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Celsion and myTomorrows Expand ThermoDox® European Early Access Program to Include Patients with Primary Liver Cancer and Liver Cancer Metastases

LAWRENCEVILLE, N.J., Aug. 10, 2015 /PRNewswire/ -- Celsion Corporation (NASDAQ: CLSN), an oncology drug development company, today announced that it has expanded its Early Access Program (EAP) for lyso-thermosensitive liposomal doxorubicin (LTLD), referred to by Celsion as ThermoDox®, with myTomorrows to include patients with primary liver cancer, also known as hepatocellular carcinoma (HCC) and liver cancer metastases, in all countries of the European Union (EU) territory, Switzerland, Turkey and Israel.Â The Company's original European EAP with myTomorrows, formed in January 2015, provides eligible patients with access to LTLD for the treatment of recurrent chest wall (RCW) breast cancer.Â The EAP for LTLD was launched in the second quarter. LTLD is Celsion's proprietary heat-activated liposomal encapsulation of doxorubicin, known as ThermoDox®.

The expanded EAP is based, in part, on data from Celsion's Phase III HEAT study of ThermoDox® in HCC. As of July 15, 2015, the latest overall survival (OS) analysis demonstrated that in a large, well bounded, subgroup of patients (n=285, 41% of the HEAT study patients), the combination of ThermoDox® and optimized RFA provided a 58% improvement in OS compared to optimized RFA alone. The Hazard Ratio at this analysis is 0.63 (95% CI 0.43 - 0.93) with a p-value of 0.0198.Â Median Overall Survival for the ThermoDox® group has been reached which translates into a 25.4 month (2.1 year) survival benefit over the optimized RFA only group (79 months for the ThermoDox® plus optimized RFA group versus 53.6 months for the optimized RFA only group).

"The survival data from the large subgroup of patients in our HEAT study provides strong support for the expansion of the LTLD EAP into this patient population that has limited treatment options," stated Dr. Nicolas Borys, Celsion's senior vice president and chief medical officer.Â "We will be working closely with myTomorrows to set up the EAP in this indication."

EAPs allow biopharmaceutical companies to provide eligible patients with ethical access to investigational medicines for unmet medical needs within the scope of the existing early access legislation.Â Access is provided in response to physician requests in a fully compliant manner, where no alternative treatment options are available to these patients.Â Celsion will provide LTLD in the EU, Switzerland, Turkey and Israel through myTomorrows. The Company expects to have LTLD available for HCC in the second half of 2015.

"This expansion of our EAP in liver cancer reflects our commitment to provide access to patients in desperate need of new treatment options," said Michael H. Tardugno, Celsion's chairman, president and chief executive officer. "We have been pleased with establishing our Early Access Program in RCW breast cancer, and look forward to being able to provide expanding access to patients with HCC and liver metastases consistent with our goal of providing effective therapies which may significantly prolong and improve the quality of life.Â In parallel with this EAP, we are also continuing to focus on enrolling patients in our global Phase III OPTIMA study in HCC designed to support registration in key markets worldwide.Â We have expanded our HCC clinical development footprint with the addition of 17 clinical sites in Spain, Germany and Italy."

About LTLD

Lyso-Thermosensitive Liposomal Doxorubicin (LTLD) 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. LTLD is being evaluated in a Phase III clinical trial for primary liver cancer and a Phase II clinical trial for recurrent chest wall breast cancer.Â Localized mild hyperthermia (39.5 - 42 degrees Celsius) releases the entrapped doxorubicin from the liposome.Â This delivery technology enables high concentrations of doxorubicin to be deposited preferentially in a targeted tumor.

About myTomorrows

myTomorrows is an online patient platform that is creating freedom of choice for patients with unmet medical needs by offering earlier access to medicines that show promising results during clinical trials, but are not officially registered yet. With the support of their doctors, patients who suffer from cancer, a neurological disorder, a rare disease or a severe depression, can have earlier access to such medicines. For more information about myTomorrows, please visit the website www.mytomorrows.com.

About Celsion Corporation

Celsion is a fully-integrated oncology company focused on developing a portfolio of innovative cancer treatments, including directed chemotherapies, immunotherapies and RNA- or DNA-based therapies. The Company's lead program is ThermoDox®, a proprietary heat-activated liposomal encapsulation of doxorubicin, currently in Phase III development for the treatment of primary liver cancer and Phase II for the treatment of recurrent chest wall breast cancer. The pipeline also includes GEN-1, a DNA-based immunotherapy for the localized treatment of ovarian and brain cancers.Â Celsion has three platform technologies for the development of novel nucleic acid-based immunotherapies and other anti-cancer DNA or RNA therapies, including TheraPlas™, TheraSilence™ and RAST™.Â 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.Â 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; the uncertainties of and difficulties in analyzing interim clinical data, particularly in small subgroups that are not statistically significant; FDA and regulatory uncertainties and risks; the significant expense, time, and risk of failure of conducting clinical trials; HEAT Study data is subject to further verification and review by the HEAT Study Data Management Committee; the need for Celsion to evaluate its future development plans; possible acquisitions or licenses of other technologies, assets or businesses or the possible failure to make such acquisitions or licenses; possible actions by customers, suppliers, competitors, regulatory authorities; and other risks detailed from time to time in the Celsion's periodic reports and prospectuses filed with the Securities and Exchange Commission.Â Celsion assumes no obligation to update or supplement forward-looking statements that become untrue because of subsequent events, new information or otherwise

Celsion Investor Contact

Jeffrey W. Church
Sr. Vice President and CFO
609-482-2455
jchurch@celsion.com

Celsion Media Contacts

Harriet ShelareÂ
Director, Communications
hshelare@celsion.com

Bill Berry
Berry & Company
212-253-8881
bberry@berrypr.com

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