Celsion Advances Global Regulatory Efforts in Support of Pivotal Phase III OPTIMA Study of ThermoDox® in Primary Liver Cancer

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LAWRENCEVILLE, N.J., May 21, 2014 /PRNewswire/ -- Celsion Corporation (NASDAQ: CLSN) today announced it has received regulatory clearance to initiate its Phase III OPTIMA Study at clinical trial sites in Taiwan, Hong Kong, South Korea and Canada. The OPTIMA Study is the Company's planned global pivotal, double-blind, placebo-controlled study evaluating ThermoDox®, its proprietary heat-activated liposomal encapsulation of doxorubicin in combination with radiofrequency ablation (RFA), in primary liver cancer, also known as hepatocellular carcinoma (HCC).

In addition, the Company continues to advance its global regulatory strategy and has filed Clinical Trial Applications in the Philippines and Thailand, as well as a request for a Voluntary Harmonization Procedure (VHP) in Europe, which provides for the assessment of multinational clinical trial applications across several European countries, including Germany, France and Spain. As previously reported, the Company has submitted an Application for Accelerated Trial Approval to the China Food and Drug Administration (CFDA). The Company also plans to expand its clinical site footprint in Europe and will meet with the European Medicines Agency (EMA) during 2014 to discuss ThermoDox trial design and registrational strategy.

"We are building momentum with our global regulatory efforts and establishing paths to approval in critical liver cancer markets worldwide," said Michael H. Tardugno, Celsion's President and Chief Executive Officer. "Following U.S. FDA clearance for the OPTIMA Study earlier this year and with the strong support of the HCC research community, we have been accelerating our efforts in support of clinical trial sites in the other major markets including China, Asia Pacific and the European Union, and are well positioned to enroll our first patient mid-year 2014."

The Phase III OPTIMA Study is expected to enroll 550 patients globally, with up to 100 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 dedicated to the development and commercialization of innovative cancer drugs, including tumor-targeting treatments using focused heat energy in combination with heat-activated liposomal drug technology. Celsion has research, license or commercialization agreements with leading institutions, including the National Institutes of Health, Duke University Medical Center, University of Hong Kong, the University of Pisa, the UCLA Department of Medicine, the Kyungpook National University Hospital, the Beijing Cancer Hospital and the University of Oxford. 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; HEAT Study data is subject to further verification and review by the HEAT Study Data Management Committee; 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. 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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