December 16, 2016

Celsion Corporation Announces Progress with ThermoDox® Development Efforts in China and Asia Pacific

CFDA Indicates that Positive Phase III OPTIMA Data Could Support Direct Regulatory Filing in China

Expect to Initiate Additional Sites for Phase III OPTIMA Trial in Vietnam in Early 2017

LAWRENCEVILLE, N.J., Dec. 16, 2016 (GLOBE NEWSWIRE) -- Celsion Corporation (NASDAQ:CLSN) today provided an update on its Phase III OPTIMA program for ThermoDox®, Celsion's proprietary heat-activated liposomal encapsulation of doxorubicin in combination with radiofrequency ablation (RFA) in primary liver cancer, also known as hepatocellular carcinoma (HCC). The Phase III OPTIMA Study is expected to enroll up to 550 patients at up to 75 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 standardized RFA alone.

The Company recently met with the China Food and Drug Administration (CFDA) to discuss the ongoing Phase 3 OPTIMA program and regulatory pathway for ThermoDox in China. During the meeting, Celsion presented the final overall survival data from the Chinese patient cohort of the HEAT study, which demonstrated a survival benefit in patients treated with ThermoDox plus optimized RFA versus optimized RFA alone. The CFDA informed Celsion that if the ongoing Phase 3 OPTIMA trial is successful, the trial could serve as the basis for a direct regulatory filing in China without the need to file for prior approval in the U.S. or European Union which is currently required for foreign company application. This would allow the Company to accelerate its plans for a regulatory filing in China and, if approved, provide for a significantly earlier launch date in China than originally expected.

"We are building momentum with our efforts for ThermoDox in the Asia Pacific region, particularly China, which represents a significant market opportunity with over 50% of new diagnosed cases of this devastating cancer," stated Michael H. Tardugno, Celsion's chairman, president and chief executive officer. "All Chinese sites will be fully activated by early 2017, enrollment is on pace to meet our objective of fully enrolling the trial by the first quarter of 2018, and we have advanced our manufacturing in China with Hisun to support a potential future launch in this region with impressive gross margins. We believe that the remarkable data from the Chinese cohort of the HEAT study underscores the potentially curative nature of ThermoDox in patients with primary liver cancer, and we are pleased that the CFDA has both recognized its potential and offered a straightforward path to a regulatory filing in China."

In support of its efforts in China, Celsion reported that recent bioequivalence studies of ThermoDox produced in China by Hisun are equivalent to batches of ThermoDox produced at its United States manufacturing site.

In addition, Celsion reported that the Company's management team recently met with the Ministry of Health in Vietnam and based on that meeting, it will move forward with launching additional trial sites for the OPTIMA study in the country. Celsion expects to have approximately 5 additional clinical trial sites in Vietnam activated by early 2017. Vietnam represents a significant market for ThermoDox where HCC incidence rates are among the world's highest.

About the OPTIMA Study

The Phase III OPTIMA Study is expected to enroll up to 550 patients in up to 75 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 standardized 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 (iDMC).

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 anticancer DNA or RNA therapies, including TheraPlas™ and TheraSilence™. The Company has a Cooperative Research and Development Agreement (CRADA) with the NIH. Any reference to NIH should not be viewed as an endorsement of Celsion, its products or services.

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; 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 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.

Celsion Investor Contact

Jeffrey W. Church

Sr. Vice President and CFO

609-482-2455

jchurch@celsion.com

Source: Celsion Corporation