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# Celsion Corporation Announces Enrollment of First Patient in the OPTIMA Study in China

## With China FDA's Approval of Celsion's Phase III Study in First Line Primary Liver Cancer, the Trial is Now Enrolling Patients in 13 Countries World-wide

LAWRENCEVILLE, N.J., April 26, 2016 /PRNewswire/ -- Celsion Corporation (NASDAQ: CLSN), an oncology drug development company, today announced that the first patient in China has been enrolled in its ongoing global Phase III OPTIMA Study evaluating ThermoDox®, Celsion's proprietary heat-activated liposomal encapsulation of doxorubicin, in combination with radiofrequency ablation standardized to 45 minutes (sRFA) versus sRFA alone to treat newly diagnosed patients with primary liver cancer, also known as hepatocellular carcinoma (HCC).

The pivotal, double-blind, placebo-controlled OPTIMA Study is expected to enroll up to 550 patients globally, and has been successfully enrolling patients at 50 clinical sites in 12 different countries in North America, Europe and Asia Pacific. In December 2015, the Company announced that it had received a Clinical Trial Application (CTA) approval from the China Food and Drug Administration (CFDA) to conduct the OPTIMA Study at up to 20 additional clinical sites in China. The Company aims to enroll more than 200 patients in the China territory, the minimum number required by the CFDA to file a New Drug Application (NDA), assuming positive clinical results.

"The enrollment of the first patient in China represents a significant milestone for the OPTIMA program," said Michael H. Tardugno, Celsion's chairman, president and chief executive officer. "With the growing incidence of primary liver cancer in China, representing approximately 50% of the 850,000 cases diagnosed annually, this country is an important element of our global registration and commercialization strategy for ThermoDox®, and we are committed to driving patient enrollment in this region as we execute our OPTIMA study."

"Survival data from the subgroup analysis in the HEAT study underscore the potential of ThermoDox® in combination with sRFA to serve as a potentially curative treatment in primary liver cancer, where very limited treatment options currently exist," said Dr. Nicholas Borys, Celsion's chief medical officer. "We look forward to working with our colleagues in China and the global research team to further explore ThermoDox® in this setting."

The primary endpoint for the OPTIMA Study is overall survival (OS). The statistical plan calls for two preplanned interim efficacy analyses by an independent Data Monitoring Committee (iDMC). The design of the OPTIMA Study is supported by a retrospective analysis of a large subgroup of 285 patients in the Company's previous 701 patient HEAT Study in primary liver cancer. In a subgroup of 285 HEAT Study participants, ThermoDox® plus standardized RFA demonstrated a statistically significant improvement in survival of over two years compared to standardized RFA alone. In this large subgroup, the median overall survival in the ThermoDox® plus standardized RFA arm was approximately 80 months (6 ½ years), which is considered a curative treatment for HCC.

**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, including TheraPlas™ and TheraSilence™. For more information on Celsion, visit our website: http://www.celsion.com. (CLSN-TD) (CLSN-OS)

*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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