January 6, 2015

Celsion Corporation Submits DNA-based Immunotherapy Clinical Protocol to the FDA as Part of a First Line Treatment for Ovarian Cancer

Lead Immunotherapy Product Candidate GEN-1 to Enter Dose Escalating Clinical Study in the Second Half of 2015

LAWRENCEVILLE, N.J., Jan. 6, 2015 /PRNewswire/ -- Celsion Corporation (Celsion) (NASDAQ:CLSN), a fully-integrated oncology company focused on the development of a portfolio of innovative cancer treatments, including directed chemotherapies, immunotherapies and RNA- or DNA-based therapies for the treatment of cancer and other difficult-to-treat diseases, today announced the submission of its Phase I clinical trial protocol to the U.S. Food and Drug Administration (FDA) for GEN-1, the Company's DNA-based immunotherapy for the localized treatment of cancer.Â The protocol, developed with guidance from the Company's Medical Advisory Board, is designed to establish a safe dose and biological activity of GEN-1 in newly diagnosed ovarian cancer patients who will be undergoing neoadjuvant chemotherapy. Â GEN-1 has demonstrated encouraging safety and efficacy data in a previous Phase I monotherapy trial in patients with peritoneally metastasized ovarian cancer, and is currently being evaluated in a Phase Ib trial in combination with PEGylated doxorubicin in patients with platinum-resistant ovarian cancer.

"GEN-1 is designed to locally activate IL-12 production which can stimulate the patient's immune system to attack and destroy cancer," stated Dr. Nicolas Borys, Celsion's Senior Vice President and Chief Medical Officer.Â "In preclinical and clinical studies performed to date, GEN-1 has demonstrated good safety and impressive immune system stimulation and activity, and this trial will evaluate its value as an adjuvant to chemotherapy in patients with a relatively healthy immune system. We now look forward to initiate the study in the second half of this year."

The clinical study will identify a safe and tolerable dose of GEN-1 while maximizing an immune response.Â The protocol intends to enroll 3 to 6 patients per dose level until a safe, tolerable and potentially therapeutically active dose is identified.Â The protocol has been submitted to the FDA for its 30 day review and comment period.Â Pending this review, the Company expects to initiate enrollment in the second half of 2015.

"Developing more effective immunotherapy approaches to ovarian cancer is a high priority for those of us who care for the thousands of patients affected by advanced ovarian cancer. Â GEN-1 is a novel IL-12 expressing lipopolymer that has demonstrated promising activity in preclinical and early phase clinical trials in ovarian cancer," stated Ronald D. Alvarez, MD, Professor and Director of the Division of Gynecologic Oncology at the University of Alabama at Birmingham (UAB) and a member of the Company's Medical Advisory Board.Â "The proposed trial to use GEN-1 in combination with neoadjuvant chemotherapy will provide a unique opportunity to assess how cytokine-based compounds such as GEN-1 directly affect ovarian cancer cells and the tumor microenvironment in newly diagnosed patients." Â

"GEN-1 holds tremendous promise as a potential cancer treatment in the rapidly emerging area of immuno-oncology. Unlike the toxicities, poor tolerability, and poor pharmacokinetics of systemically administered recombinant IL-12, the beauty of GEN-1 is that it inspires secretion of highly-tolerable endogenous IL-12," said Michael H. Tardugno, the Company's Chairman, President and Chief Executive Officer. "Designed in consultation with leading thought leaders, this Phase I trial is expected to define an optimal dose, potentially an enhanced population, and provide insights on powering for a registration program as the candidate progresses through development."

About GEN-1 Immunotherapy

GEN-1, designed using the TheraPlas™ platform technology, is an IL-12 DNA plasmid vector encased in a nanoparticle delivery system which enables cell transfection followed by persistent, local secretion of the IL-12 protein.Â IL-12 is one of the most active cytokines for the induction of potent anti-cancer immunity acting through the induction of T-lymphocyte and natural killer (NK) cell proliferation.Â Â The Company has previously reported positive safety and encouraging Phase I results with GEN-1 given as monotherapy in patients with peritoneally metastasized ovarian cancer.Â A Phase Ib trial of GEN-1 in combination with PEGylated doxorubicin in patient with platinum-resistant ovarian cancer is currently ongoing.Â GEN-1 has also demonstrated preclinical activity in glioblastoma multiforme (brain cancer) and the Company plans to initiate a Phase I study in this indication.

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 EGEN-001, 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; 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

To view the original version on PR Newswire, visit:http://www.prnewswire.com/news-releases/celsion-corporation-submits-dna-based-immunotherapy-clinical-protocol-to-the-fda-as-part-of-a-first-line-treatment-for-ovarian-cancer-300016074.html

SOURCE Celsion Corporation