November 20, 2017

Celsion Announces Publication of the Study of ThermoDox® + Ultrasound, "TARDOX Study Protocol" in the Journal of Therapeutic Ultrasound

Collaboration with University of Oxford to Execute a Clinical Trial Using Focused Ultrasound and ThermoDox® for Primary and Metastatic Liver Cancer

Presentation of TARDOX Study Phase I Findings at the Upcoming RSNA 2017 Annual Meeting

First Ever Study Evaluating ThermoDox® with Focused Ultrasound in Humans

LAWRENCEVILLE, N.J., Nov. 20, 2017 (GLOBE NEWSWIRE) -- Celsion Corporation (NASDAQ:CLSN) today announced publication of the manuscript, "Clinical trial protocol for TARDOX: a phase I study to investigate the feasibility of targeted release of lyso-thermosensitive liposomal doxorubicin (ThermoDox®) using focused ultrasound in patients with liver tumours," in the *Journal of Therapeutic Ultrasound 2017 5:28*.

The article describes the clinical trial design for the TARDOX Study. This proof of concept study was designed to demonstrate the safety and feasibility of targeted drug release and enhanced delivery of doxorubicin from thermally sensitive liposomes (ThermoDox®) triggered by mild hyperthermia induced by focused ultrasound in primary and metastatic solid liver tumors.

- The primary outcome measures for the study was the direct quantification of the doxorubicin concentration before and after focused ultrasound (FUS) mediated hyperthermia from tumor biopsies, using high performance liquid chromatography (HPLC).
- The secondary outcome measures for the study relate to the safety and feasibility of inducing controlled FUS-mediated targeted hyperthermia in the target tumor non-invasively in order to achieve ThermoDox® release.

The TARDOX Study, which is supported by the National Institute for Health Research (NIHR) Oxford Biomedical Research Centre, was carried out as a multi-disciplinary collaboration between Celsion, the Oxford University Institute of Biomedical Engineering (Prof. Constantin Coussios), the Oncology Clinical Trials Office (OCTO) and the Oxford University Hospitals NHS Foundation Trust (Prof. Fergus Gleeson, Radiology and Prof. Mark Middleton, Oncology). The first author is Dr. Paul Lyon (academic clinical fellow, Oxford University Hospitals NHS Foundation Trust) and the article is available online in the November 2, 2017 issue of the *Journal of Therapeutic Ultrasound:*

https://jtultrasound.biomedcentral.com/articles/10.1186/s40349-017-0104-0

"Both Celsion and Oxford believe there is significant potential when combining ThermoDox® with focused ultrasound to treat a broad range of malignancies, including primary liver cancer," said Michael H. Tardugno, Celsion's chairman, president and chief executive officer. "TARDOX, the ThermoDox®/Focused Ultrasound trial, is an important step in demonstrating that ultrasound-induced hyperthermia can enable the highly targeted delivery of chemotherapeutic agents to tumors non-invasively. This represents another unquestionable example confirming ThermoDox®'s mechanism of action in a clinical setting and further establishes that ThermoDox® may be used with multiple heating technologies allowing for successful targeting of a broad range of primary and metastatic solid tumors with high concentrations of chemotherapy."

The Company also announced that an abstract for the TARDOX Study has been accepted for presentation at the Radiological Society of North America (RSNA) 2017 Annual Meeting which will take place from November 26, 2017 - December 1, 2017 at the McCormick Center in Chicago, IL.

- The abstract, entitled "Clinical Results of a Phase I First in Man Study of Targeted Delivery of Lyso-thermosensitive Liposomal Doxorubicin by Extracorporeal Focused-Ultrasound Hyperthermia for Liver Tumours," will be presented by Dr. Paul Lyon on Monday, November 27, 2017 at 11:40 am (local time) during Vascular Interventional (10-Liver Cancer) Session - Room E352.

- The presentation will summarize clinical findings from all patients treated in the TARDOX Study, a Phase I clinical study of ThermoDox®, Celsion's heat-activated liposomal encapsulation of doxorubicin, in combination with focused ultrasound to treat primary and metastatic liver cancer.

Professor Constantin-C. Coussios, senior author and Director of the Institute of Biomedical Engineering at the University of Oxford, commented, "This clinical program builds upon many years of experience with ultrasound-guided HIFU, as well as laboratory studies of ThermoDox® release by ultrasound, at our institution since 2007. This is the first study in humans to explore extra corporeally triggered drug release and targeted drug delivery in oncology. We look forward to exploring the combination of ThermoDox®, a well-characterized anti-cancer therapy triggered by heat, with focused ultrasound to cause hyperthermia, rather than ablation, non-invasively. We are excited by the potential of this combination to advance treatment within a significantly underserved population."

About ThermoDox®

Celsion's most advanced program is a heat-mediated, tumor-targeting drug delivery technology that employs a novel heat-sensitive liposome engineered to address a range of difficult-to-treat cancers. The first application of this platform is ThermoDox®, a lyso-thermosensitive liposomal doxorubicin (LTLD), whose novel mechanism of action delivers high concentrations of doxorubicin to a region targeted with the application of localized heat at 40°C, just above body temperature. In one of its most advanced applications, ThermoDox®, when combined with radiofrequency thermal ablation (RFA), has the potential to address a range of cancers. For example, RFA in combination with ThermoDox® has been shown to expand the "treatment zone" with a margin of highly concentrated chemotherapy when treating individual primary liver cancer lesions. The goal of this application is to significantly improve efficacy.

Celsion's LTLD technology leverages two mechanisms of tumor biology to deliver higher concentrations of drug directly to the tumor site. The first: Rapidly growing tumors have leaky vasculature, which is permeable to liposomes and enables their accumulation within tumors. Leaky vasculature influences a number of factors within the tumor, including the access of therapeutic agents to tumor cells. Administered intravenously, LTLD is engineered to allow significant accumulation of liposomes at the tumor site at the time of radiofrequency ablation as these liposomes recirculate in the blood stream. The second: When the tumor tissue is heated to a temperature of 40°C or greater, the heat-sensitive liposome rapidly changes structure and the liposomal membrane selectively dissolves, creating openings that release the chemotherapeutic agent directly into the tumor and into the surrounding vasculature. Drug concentration increases as a function of the accumulation of liposomes at the tumor site, but only where the heat is present. This method targets only the tumor and the area related to tumor invasion, supporting precise drug targeting.

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 in Phase II development 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. Celsion has two platform technologies for the development of novel nucleic acid-based immunotherapies and other anti-cancer DNA or RNA therapies. For more information on Celsion, visit our website: http://www.celsion.com (CLSN-LTSL/ThermoDox®)

About the NIHR Oxford Biomedical Research Centre

The NIHR Oxford Biomedical Research Centre (BRC) is based at the Oxford University Hospitals NHS Foundation Trust and run in partnership with the University of Oxford, funded by the National Institute for Health Research (NIHR).

The NIHR improves the health and wealth of the nation through research. Established by the Department of Health, the NIHR:

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- works with the life sciences industry and charities to benefit all
- involves patients and the public at every step

For further information, visit the NIHR website www.nihr.ac.uk.

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; 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; the need for Celsion to evaluate its future development plans; possible acquisitions or licenses of other technologies, assets or businesses; 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. 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

Source: Celsion Corporation