Celsion Announces Publication Highlighting the Potential of Celsion's Gene-Mediated Immunotherapy to Improve Administration of IL-12 and Progression-Free Survival in Ovarian Cancer Patients

October 22, 2018

Analysis in peer-reviewed journal, *Future Oncology,* outlines the ability of GEN-1, a non-viral nanoparticle delivery system, to support persistent local production of IL-12

LAWRENCEVILLE, N.J, Oct. 22, 2018 (GLOBE NEWSWIRE) -- Celsion Corporation (NASDAQ: CLSN), an oncology drug development company, today announced that a program overview of the Company's novel, immunotherapy agent GEN-1 was published in the peer-reviewed journal, *Future Oncology*. The article is co-authored by Premal H. Thaker, M.D., M.S., associate professor of obstetrics and gynecology at the Siteman Cancer Center at the Washington University School of Medicine in St. Louis, Mo. and principal investigator in Celsion's GEN-1 development program. The publication outlines the DNA plasmid, gene-based concept and the key attributes supporting GEN-1's mechanism of action characterized by local and persistent delivery of IL-12 and modulation of tumor microenvironment favoring immune stimulation. GEN-1 is an investigational immunotherapy designed for the localized treatment of ovarian cancer as an adjuvant to standard of care chemotherapy treatment. GEN-1's ability to deliver IL-12 locally in a persistent manner to alter tumor microenvironment in favor of immune stimulation may have applications in tumor immunotherapy based on IL-12's proven ability to activate both innate (NK cells) and adaptive (cytotoxic T lymphocytes) immunities. Formulated using Celsion's proprietary TheraPlas platform technology, the GEN-1 DNA plasmid is incorporated into a non-viral nanoparticle delivery system. Administered locally, the TheraPlas system protects the DNA plasmid while enabling cellular uptake. This novel approach then results in persistent, local, cellular production and secretion of the IL-12 protein at the cancer site.

"Ovarian cancer is a disease of high unmet need, with only marginal improvements in treatment outcomes over the last two decades," said Dr. Thaker. "It is characterized by a strong immunosuppressive environment and spontaneous anti-tumor reactive T-cells and antibodies. Celsion's GEN-1 is a novel immunotherapy agent delivered intraperitoneally and engineered to provide a steady dose of IL-12 immunotherapy to women with ovarian cancer in a localized and durable manner. Importantly, GEN-1 has the potential to reduce the risk of toxicities associated with use of recombinant IL-12 protein that has severely limited this therapy as a treatment option."

"Clinical experience with GEN-1 in women with recurrent ovarian cancer shows treatment feasibility with good safety," Dr. Thaker continued. "Currently median progression free survival in treatment of newly diagnosed ovarian cancer following neoadjuvant chemotherapy treatment is 12 months. If GEN-1 is able to support significant improvements in PFS in this patient population, this could represent a major advancement in care in the years ahead"

Celsion has begun dosing patients in the dose escalation portion of the two-arm, randomized OVATION 2 Study of GEN-1. OVATION 2 is powered to evaluate a clinically significant improvement in PFS and will include up to 130 patients newly diagnosed with Stage III/IV ovarian cancer. The first 12 patients will be treated in the Phase I dose escalation portion followed by 118 patients in Phase II. The Study will be conducted in up to 15 medical centers. Data from the dose-escalating portion of OVATION 2 are expected in the first half of 2019.

Full Article Available on Celsion's Website

To view the complete article in *Future Oncology*, please visit Celsion's corporate website at http://investor.celsion.com/scientific-presentations.

About OVATION I Study

The Phase IB OVATION I Study evaluated escalating doses of GEN-1 in combination with neoadjuvant chemotherapy in the treatment of newly diagnosed patients with Stage III/IV ovarian cancer. Concurrently with neoadjuvant chemotherapy, enrolled patients received escalating weekly doses of GEN-1, from levels beginning at 36mg/m², to 47mg/m², 61mg/m² and 79mg/m² weekly for eight treatments in total, followed by interval debulking surgery. A total of 18 patients were enrolled to one of four dosing cohorts described above. Three patients dropped out of the study after 13 days or less receiving only one of eight GEN-1 doses, and two patients did not receive complete GEN-1 plus neoadjuvant chemotherapy treatment.

About OVATION 2 Study

OVATION 2 is a Phase I/II study designed with a single dose-escalation phase to 100 mg/m² of GEN-1 administered intraperitoneally in the Phase I portion, followed by a continuation at the selected dose in Phase II, in an open-label, 1:1 randomized design. In OVATION 2, patients in the GEN-1 treatment arm will receive GEN-1 plus chemotherapy prior to debulking surgery, with continued GEN-1 and chemotherapy dosing following surgery. OVATION 2 will include up to 130 patients with Stage III/IV ovarian cancer, with approximately 12 patients in the Phase I portion and 118 patients in Phase II. The study is powered to show a 33% improvement in the primary endpoint, progression-free survival (PFS), when comparing GEN-1 with chemotherapy versus chemotherapy alone. The PFS primary analysis will be conducted after at least 80 events have been observed or after all patients have been followed for at least 16 months, whichever is later. Under the open-label design, clinical data will be disclosed throughout the execution of the trial as it is released by the study's investigators. Data from the dose-escalating portion of OVATION 2 are expected in the first half of 2019.

About GEN-1 Immunotherapy

GEN-1, designed using Celsion's proprietary TheraPlas platform technology, is an IL-12 DNA plasmid vector encased in a synthetic, non-viral, nanoparticle delivery system, which enables cell transfection followed by persistent, local production and secretion of the IL-12 protein and its key downstream cell signaling cytokine, IFN-g. 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 and maturation. The Company has previously reported positive safety and encouraging Phase I results with GEN-1 given as monotherapy in patients with advanced peritoneally metastasized platinum-resistant recurrent ovarian cancer, and a Phase Ib trial of GEN-1 in combination with PEGylated doxorubicin in patients with platinum-resistant recurrent advanced ovarian cancer.

About Celsion Corporation

Celsion is a fully-integrated oncology company focused on developing a portfolio of innovative cancer treatments, including directed chemotherapies, and RNA- or DNA-based therapies including immunotherapies. 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 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-G1 CLSN-OV).

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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Source: Celsion CORP