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Celsion Corporation Receives VHP Approval to Initiate OPTIMA Study in Europe

LAWRENCEVILLE, N.J., Nov. 5, 2014 /PRNewswire/ -- Celsion Corporation (NASDAQ: CLSN) announced today that the Phase III OPTIMA Study was approved via Europe's centralized Voluntary Harmonization Procedure (VHP).Â The approval allows Celsion to conduct the OPTIMA Study, its Phase III trial of ThermoDox® in primary liver cancer, also known as hepatocellular carcinoma (HCC), in Europe.Â In addition to Italy, the OPTIMA Study will now include sites in Spain and Germany.Â The OPTIMA Study is the Company's global pivotal, double-blind, placebo-controlled trial, 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 patients with non-resectable HCC lesions. HCC is the largest unmet medical need remaining in oncology with annual incidence over 750,000 and non-resectable RFA candidates representing some 30% of the newly diagnosed patients. The OPTIMA Study is actively recruiting and enrolling patients at sites in the United States, Hong Kong, South Korea, Malaysia and Thailand.Â Additional clinical sites in Canada, Taiwan, and the Philippines are expected to begin recruitment before the end of the year with China FDA (CFDA) regulatory approval to follow in early 2015.Â

"This approval allows us to expand our clinical program into key European countries, a critical element of our strategy to ensure study participation and thought leader support in major liver cancer markets worldwide," said Michael H. Tardugno,Â Celsion'sÂ Chairman, President and Chief Executive Officer. *Â* "We are aggressively recruiting patients at sites in North America and the Asia Pacific region, and continue to pursue additional clinical trial application approvals in other key markets to further support this global trial."

The Phase III OPTIMA Study is expected to enroll up to 550 patients globally, in up to 100 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 sites for treating lesions 3 to 7 centimeters, versus standardized RFA alone. The primary endpoint for the trial is overall survival (OS), which is supported by post-hoc analysis of data from the Company's 701 patient HEAT Study, where optimized RFA has demonstrated 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. The pipeline also includes EGEN-001, a DNA-based immunotherapy for the localized treatment of ovarian and brain cancers.Â Celsion has three 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; 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 or the possible failure to make such acquisitions or licenses; 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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