vice President and CFO
609-482-2455
jchurch@celsion.com

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