



## **Celsion and Yakult Honsha Announce Start-up of Japanese Clinical Trial Sites in Celsion's Global Phase III ThermoDox(R) Trial for Primary Liver Cancer**

COLUMBIA, Md., Jul 27, 2009 (BUSINESS WIRE) -- Celsion Corporation (NASDAQ: CLSN) and Yakult Honsha Co., Ltd. (Tokyo: 2267) announced today that Celsion's global Phase III ThermoDox trial for the treatment of primary liver cancer will be extended to Japan by Yakult's expertise. This is an important step towards a potential application to market the drug in Japan. Yakult Honsha is the exclusive licensor of Celsion's ThermoDox in Japan.

"We are proud to announce that Yakult will initiate trial sites and begin patient enrollment in Japan for our Phase III liver cancer trial, and we look forward to working with Yakult," stated Michael H. Tardugno, President and Chief Executive Officer. "The extension of our PIII study to Japan will enable us to accelerate patient enrollment in the trial and has the potential to decrease the time to market in Japan."

"Japan has the highest rate of liver cancer in industrialized countries," said Dr. Kiyoshi Terada, Head, Pharmaceutical Division/Senior Managing Director, Member of the Board of Yakult Honsha. "Given there are limited effective treatment options for these patients, we are pleased to have the opportunity to provide ThermoDox to them in the clinical trial setting,"

Under the license agreement between Celsion and Yakult, Yakult is financially responsible for the patients enrolled in clinical trials in the Japanese sites and all the data generated in Japan will be jointly owned by Celsion and Yakult and can be used by Celsion to support regulatory filings in territories outside of Japan.

Additional information on Celsion's Phase III ThermoDox trial for primary liver cancer can be found at <http://www.clinicaltrials.gov/>

### **About ThermoDox**

ThermoDox in combination with hyperthermia has the potential to provide local tumor control and improve quality of life. 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 including breast cancer. Localized mild hyperthermia (40-42 degrees Celsius) releases the entrapped doxorubicin from the liposome. This delivery technology enables high concentrations of doxorubicin to be deposited preferentially in a targeted tumor.

ThermoDox has also demonstrated evidence of efficacy in a Phase I study for primary liver cancer. Celsion has been granted FDA Orphan Drug designation for ThermoDox and is conducting a pivotal global Phase III study in primary liver cancer under a FDA Special Protocol Assessment.

*ThermoDox(R) is a registered trademark of Celsion Corporation*

### **About Primary Liver Cancer**

Primary liver cancer is one of the most deadly forms of cancer and ranks as the fifth most common solid tumor cancer. The incidence of primary liver cancer is approximately 20,000 cases per year in the United States and is rapidly growing worldwide at approximately 1,000,000 cases per year, due to the high prevalence of Hepatitis B and C in developing countries. The standard first line treatment for liver cancer is surgical resection of the tumor, however 80% to 90% of patients are ineligible for surgery. Radio frequency ablation (RFA) has increasingly become the standard of care for non-resectable liver tumors, but the treatment becomes less effective for larger tumors. There are few non-surgical therapeutic treatment options available as radiation therapy and chemotherapy are largely ineffective in the treatment of primary liver cancer.

### **About Yakult**

Yakult is a leading Japanese company focused on the development and marketing of pharmaceuticals, foods, beverages, and cosmetics with an emerging presence in oncology. For more information on Yakult, visit: [www.yakult.co.jp](http://www.yakult.co.jp) or view the following company profile:

<http://www.yakult.co.jp/english/pdf/profile2008-2009.pdf>

## About Celsion

Celsion is dedicated to the development and commercialization of innovative oncology drugs including tumor-targeting treatments using focused heat energy in combination with heat-activated drug delivery systems. Celsion has licensed ThermoDox(R) to Yakult-Honsha for the Japanese market and has a partnership agreement with Phillips Medical to jointly develop its heat activated liposomal technology in combination with high intensity focused ultrasound to treat difficult cancers. Celsion has research, license, or commercialization agreements with leading institutions such as the National Institutes of Health, Duke University Medical Center, University of Hong Kong, Cleveland Clinic, and the North Shore Long Island Jewish Health System.

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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