



Celsion and Yakult Honsha Announce Treatment of First Patient in Japan in Celsion's Global Phase III ThermoDox(R) Trial for Primary Liver Cancer

COLUMBIA, Md., Oct 27, 2009 (BUSINESS WIRE) -- Celsion Corporation (NASDAQ: CLSN) and Yakult Honsha Co., Ltd. (Tokyo: 2267) announced today that the first patient has been enrolled and treated in Japan as part of Celsion's global Phase III ThermoDox HEAT trial for the treatment of hepatocellular carcinoma (HCC), the most common form of primary liver cancer.

Yakult is the exclusive licensee of Celsion's ThermoDox for the Japanese territory and is responsible for funding clinical trials in Japan and obtaining regulatory and marketing approval. The clinical data from the Japanese cohort will be incorporated into Celsion's overall ThermoDox Phase III study results and is also intended to support a potential marketing approval submission by Yakult in Japan.

"Yakult's rapid start up of clinical sites and the enrollment of the first Japanese patient is a testament to their oncology expertise and strong commitment to commercialize ThermoDox in Japan," stated Michael H. Tardugno, Celsion's Chief Executive Officer. "With Yakult's recent decision for participation to the study to include Japanese sites we expect to see an acceleration of patient enrollment and the potential to significantly decrease ThermoDox's time to market in Japan should the data support registration."

"ThermoDox holds the potential to become a significant drug in our pharmaceutical portfolio and an important addition to our oncology franchise," stated Dr. Kiyoshi Terada, Head, Pharmaceutical Division/Senior Managing Director, and Member of the Board of Yakult. "Yakult's decision to invest in ThermoDox was based on the remarkable evidence of clinical activity demonstrated in early stage clinical trials. ThermoDox holds great promise for those afflicted with HCC, as currently there is no chemotherapeutic standard of care."

ThermoDox Global Phase III HCC Study

The global Phase III HCC study is evaluating the safety and efficacy of ThermoDox in combination with radiofrequency ablation (RFA) when compared to RFA alone. The trial will enroll up to six hundred patients at clinical sites in Japan, China, Malaysia, Thailand, Philippines, Hong Kong, Korea, Taiwan, Italy, the United States and Canada. By year-end 2009, Celsion expects to have up to sixty clinical sites activated and patient enrollment is expected to complete within the first half of 2010. Additional information can be found at: <http://www.clinicaltrials.gov/>

About Primary Liver Cancer

Primary liver cancer is a type of cancer that begins in the cells of the liver and is not typically detected early, often resulting in a poor patient prognosis. According to the National Cancer Center of Japan, primary liver cancer is the third leading cause of cancer deaths in Japan among adults and more than 40,000 people are diagnosed with the disease annually. Globally, 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 660,000 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, but 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 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 demonstrated evidence of efficacy in a Phase I study for primary liver cancer. Celsion has been granted FDA Orphan Drug designation for the primary liver indication and the global Phase III study is being conducted under a FDA Special Protocol Assessment. For recurrent chest wall breast cancer, ThermoDox(R) is being evaluated in a pivotal Phase I/II open-label, dose-escalating trial that is designed to measure durable local complete response at the tumor site. Celsion expects to

enroll approximately 100 patients in the U.S. within calendar year 2010

ThermoDox(R) is a registered trademark of Celsion Corporation

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/english/index.html or view the following company profile: <http://www.yakult.co.jp/english/top.html>

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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