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Celsion Treats First Patient in Phase I Clinical Trial of ThermoDox with Heat for Liver Cancer

COLUMBIA, Md., Feb 16, 2005 (BUSINESS WIRE) -- Celsion Corporation (AMEX:CLN) today announced that it has treated the first patient in its Phase I clinical trial to investigate the use of ThermoDox™ in combination with Radio Frequency Ablation (RFA) for liver cancer. 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 Phase I trial, which is being conducted at the National Institutes of Health (NIH) Clinical Center in Bethesda, Maryland, is designed to determine the safe maximum tolerated dose and pharmacokinetic profile of systemically delivered ThermoDox administered in combination with RFA in the treatment of liver lesions. The investigational combination technology is designed to utilize an FDA-approved RFA device to ablate (destroy) the center of the tumor and to thermally activate the ThermoDox liposome to release its encapsulated doxorubicin to kill remaining viable cancer cells throughout the heated area, including the tumor margins.

Dr. Augustine Cheung, Celsion's President and Chief Executive Officer said, "We are very excited to have treated this patient. This is the first step in Celsion's clinical plan to develop and commercialize ThermoDox as a heat-activated cancer drug for liver cancer treatment. We believe that the mechanism of action of RFA in conjunction with ThermoDox could result in the ablation of the tumor as well as viable cancer cells in the tumor margins. Effective destruction of cancer cells in the tumor margins may lead to a significant reduction in local tumor recurrence, which is the major limitation of RFA alone in treating liver cancer."

Dr. Cheung continued, "We believe that liver cancer presents a significant opportunity for Celsion. Although the incidence of primary liver cancer in the U.S. is relatively low, presently, approximately 11,000 cases per year, the global incidence is estimated to be as much as 500,000 cases annually, with nearly an equivalent number of deaths. These worldwide cases are concentrated in Asia, particularly in China."

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 in combination with other therapeutic devices, heat-activated genes and 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: 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 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.

SOURCE: Celsion Corporation

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