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Celsion's Global Phase III ThermoDox(R) Trial Expands to Malaysia and the Philippines

ThermoDox's global footprint covers all major HCC markets

COLUMBIA, Md., Oct 19, 2009 (BUSINESS WIRE) -- Celsion Corporation (NASDAQ: CLSN) announced today that it has received approval from the regulatory agencis in the Philippines and Malaysia for its Pivotal Phase III primary liver cancer Clinical Trial Application.

Celsion's global Phase III 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 China, Japan, Hong Kong, Korea, Taiwan, Italy, the United States and Canada. Expansion of the trial to the Philippines and Malaysia provides assurance that the trial will be enrolled in an efficient and timely manner. With recently announced CTA approval by the Chinese sFDA and imminent agreement by the Thai FDA, Celsion expects to have 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 by the Philippine and Malaysian regulatory authorities provides Celsion with trial agreements in key countries where primary liver cancer is most prevalent. We have again posted a significant milestone and are executing against our strategy to conduct our Phase III HCC study in a manner that will provide basis for NDA submissions in regions where liver cancer is endemic," stated Michael H. Tardugno, Celsion's President and Chief Executive Officer. "We now successfully secured regulatory authorization in 10 of 11 targeted countries covering approximately 80% of the world's HCC population. With the incidence of HCC growing at a reported 5% annually, the World Health Organization projects it to be the world's #1 cancer by 2020."

Mr. Tardugno concluded, "With RFA emerging as the global first line treatment for early stage HCC; ThermoDox's potential to improve the efficacy of this cost effective procedure provides Celsion with a significant ready made market. Our goal is to provide the promise of our tumor targeting anti-cancer technology to HCC patients with few options as rapidly as possible."

About Primary Liver Cancer

Mortality among primary liver cancer patients is one of the world's highest and ranks as the fifth most common solid tumor cancer. The incidence of primary liver cancer in the USA is approximately 20,000 cases per year and is rapidly growing worldwide. Globally there are approximately 660,000 cases per year, with the major risk factor being Hepatitis B and C in high prevalence in developing countries. The standard first line treatment for liver cancer is surgical resection of the tumor, but 70% to 80% of patients are ineligible for surgery. Radio frequency ablation (RFA) has increasingly become the standard of care for non-resectable liver 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. . Celsion is evaluating it's lead drug, ThermoDox, in combination with RFA to improve the rang and efficacy of the procedure.

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

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.

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