Celsion Corporation Announces Issuance of New Patent for ThermoDox®

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Represents a Significant Advance for Celsion's Life Cycle Management Program for ThermoDox®

Establishing Bioequivalence Will Extend Market Exclusivity to 2033

LAWRENCEVILLE, N.J, April 17, 2019 (GLOBE NEWSWIRE) -- Celsion Corporation (NASDAQ: CLSN), a clinical stage oncology drug development company, today announced that the United States Patent and Trademark Office has granted U.S. Patent No. 10,251,901 B2 – *Thermosensitive Nanoparticle Formulations and Method of Making the Same*, which is directly applicable to the method of treating cancer using a new ThermoDox® formulation. The claim covers a method for preparing (as well as the composition of) a doxorubicin sulfate temperature-sensitive liposome and extends coverage time over ThermoDox's current patent portfolio to 2033.

This new patent strengthens the coverage of ThermoDox®, Celsion's heat-activated liposomal platform technology, currently in Phase III development for the treatment of primary liver cancer, also known as hepatocellular carcinoma (HCC). The Company's pivotal 556-patient global Phase III OPTIMA Study in HCC completed enrollment in August 2018 at 65 clinical sites in North America, Europe, China, S. Korea, Taiwan, and Southeast Asia. The first of two preplanned, interim efficacy analyses for the OPTIMA Study is expected in the second half of 2019 and mid-2020, respectively.

"We continue to build our plans for market exclusivity through our strong science capability," said Khursheed Anwer, Ph.D., Celsion's Executive Vice President and Chief Science Officer. "Along with the strong parameter we have established with our granted methods patents, the issuance of this novel composition of matter patent further positions Celsion as a leader in the science of liposomal delivery of therapeutics and in the development of directed chemotherapeutics designed to address some of the most difficult-to-treat cancers."

"In conjunction with granted Orphan Drug Designation in the United States and Europe, this new patent provides Celsion with a strong market position and broadens our intellectual property portfolio providing for life cycle management of ThermoDox® well into the future," said Michael H. Tardugno, Celsion's Chairman, President and Chief Executive Officer. "HCC is growing at over 3 percent per year with annual incidence of 775,000 new cases and is projected to be the third leading cause of cancer-related deaths by 2030. We now look forward to data from our fully enrolled OPTIMA Study, a 556-patient Phase III trial in newly diagnosed HCC patients and the promise of a remarkable improvement in survival that ThermoDox may provide."

About ThermoDox®

Celsion's most advanced program is a heat-mediated 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. ThermoDox® is positioned for use with multiple heating technologies and has the potential to treat of a broad range of cancers including metastatic liver, recurrent chest wall (RCW) breast cancer and non-muscle invading bladder cancers.

Celsion's LTLD technology leverages two mechanisms of tumor biology to deliver higher concentrations of drug directly to the tumor site. In the first mechanism, 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, ThermoDox® is engineered with a half-life to allow significant accumulation of liposomes at the tumor site as these liposomes recirculate in the blood stream. In the second mechanism, when an external heating device heats tumor tissue to a temperature of 40°C or greater, the heat-sensitive liposome rapidly changes structure and the liposomal membrane selectively dissolves, creating openings that can release a 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 damages only the tumor and the area related to tumor invasion, supporting more 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 development for other cancer indications. The Company's product pipeline also includes GEN-1, a DNA-based immunotherapy for the localized treatment of ovarian cancer. 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 (LTSL/ThermoDox®, HEAT Study/HCC, OPTIMA Study/HCC).

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.

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