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Celsion Announces Presentation of DIGNITY Phase I/II ThermoDox® Data at the 2015 San Antonio Breast Cancer Symposium

Local Responses Observed in over 60% of Evaluable Recurrent Chest Wall Breast Cancer Patients

LAWRENCEVILLE, N.J., Dec. 14, 2015 /PRNewswire/ -- Celsion Corporation (NASDAQ: CLSN) today announced the presentation of results from its ongoing Phase I/II US DIGNITY Study of ThermoDox® in combination with mild hyperthermia in patients with recurrent chest wall (RCW) breast cancer.Â The data, which demonstrated a combined local response rate of 61.9% among evaluable patients treated with ThermoDox®, were presented on Saturday, December 12, 2015 at the San Antonio Breast Cancer Symposium during a poster session titled *New Drugs and Treatment Strategies.* Â Celsion Corporation is a fully-integrated oncology company focused on the development of a portfolio of innovative cancer treatments, including directed chemotherapies, immunotherapies and RNA- or DNA-based therapies for the treatment of cancer and other difficult-to-treat diseases.

"Results from this study are very encouraging and suggest that ThermoDox® combined with superficial hyperthermia offers a promising and well tolerated treatment option for patients with recurrent chest wall disease from breast cancer, a highly refractory form of breast cancer associated with poor quality of life and limited treatment options," said Hope Rugo, M.D., Clinical Professor, Department of Medicine and Director, Breast Oncology Clinical Trials Program at the University of California, San Francisco, and lead investigator of the study. Â "These findings underscore the potential for this therapy to serve as a much needed treatment for these patients, and further define the importance of advancing development of ThermoDox® in this indication," Dr. Rugo added.

In the Phase I/II trials, which were designed to evaluate the safety and anti-tumor activity of ThermoDox® in combination with mild hyperthermia in RCW breast cancer, a total of 28 patients were treated at doses of either 40 or 50 mg/m^2. In addition to a local response rate of 61.9% among evaluable patients, a combined local response rate was observed in 46.4% of the intent-to-treat population (13/28), notably consisting of five patients demonstrating a durable local response lasting greater than three months, including four complete responses (CR) and one partial response (PR). Â Patients dosed at 40 mg/m^2 displayed a comparable response rate and a more favorable safety profile to that of patients receiving 50 mg/m^2.Â As a result, 40 mg/m^2 will be the recommended dose for future clinical trials in this indication.

"ThermoDox® in RCW breast cancer continues to yield striking response data in this vulnerable patient population, further validating our commitment to expanding this program, including the initiation of the Euro-DIGNITY Trial, a multi-center study designed to evaluate ThermoDox's potential to locally control chest wall lesions in earlier-stage patients," said Michael H. Tardugno, Celsion's chairman, president and CEO. "Additionally, we remain committed to providing patients who are suffering from this aggressive form of breast cancer with access to ThermoDox®, and are continuing to work closely with myTomorrows to ensure the success of our Early Access Program in Europe for ThermoDox® in RCW breast cancer."

The Company anticipates completion of the Phase II US DIGNITY trial by year-end, and plans to initiate a 70 patient Phase II study in Europe and Israel in less advanced, less heavily pretreated patients as part of the Euro-DIGNITY Trial. The Euro-DIGNITY Trial will evaluate ThermoDox® plus radiation and hyperthermia in RCW breast cancer patients and is designed to support a registration filing in Europe.Â This study will be initiated throughout Europe and Israel and with assistance from MedLogics Corporation, an Italian-based hyperthermia device company. In addition, Celsion has a license and distribution agreement with myTomorrows to implement an Early Access Program (EAP) for ThermoDox® in all countries of the European Union territory plus Switzerland for the treatment of patients with RCW breast cancer. The EAP provides physicians with access to products in later stage development demonstrating evidence of clinical benefit, with an acceptable safety profile and a quality manufacturing process in place.

The poster presentation is available on Celsion's website at http://investor.celsion.com/events.cfm.

About Celsion Corporation

Celsion is a fully-integrated oncology company focused on developing a portfolio of innovative cancer treatments, including directed chemotherapies, immunotherapies and RNA- or DNA-based therapies. The Company's lead program is ThermoDox®, a proprietary heat-activated liposomal encapsulation of doxorubicin, currently in Phase III development for the treatment of primary liver cancer and in Phase II development for the treatment of recurrent chest wall breast cancer.Â The pipeline also includes GEN-1, a DNA-based immunotherapy for the localized treatment of ovarian and brain cancers.Â Celsion has two platform technologies for the development of novel nucleic acid-based immunotherapies and other anti-cancer DNA or RNA therapies, including TheraPlas™ and TheraSilence™.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; FDA and regulatory uncertainties and risks; the significant expense, time, and risk of failure of conducting clinical trials; possible acquisitions or licenses of other technologies, assets or businesses; 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.

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