



October 17, 2017

Celsion Provides Summary of Research and Development Day Held on Thursday, October 12, 2017

Leading Liver Cancer Experts Discuss ThermoDox® Clinical Programs in Primary Liver Cancer

LAWRENCEVILLE, N.J., Oct. 17, 2017 (GLOBE NEWSWIRE) -- Celsion Corporation (NASDAQ:CLSN), an oncology development company, today provided a summary of ThermoDox® related presentations made during the Company's Research and Development (R&D) Day held on Thursday, October 12, 2017. This summary is intended to provide easy access to pertinent, top line information discussed during the conference. A complete webcast of the presentations is available on Celsion's website at www.celsion.com under the heading *News & Investors / Financial Events / Featured Events - October 12, 2017 - Celsion to Host Research and Development Update*.

The presentations focused on the Company's research and development program using ThermoDox®, Celsion's proprietary heat-activated liposomal encapsulation of doxorubicin, for the treatment of primary liver cancer, also known as hepatocellular carcinoma or HCC. Leading OPTIMA Study clinical investigators representing various geographical regions (Asia-Pacific and Europe) and multiple medical disciplines (hepatology, interventional radiology and surgery) presented their past and current experiences with ThermoDox® for the treatment of primary liver cancer.

-- **Nicholas Borys, M.D.**, Celsion's Senior Vice President & Chief Medical Officer, presented the following:

- i ThermoDox's mechanism of action and how it utilizes tumor biology to deliver high concentrations of drug (Doxorubicin) directly to the tumor site and the importance of heating time.
- i Key learnings from the Company's 701 patient HEAT Study including results from (i) computer simulation studies, (ii) preclinical animal studies and (iii) a *post hoc* subgroup analysis, all of which establishes a clear understanding of a key ThermoDox® heat-based mechanism of action: the longer the target tissue is heated, the greater the doxorubicin tissue concentration.
- i Hypothesis prompted by the HEAT Study *post-hoc* findings: ThermoDox®, when used in combination with Radiofrequency Ablation (RFA) standardized to a minimum dwell time of 45 minutes (sRFA > 45 min), appears to increase the overall survival (OS) of patients with HCC.
- i Results from an independent retrospective analysis conducted by the National Institutes of Health on the intent-to-treat population of the HEAT Study which sought to evaluate the correlation between RFA burn time per tumor volume (min/ml) and clinical outcome. The analysis concluded that increased RFA "burn time" per tumor volume significantly improved overall survival (OS) in patients with solitary lesions treated with sRFA + ThermoDox® compared to patients treated with sRFA alone.
- i Update on the current enrollment status of the OPTIMA Study which is approaching 70% of the 550 patients necessary to ensure that its primary end point, overall survival, can be evaluated with statistical significance. The statistical plan for the OPTIMA Study calls for two interim efficacy analyses by the IDMC. The Company projects full patient enrollment by mid-2018 and the first pre-planned efficacy analysis after 118 overall survival events by the first quarter of 2019.

-- **Won Young Tak, M.D., Ph.D.**, Professor Internal Medicine, GI & Hepatology Kyungpook National University Hospital Daegu, Republic of Korea presented the following:

- i RFA has limited efficacy in larger tumors due to microsatellite nodules or viable tumors.
- i Patients treated with ThermoDox® in the HEAT Study had excellent survival outcome. Two cases presented for the HEAT Study showed five and nine year survival benefit for patients treated with ThermoDox® plus sRFA.

-- **Stephen N. Wong, M.D.**, Principal Investigator OPTIMA, Chinese General Hospital, Philippines presented the following:

- i HEAT Study patients treated with ThermoDox® demonstrated a high complete response rate compared to other studies
- i A strong correlation exists between complete response and better survival.

-- **Robert M. Eisele, M.D.**, Deputy Head of Department, Dept. of General, Visceral, Vascular and Pediatric Surgery, Medical Faculty of the University of Saarland, Homburg, Germany presented the following:

- i HCC is a worldwide problem with high incidence that continues to rise.
- i Treatment strategies for treating HCC should be tailored.
- i Until ThermoDox®, RFA was insufficient in treating intermediate to large tumors.
- i Data from the HEAT Study suggests a new role for RFA plus ThermoDox® in HCC - a "promising option."

About the OPTIMA Study

The Phase III OPTIMA Study is expected to enroll up to 550 patients in up to 70 clinical sites in the United States, Europe, China and Asia Pacific, and will evaluate ThermoDox® in combination with optimized RFA, which will be standardized to a minimum of 45 minutes across all investigators and clinical sites for treating lesions three to seven centimeters, versus optimized RFA alone. The primary endpoint for the trial is Overall Survival, which is supported by post-hoc analysis of data from the Company's 701 patient HEAT Study, where optimized RFA has demonstrated the potential to significantly improve survival when combined with ThermoDox®. The statistical plan calls for two interim efficacy analyses by an independent Data Monitoring Committee.

ThermoDox® has received U.S. FDA Fast Track Designation and has been granted orphan drug designation for primary liver cancer in both the U.S. and Europe. Further, the U.S. FDA has provided ThermoDox® with a 505(b)(2) registration pathway. Subject to a successful trial, the OPTIMA Study has been designed to support registration in all key primary liver cancer markets. Celsion fully expects to submit registrational applications in the USA, Europe and China. The Company believes that applications will be accepted in South Korea, Taiwan and Vietnam, three other large and important markets for ThermoDox® subject to approval in Europe, China or the USA.

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. The pipeline also includes GEN-1, a DNA-based immunotherapy for the localized treatment of ovarian and brain cancers. Celsion has two platform technologies for the development of novel nucleic acid-based immunotherapies and other anti-cancer DNA or RNA therapies. For more information on Celsion, visit our website: <http://www.celsion.com>. (CLSN-LTSL/ThermoDox® CLSN-Optima Study/HCC) (CLSN-G1 CLSN-OV)

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; 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; the need for Celsion to evaluate its future development plans; 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. 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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