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FDA Clears Celsion to Initiate Clinical Trials for the Use of ThermoDox with RFA in the Treatment of Liver Cancer

COLUMBIA, Md.--(BUSINESS WIRE)--Aug. 31, 2004--CELSION CORPORATION (AMEX:CLN) today announced that the Food and Drug Administration (FDA) will allow the human clinical trial for its investigational therapy for the treatment of liver cancer to proceed. The Phase I study will investigate the use of Celsion's proprietary product, ThermoDox™, in combination with Radiofrequency Ablation (RFA). ThermoDox, Celsion's temperature-sensitive liposomal encapsulation of doxorubicin, a common cancer drug, allows focused, concentrated delivery of the drug to the tumor target.

The trial will be conducted at the National Institutes of Health (NIH) Clinical Center in Bethesda, Maryland and will be funded under a Collaborative Research and Development Agreement between Celsion and NIH. Under the agreement, Celsion will supply ThermoDox and provide regulatory and clinical support and NIH will enroll and treat the patients.

The trial is designed to determine the maximum safely tolerated dose and pharmacokinetic profile of ThermoDox when used in combination with RFA in the treatment of liver cancer. The study approach will utilize RFA (80 degrees celsius or above) to ablate (destroy) the center of the tumor and the lower temperature zone (greater than 40 degrees celsius) in the tumor margins to activate and release the doxorubicin to kill any remaining viable cancer cells. Celsion hopes to commence the study before the end of the year.

The clinical plans for liver cancer rely, in part, on the preclinical results of the work conducted in large animals by the FDA in conjunction with NIH. These results were presented by Dr. Bradford J. Wood, Senior Clinical Investigator, Diagnostic Radiology Department, Imaging Sciences Program, NIH Clinical Center; Surgery Branch, National Cancer Institute, at the National Institutes of Health at the 89th Annual Radiological Society of North America (RSNA) in December 2003. These results demonstrated that ThermoDox, used in this manner, deposited fifteen times more drug at the tumor site than conventional, intravenous delivery of doxorubicin.

Dr. Augustine Cheung, Celsion's President and Chief Executive Officer said, "Initiating this study is a major step in the evolution of Celsion from a medical device company to a company focused on targeted drug delivery using combination therapies. We believe that the mechanism of action of RFA in conjunction with ThermoDox, using heat-sensitive nanoparticles to target ThermoDox, could result in high deposits of the encapsulated drug, doxorubicin, in the tumor, thus ablating the tumor as well as viable cancer cells in the tumor margin. This may lead to a significant reduction of local tumor recurrence, which is currently the major limitation in using RFA alone to treat liver cancer."

Tony Deasey, Celsion's Chief Operating Officer, added, "Clearance to initiate this study enables us to attempt to address a significant unmet medical need by treating liver cancer. This trial increases our cancer treatment portfolio, building upon our ongoing Phase I trial using ThermoDox to treat prostate cancer in conjunction with Celsion's proprietary microwave heating technology (Prolieve™) and further establishes Celsion as a leader in the area of heat-activated drug therapy for the treatment of cancer."

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About Celsion: Celsion Corporation, based in Columbia, Maryland, is a biotechnology company dedicated to the development and commercialization of treatment systems for cancer and other diseases using focused-heat energy, either administered alone, or in combination with other therapeutic devices, heat-activated genes or heat-activated drugs.

Celsion has research, license or commercialization agreements with leading institutions such as the National Institutes of Health, Duke University Medical Center, Massachusetts Institute of Technology, Harbor UCLA Medical Center, Montefiore Medical Center and Memorial Sloan-Kettering Cancer Center in New York City, Roswell Park Cancer Institute in Buffalo, New York and Duke University. For more information on Celsion, visit our website: 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 by others; possible acquisitions of other technologies, assets or businesses; possible actions by customers, suppliers, competitors, regulatory authorities; and other risks detailed from time to time in the Company's periodic reports filed with the Securities and Exchange Commission.

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