Celsion's New Subsidiary in China to Serve as Beachhead for Commercializing ThermoDox® in China and Southeast Asia

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- *Memorandum of Understanding completed with Chinese government officials in the Yuhang district of Hangzhou, China's biotech hub, to develop and commercialize innovative cancer therapies starting with ThermoDox®.*
- *Agreement includes numerous financial and non-financial incentives including grants tied to clinical research, personnel expenses and tax abatements subject to certain development and commercial milestones.*
- *Subsidiary will provide Celsion with base for commercializing ThermoDox® in China and nearby developing markets including the Philippines, Malaysia, Thailand, Vietnam, Taiwan and South Korea.*
- *Celsion's Chinese manufacturing partner, Hisun, to provide ThermoDox ® with an economically viable cost structure in China and other emerging markets.*

LAWRENCEVILLE, N.J., Dec. 18, 2019 (GLOBE NEWSWIRE) -- **Celsion Corporation (NASDAQ: CLSN)**, an oncology drug development company, announces the signing of a memorandum of understanding (MOU) with officials from the Hangzhou Yuhang Economic Development Area to establish a subsidiary in the Yuhang District of Hangzhou, the capital of China's Zhejiang Province. The Area, also known as the Qianjing Economic Development Area, is located in China's biotech hub, where the Chinese government has made the development of advanced medical technologies that address unmet patient needs a high priority.

The primary purpose of this new subsidiary is to commercialize innovative cancer therapies starting with ThermoDox®, the Company's treatment for hepatocellular carcinoma (HCC), or primary liver cancer. ThermoDox is currently in global Phase III studies including 17 sites in China. In addition to China, the subsidiary will focus on all nearby developing markets including the Philippines, Malaysia, Thailand and Vietnam. Hisun, Celsion's local manufacturing partner, is expected to provide an economically viable ThermoDox® cost structure by establishing a low-cost base of production for these geographies. Registration of the subsidiary is expected to be completed in 2020, with full operation expected in the first half of 2021.

The MOU provides numerous incentives from the Hangzhou municipal government under the central government's policy that are expected to benefit Celsion and the new subsidiary including reimbursement for personnel recruiting, rent-free office space for three years and tax abatements associated with certain capital investments. The Company's immediate financial obligation under the agreement will be offset by future grants tied to progress with clinical research programs.

"We are delighted progress is being made with the Chinese government and Hisun as our manufacturing partner to establish a subsidiary in the biotech capital of China," said Mr. Michael Tardugno, Celsion's chairman, president and CEO. "This agreement presents an excellent path to value creation for our shareholders, while providing Celsion with a physical presence in China. China has the world's largest middle class and the second largest healthcare market, and annual healthcare expenditures are expected to increase from $750 billion in 2017 to $1.1 trillion by 2021, with a compound annual growth rate thereafter of 20%," he added. "We are grateful for the support of the Chinese government as we establish our commercial footprint, with plans to tap into nearby developing Asian economies. The structure of the agreement permits us to leverage the subsidiary platform and capabilities to in-license, develop and commercialize additional products, as well as expanded indications for heat-sensitive liposomes. The subsidiary structure also provides opportunities to raise capital in China through the Hong Kong or Shanghai Stock Exchange in the future."

Mr. Tardugno added, "With China accounting for half of the 850,000 new cases of HCC worldwide, the disease is a major public health problem. Celsion and ThermoDox are well known to Chinese KOLs as the current fully enrolled Phase III OPTIMA Study of ThermoDox plus radiofrequency ablation (RFA) to treat HCC includes 17 sites in China. Because principal investigators there were also involved with our earlier Phase III HEAT Study, they are familiar with the pooled subgroup data upon which the OPTIMA Study is based. Those data showed a two-year overall survival benefit from ThermoDox when compared with RFA alone. The NMPA, China's pharmaceutical regulatory agency, is supportive of our development work with ThermoDox and is eager to find new treatments for HCC."

"We expect a second interim efficacy analysis for the OPTIMA Study to occur in the second quarter of 2020, so the timing is right to establish a subsidiary in China to prepare to enter this very large market as quickly as possible, should the drug be approved. In addition, we expect the decades of experience Celsion management and its board of directors have in building healthcare businesses in China to support all aspects of this new venture," Mr. Tardugno added.

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 a broad range of cancers including metastatic liver, recurrent chest wall 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 higher, 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 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 subject 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. The 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, please visit 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; the uncertainties of and difficulties in analyzing interim clinical data; 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 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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