



Celsion's Global Phase III ThermoDox(R) Trial Approved by SFDA in China

ThermoDox Clinical Trial for Primary Liver Cancer Expanded to China

COLUMBIA, Md., Oct 15, 2009 (BUSINESS WIRE) -- Celsion Corporation (NASDAQ: CLSN) announced today that it has received official approval from China's State Food and Drug Administration ("SFDA") for its Clinical Trial Application for ThermoDox that permits Celsion to include Chinese clinical trial sites in its Phase III ThermoDox HEAT trial for the treatment of primary liver cancer, also known as hepatocellular carcinoma (HCC).

Celsion's global Phase III ThermoDox(R) clinical trial is evaluating the efficacy and safety of ThermoDox in combination with radiofrequency ablation (RFA) when compared to RFA alone. The trial will enroll up to six hundred patients and is currently being conducted in Japan, Hong Kong, Korea, Taiwan, Italy, the United States and Canada. In addition to China, Celsion expects to receive CTA acceptance in Thailand, Malaysia, and the Philippines during the fourth quarter of 2009 and will have up to sixty sites activated by the end of the year. Completion of patient enrollment is expected to occur in the first half of 2010.

"Acceptance of our CTA in China is an important milestone for Celsion because China represents a significant market opportunity for ThermoDox", stated Michael H. Tardugno, Celsion's President and Chief Executive Officer. "The incidence of HCC in China is growing faster than any other country at over 350,000 patients per year (55% of world's total incidence) and the use of RFA is becoming the standard of care for the treatment of early-stage HCC. Concurrent with sFDA's review of our application, we have identified and qualified rapid start-up sites in China which should enable patient enrollment to commence in the near-term. The expansion of the trial to China not only accelerates patient enrollment, but builds on our global strategy to conduct our Phase III trial in regions where the incidence of HCC is significant. Our goal is to enroll patients in key markets outside of the United States to facilitate regulatory approval in multiple countries, mainly East Asia, where the incidence is among the highest in the world."

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 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 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. 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 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

Celsion Corporation
Sean Moran, 410-290-5390
Senior Vice President and Chief Financial Officer
smoran@celsion.com

or
The Trout Group
Marcy Nanus, 646-378-2927
mnanus@troutgroup.com

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