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Celsion Receives CFDA Approval to Conduct the OPTIMA Study in China

25 Additional Clinical Sites To Be Added To Global Pivotal Phase III Study For The Treatment of Primary Liver Cancer

LAWRENCEVILLE, N.J., Dec. 16, 2015 /PRNewswire/ -- Celsion Corporation (NASDAQ: CLSN) today announced that it has received Clinical Trial Application (CTA) approval from the China Food and Drug Administration (CFDA) to conduct the ongoing Phase III OPTIMA Study at clinical sites in China. The OPTIMA Study is the Company's global pivotal, double-blind, placebo-controlled trial, evaluating ThermoDox®,Â Celsion'sÂ proprietary heat-activated liposomal encapsulation of doxorubicin, in combination with radiofrequency ablation standardized to 45 minutes (sRFA) versus sRFA alone to treat patients with primary liver cancer, also known as hepatocellular carcinoma (HCC).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.Â

"The OPTIMA Study is the only global Phase III clinical trial being conducted in HCC, and the China market is an important element of our global development strategy for ThermoDox®, representing approximately 50% of the 850,000 new cases of primary liver cancer diagnosed each year," noted Michael H. Tardugno,Â Celsion'sÂ chairman, president and chief executive officer. "We believe that this approval by the China FDA represents another important validation of our development program for ThermoDox®, which shows the potential for improvement in overall survival in HCC patients. This approval also positions us as a leader in research in a major global market for primary liver cancer," Mr. Tardugno said.

The Phase III 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. The CTA approval will now allow Celsion to enroll patients at up to 25 additional clinical sites in China. With the addition of these Chinese clinical sites, the Company expects to complete enrollment in the OPTIMA Study by the end of 2017. Results from the OPTIMA Study, if successful, will provide the basis for a global registration filing and marketing approval.

The primary endpoint for the OPTIMA Study is overall survival (OS). The statistical plan calls for two 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 OS in the ThermoDox® plus standardized RFA arm was approximately 80 months, which is considered a curative treatment for HCC.

"There is significant interest in the curative potential for ThermoDox® among leading liver cancer experts in China and the world, and we have a number of highly-motivated sites eager to enroll patients in this important study," Mr. Tardugno added. "We are aggressively recruiting patients worldwide, and look forward to building our relationships with these key study sites in China as the trial progresses."

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.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™. 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; 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 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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