Celsion Announces Progression-Free Survival Data From GEN-1 Phase I Immuno-Oncology Study of Patients with Stage III/IV Ovarian Cancer

October 24, 2018

Single Arm Study Demonstrated a Median Progression-Free Survival (PFS) of 24.3 Months for Patients Treated per Protocol;

Patients in the Intent-to-Treat Population had a Median PFS of 17.1 months versus Historical Median PFS of 12 Months

All Patients Treated at the Highest Dose Cohort Achieved Complete Surgical Resection After Interval Debulking Surgery

Study Demonstrated That GEN-1 is Well Tolerated and That Intraperitoneal Administration is Feasible with Broad Patient Acceptance

LAWRENCEVILLE, N.J, Oct. 24, 2018 (GLOBE NEWSWIRE) -- Celsion Corporation (NASDAQ: CLSN), an oncology drug development company, today announced results from its dose escalating Phase IB OVATION I trial evaluating neoadjuvant chemotherapy (NAC) treatment for six cycles and GEN-1 given weekly for a total of eight doses prior to interval debulking surgery in newly diagnosed patients with Stage III/IV ovarian cancer. Median progression-free survival (PFS) in patients treated per protocol (n=13) was 24.3 months and was 17.1 months for the intent-to-treat population (n=18) for all dose cohorts, including three patients who dropped out of the study after 13 days or less, and two patients who did not receive full neoadjuvant chemotherapy (NAC) and GEN-1 cycles. The results from the OVATION I Study support continued evaluation of GEN-1 based on promising tumor response, as reported in the PFS data, and the ability for surgeons to completely remove visible tumor at debulking surgery.

“The OVATION I Study results are highly encouraging,” said Premal H. Thaker, M.D., M.S., Professor of Gynecologic Oncology 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. “Under the current standard of care, in women with Stage III/IV ovarian cancer undergoing neoadjuvant chemotherapy the disease, on average, progresses within about 12 months (http://ascopubs.org/doi/full/10.1200/JCO.2016.68.6907) before it comes back. Even with only limited GEN-1 plus standard NAC, treatment doubled PFS to an average of over 24 months for women in this small study. If the results from this early-stage study can be reproduced in a larger patient population, GEN-1 could represent a breakthrough treatment for newly diagnosed ovarian cancer patients.”

In the OVATION I Study, complete tumor resections (R0s) were achieved for all patients receiving the highest dose of GEN-1, and approximately 86% of patients in OVATION I had a complete or partial response. Patients administered GEN-1 and NAC demonstrated meaningfully longer PFS compared to the historical average for chemotherapy alone, with longer PFS observed in the higher dose cohorts. GEN-1 was well tolerated and no dose-limiting toxicities were detected. Intraperitoneal administration of GEN-1 was feasible with broad patient acceptance.

"We are very pleased with the results from the OVATION I trial,” said Dr. Nicholas Borys, Celsion's Senior Vice President and Chief Medical Officer. “As with most solid tumors, the greatest hope comes with catching the disease early and with the surgeon’s ability to remove the cancer completely. In our OVATION I Study, complete surgical removal of tumors was achieved for all patients who received eight doses of the highest dose of GEN-1. We hope this translates to an excellent long-term outcome for these women. We are evaluating GEN-1 at a higher dose of 100 mg/m^2 as part of the open-label OVATION 2 Study now underway.”

“The observed clinical benefit in the OVATION I Study is not only remarkable, it is supported with convincing translational data. The ability of GEN-1 with NAC to improve survival is now being further evaluated in our recently initiated Phase I/II OVATION 2 Study,” said Michael H. Tardugno, Celsion's Chairman, President and Chief Executive Officer. “Our first data analysis from this open-label study is expected in the first half of 2019 and has the potential to be an important first proof point in determining the reproducibility of the OVATION I results.”

About OVATION I Study

The Phase IB OVATION I Study evaluated escalating doses of GEN-1 in combination with three cycles of neoadjuvant chemotherapy prior to interval surgery followed by three cycles of NAC 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 (Cohort 1: 36 mg/m^2; Cohort 2: 47 mg/m^2; Cohort 3: 61 mg/m^2; Cohort 4: 79 mg/m^2). Three patients dropped out of the study after 13 days or less, 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 chemotherapy and GEN-1 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 up to 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 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. 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 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 advanced 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, 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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