



Celsion Provides Update on Its Global Pivotal Phase III Primary Liver Cancer Trial

COLUMBIA, Md., Sep 24, 2008 (BUSINESS WIRE) -- CELSION CORPORATION (NASDAQ: CLSN) announced today that its global Phase III Primary Liver Cancer trial is proceeding as planned. In addition to the receipt of FDA agreement in January of 2008 for our pivotal Phase III Primary Liver Cancer trial in the United States, the Company reports that it has obtained regulatory approval to conduct its study titled "A Phase III, Randomized, Double-Blinded, Dummy-Controlled Study of the Efficacy and Safety of ThermoDox(R) (Thermally Sensitive Liposomal Doxorubicin) in Combination with Radiofrequency Ablation (RFA) Compared to RFA Alone in the Treatment of Non-Resectable Hepatocellular Carcinoma (HCC)" in Hong Kong, Taiwan, Korea, Canada, and Italy, and anticipates that a Clinical Trial Agreement will be obtained in China before the end of 2008. In addition, Celsion reports that site initiation and patient enrollment are tracking well against its most recent projections.

Mr. Michael H. Tardugno, Celsion's President and Chief Executive Officer commented, "Since receiving agreement from the FDA through SPA guidance for our pivotal trial in January, Celsion has accomplished its key milestones related to its development initiatives. Gaining regulatory agreement for our study in six countries represents another significant milestone for the Company and speaks to the commitment and capability of our Clinical and Regulatory team. Additionally, our progress provides us with continued confidence that Celsion has the financial resources to fund our Phase III primary liver cancer study to a point where we have sufficient results to determine if there is support for an NDA filing."

"Celsion remains focused on efficiently conducting and completing our pivotal liver cancer study and we believe that advancing our platform technology is within our financial means," continued Mr. Tardugno. "The Company is evaluating improvements to its platform heat sensitive liposome technology, as well as demonstrating feasibility for additional formulations, including liposomal docetaxel. Moreover, we continue to make progress in accelerating our Recurrent Chest Wall (RCW) cancer trial and anticipate initiating our Pivotal Phase II study before the end of this year."

In a related event, Celsion reports that Yakult Honsha is proceeding with its plans to initiate a clinical program in Japan to study ThermoDox(R) for the treatment of primary liver cancer. As announced in earlier press releases, Yakult will commence pre-clinical and clinical studies of ThermoDox(R) to support requirements for drug registration in Japan. Celsion and Yakult have executed a letter of intent relating to the commercialization of ThermoDox(R) for the Japanese markets subject to the execution of definitive agreements.

About ThermoDox(R): ThermoDox(R) is Celsion's proprietary heat-sensitive liposomal encapsulation of doxorubicin, an approved and frequently used anti-cancer drug used in the treatment of various cancers. Localized heat (at 40-42 degrees Celsius and above) releases the entrapped doxorubicin from the liposome. This delivery technology enables high concentrations of doxorubicin to be deposited preferentially in a targeted tumor.

About Celsion: Celsion is dedicated to the development and commercialization of oncology drugs including tumor-targeting treatments using focused heat energy in combination with heat-activated drug delivery systems. 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, 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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