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Celsion Announces FDA Clearance of the OPTIMA Study - A Pivotal Phase III Trial of ThermoDox in Primary Liver Cancer

Study Developed in Consultation with Clinical Advisors, Statistical Experts and FDA
Compelling Survival Data Supports Development
Trial Advances Global Regulatory Strategy in Key Markets

LAWRENCEVILLE, N.J., Feb. 24, 2014 /PRNewswire/ -- Celsion Corporation (NASDAQ: CLSN) announced today that the U.S. Food and Drug Administration (FDA) has reviewed and provided clearance for the Company's planned pivotal, double-blind, placebo-controlled Phase III trial of ThermoDox®, its proprietary heat-activated liposomal encapsulation of doxorubicin in combination with radio frequency ablation (RFA) in primary liver cancer, also known as hepatocellular carcinoma (HCC). The trial design is based on a comprehensive analysis of data from the Company's Phase III HEAT Study, which demonstrated that treatment with ThermoDox resulted in a 55% improvement in overall survival in a substantial number of HCC patients that received an optimized RFA treatment.Â Celsion expects to launch the study in the first half of 2014.

The Phase III trial, known as the OPTIMA Study, was designed with extensive input from globally recognized HCC researchers and clinicians, and after formal consultation with FDA. The 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 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).Â The statistical plan calls for two interim efficacy analyses by an independent Data Monitoring Committee (iDMC).

"ThermoDox appears to hold great promise as a first-line treatment when used in combination withÂ optimized RFA, for primary liver cancer, one of the most deadly and prevalent forms of cancer worldwide," stated Nicholas Borys, MD, Celsion's Chief Medical Officer. "Consistency of the retrospective data emerging from the HEAT Study over the past year has been remarkable, and underscores the potential of ThermoDox to extend survival in primary liver cancer patients. Now informed by critical insights from our HEAT Study, I am confident that the OPTIMA Study is robust, well-designed and well-supported by HCC researchers worldwide.Â We look forward to initiation and timely completion of this important study."

As reported in January 2014, post-hoc data from the Company's Â HEAT Study demonstrate that the patient subgroup in the ThermoDox arm whose RFA procedure lasted longer than 45 minutes (285 patients or 63% of single lesion patients), experienced a 55% improvement in overall survival, with a Hazard Ratio of 0.64 (95% CI 0.41 - 1.00) and a P-value = 0.0495. Median overall survival for this subgroup has not yet been reached. Celsion will continue to follow patients in the HEAT Study on a quarterly basis.

"FDA allowance of the Phase III OPTIMA Study represents a significant step forward in our global development strategy for ThermoDox and establishes a clear regulatory pathway that advances our goal of delivering a new treatment option to patients with this devastating and underserved disease," stated Michael H. Tardugno, Celsion's President and CEO. "In parallel with our efforts in the United States, we continue to advance discussions with regulators in other important global markets, including a recent positive meeting with China FDA (CFDA) and near-term plans to meet with European regulatory authorities."Â

In support of the Company's global regulatory efforts, Celsion recently met with CFDA to discuss the Phase III trial, including minimum patient enrollment requirements supporting ThermoDox's registration in China. Based on those discussions, Celsion is submitting an application for accelerated approval of the study in China. Celsion will expand its clinical site footprint in Europe and plans to meet with the European Medicines Agency (EMA) in the first half of 2014.

The HEAT Study and prior post-hoc analyses were presented at three medical conferences in 2013, including the World Conference on Interventional Oncology in May; the European Conference on Interventional Oncology in June and the International Liver Cancer Association Annual Conference in September.Â Presentations were made by some of the most highly recognized liver cancer researchers and key HEAT Study investigators. Â Quarterly overall survival data analyses have been conducted with the full support of these researchers and clinical investigators.

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.Â 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.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; 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.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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