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Celsion Corporation Initiates Development Program for Glioblastoma Brain Tumors with ThermoDox® and HIFU

Preclinical Studies Initiated at Brigham and Women's Hospital, Harvard Medical School

LAWRENCEVILLE, N.J., Jan. 21, 2014 /PRNewswire/ -- Celsion Corporation (NASDAQ: CLSN), a leading oncology drug development company, announced today that the company is formalizing a program to pursue the development of ThermoDox® to investigate applications for treating brain cancer tumors, notably Glioblastoma Multiforme or GBM.Â In addition to jointly submitting multiple grant applications, the company is also pursuing preclinical studies in collaboration with Dr. Costas D. Arvanitis at the Brigham and Women's Hospital and Harvard Medical School.Â Experiments will study the use of ThermoDox in combination with MR guided High Intensity Focused Ultrasound (HIFU) to treat brain tumors, initially in animal models.Â

"Brain cancer tumors represent a very high unmet medical need, and researchers have been pursuing applications with HIFU for many years," said Nicholas Borys, MD, Celsion's Chief Medical Officer.Â "We are excited to investigate the addition of ThermoDox, our heat-activated liposomal encapsulation of doxorubicin, which could provide some clinical benefit for a population that desperately needs more applications."

Dr. Arvanitis, research fellow at Brigham and Women's Hospital and Harvard Medical School stated, "We have investigated the use of MR-guided focused ultrasound to treat brain tumors for many years and have identified the need for drugs that will improve our ability to treat brain tumors. We are excited about this drug design, which is positioned to work with heat and specifically HIFU, and its potential to cross the blood-brain barrier and potentially demonstrate drug concentration in ways that other drugs cannot. We are grateful for Celsion's support in this research and look forward to pursuing this initial, pre-clinical research with the hope of bringing this application to the clinic in the future."

About Glioblastoma Multiforme (GBM) Brain Tumors

Glioblastoma multiforme (GBM), WHO classification name "glioblastoma", is the most common and most aggressive malignant primary brain tumor in humans, involving glial cells and accounting for over 50% of all functional tissue brain tumor cases and nearly 20% of all intracranial tumors.Â In 2013, projected US incidence of brain tumors approaches 23,000 cases, with projected mortality at 14,000. Treatment can involve chemotherapy, radiation and surgery. Median survival with standard-of-care radiation and chemotherapy is normally 15 months, andÂ Median survival without treatment is approximately 4½ months.

About ThermoDox®

ThermoDox® is a proprietary heat-activated liposomal encapsulation of doxorubicin, an approved and frequently used oncology drug for the treatment of a wide range of cancers. In the HEAT Study, ThermoDox® is administered intravenously in combination with RFA. Localized mild hyperthermia (39.5 - 42 degrees Celsius) created by the RFA releases the entrapped doxorubicin from the liposome. This delivery technology enables high concentrations of doxorubicin to be deposited preferentially in a targeted tumor.

For primary liver cancer, ThermoDox® is being evaluated in a 701 patient global Phase III study at 79 clinical sites under an FDA Special Protocol Assessment. The study is designed to evaluate the efficacy of ThermoDox® in combination with RFA when compared to patients who receive RFA alone as the control. On January 31, 2013, Celsion announced that ThermoDox® in combination with RFA did not meet the primary endpoint of the HEAT study in patients with hepatocellular carcinoma, also known as primary liver cancer.Â Celsion has conducted a comprehensive analysis of the data from the Phase III HEAT Study with key principal investigators, data experts and liver cancer experts.Â Emerging data from the HEAT Study post hoc analysis demonstrates that ThermoDox® markedly improves PFS and overall survival in patients if their lesions undergo RFA for 45 minutes or more.Â These findings apply to HCC lesions from both size cohorts of the HEAT Study (3-5 cm and 5-7 cm) and represent a sizable subgroup of approximately 300 patients.

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 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; termination of the Technology Development Contract or collaboration between Celsion and HISUN at any time; 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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