Celsion Announces First Patient Randomized in the Gene-Mediated Immunotherapy (GEN-1) Study of Newly Diagnosed Stage III/IV Ovarian Cancer Patients

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OVATION II Study Will Evaluate Initial and Maintenance Dosing of GEN-1 on Progression-Free Survival in a Two-Arm, Randomized Trial of Up to 130 Patients

LAWRENCEVILLE, N.J., Sept. 06, 2018 (GLOBE NEWSWIRE) -- Celsion Corporation (NASDAQ: CLSN), an oncology drug development company, today announced it has begun dosing patients in the recently initiated OVATION II Study, the Company's randomized, Phase I/II clinical trial of GEN-1, its DNA-based immunotherapy for the localized treatment of ovarian cancer as an adjuvant to chemotherapy current standard of care. GEN-1, designed using Celsion's proprietary TheraPlas platform technology, is an interleukin-12 (IL-12) DNA plasmid vector encased in a non-viral nanoparticle delivery system, which enables cell transfection followed by persistent, local secretion of the IL-12 protein.

"In previous studies, GEN-1 was shown to be well tolerated at doses up to 79 mg/m^2 with meaningful, dose-dependent, pro-immune clinical activity," said Dr. Nicholas Borys, Celsion's senior vice president and chief medical officer. "The overall median progression-free survival (PFS) in the first OVATION Study recently reached 24 months among patients treated per protocol. These data compare favorably to the historical median PFS of 12 months for newly diagnosed patients with Stage III and IV ovarian cancer who undergo neoadjuvant chemotherapy followed by interval debulking surgery. We continue to follow these patients and expect to report the final median PFS in the second half of 2018. GEN-1's safety profile and evident dose response have led us to initiate this new trial at a higher dose of 100 mg/m^2. We believe that GEN-1 dosing before and after debulking surgery in combination with neoadjuvant chemotherapy will maximize the therapeutic effect of GEN-1. We are looking forward to ongoing data readouts as the OVATION II Study progresses."

OVATION II is a Phase I/II study designed with a single dose escalation phase to 100 mg/m² of GEN-1 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 II, patients in the GEN-1 treatment arm will receive GEN-1 plus chemotherapy pre- and post-debulking surgery. OVATION II will include up to 130 patients with Stage III/IV ovarian cancer, with 12 patients in the Phase I portion and up to 118 patients in Phase II, at ten U.S. medical centers. The study is powered to show a 33% improvement in the primary endpoint, PFS, when comparing GEN-1 with adjuvant chemotherapy versus adjuvant 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.

Developed with extensive input from the company's Medical Advisory Board, the OVATION II Study builds on promising clinical and translational research data from the Phase IB dose-escalation OVATION I Study in which enrolled patients received escalating weekly doses of GEN-1 up to 79 mg/m² for a total of eight treatments in combination with neoadjuvant chemotherapy, followed by interval debulking surgery. In addition to exploring a higher dose of GEN-1 in the OVATION II study, patients will continue to receive GEN-1 after their interval debulking surgery.

"We are very excited to advance our ovarian cancer research, the foundation of which is based on a known anti-cancer agent, IL-12. Over the past three decades, IL-12 has convincingly demonstrated its capability to actively recruit the body's immune system to work against cancers. However, its clinical promise has been limited by a poor safety profile. GEN-1 has the potential to address this. In our novel, gene-mediated formulation, we believe GEN-1 has the potential to effectively harness IL-12's antitumor activity for cancer patients with a dimension of safety not found in the free, recombinant form," said Michael H. Tardugno, Celsion's chairman, president and chief executive officer. "OVATION II is designed to define the optimal dose of GEN-1 and provide important insights into GEN-1's clinical benefit as an adjuvant therapy both before and after debulking surgery with the potential to stimulate an anticancer immune response, compared to the current standard of care alone."

About GEN-1 Immunotherapy

GEN-1, designed using Celsion's proprietary 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. 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. The Company has previously reported positive safety and encouraging Phase I results with GEN-1 given as monotherapy in patients with peritoneally metastasized recurrent ovarian cancer, and a Phase Ib trial of GEN-1 in combination with PEGylated doxorubicin in patients with platinum-resistant recurrent ovarian cancer.

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 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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