Celsion Announces GEN-1 Data Presentation at ASCO-SITC Clinical Immuno-Oncology Symposium

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100% Objective Response Rates and 88% Complete (R0) Resection Rates in Highest Dose Cohorts

GEN-1 Intraperitoneally Delivered Durable Local Levels of Pro-Immune IL-12 and Related Cytokines

Dose Dependent Reduction in Immunosuppressive Biomarkers Suggest Positive Effect on Tumor Microenvironment

LAWRENCEVILLE, N.J., March 04, 2019 (GLOBE NEWSWIRE) -- Celsion Corporation (NASDAQ: CLSN), an oncology drug development company, today announced the oral presentation of data highlighting the safety, clinical response and translational data from its recently completed OVATION I Study. This Phase IB study evaluated patients newly diagnosed with Stage III/IV ovarian cancer and were treated with Celsion's DNA-based, IL-12 immunotherapy, GEN-1, in combination with neoadjuvant chemotherapy (NAC). Also presented were new data from the study demonstrating reduced immunosuppression in the tumor microenvironment (TME) following treatment with GEN-1. The data were presented at the ASCO-SITC Clinical Immuno-Oncology Symposium by Premal H. Thaker, M.D., M.S., Professor of Obstetrics and Gynecology at the Siteman Cancer Center at the Washington University School of Medicine in St. Louis, MO and lead investigator in Celsion's GEN-1 development program.

"In this Phase IB dose-escalation study, the 14 patients who were evaluable for response, 100% of patients administered NAC plus the two higher doses of GEN-1 experienced an objective tumor response (defined as a partial or complete response) compared to only 60% of patients given the two lower doses," said Dr. Thaker. "Patients in the higher dose cohorts also had a high surgery success rate, with 88% of these patients achieving the optimal outcome of a complete (R0) resection. Pre- and post-treatment levels of key ovarian cancer biomarkers were also measured as part of this study and showed marked reduction in immunosuppressive response across multiple biomarkers post-treatment, including FOXP3 and IDO-1 – an outcome not previously observed with NAC treatment alone. Together, these findings indicate that GEN-1 may alter the tumor microenvironment and may improve ovarian cancer outcomes in combination with NAC. As a clinician, these observations are very encouraging, and I look forward to further data from the GEN-1 development program to more fully characterize GEN-1's potential to treat patients with this deadly disease."

"The OVATION I Study has provided important data that not only suggest GEN-1's ability to safely be administered with standard NAC but also indicate its potential to meaningfully influence progression-free survival (PFS), which for patients treated per protocol in this study demonstrated a median PFS of 21 months, a favorable result relative to the PFS historical average of 12 months for women with ovarian cancer," said Nicholas Borys, M.D., Celsion's Senior Vice President and Chief Medical Officer. "The results from OVATION I and other evaluations of GEN-1 have provided us with informative and encouraging data that suggest significant potential in treating ovarian cancer, and we look forward to further study of the selected GEN-1 dose in a larger patient population as part of our ongoing OVATION 2 Study, which will include a control arm as well as continued GEN-1 treatment after the interval debulking surgery."

The Phase IB OVATION 1 Study, which evaluated escalating doses of GEN-1 (36 mg/m^2, 47 mg/m^2, 61 mg/m^2 and 79 mg/m^2) administered intraperitoneally in combination with three cycles of neoadjuvant chemotherapy prior to interval debulking surgery, followed by three cycles of NAC in the treatment of newly diagnosed patients with Stage III/IV ovarian cancer, demonstrated median PFS of 21 months in patients treated per protocol (n=13) and 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 NAC and GEN-1 cycles.

Pathological changes were assessed as part of the study, with the density of markers measured in tissue sections assessed via immunohistochemistry staining. Among patients administered the high doses of GEN-1 (n=8), pre-treatment to post-treatment reductions in key biomarkers were observed (FoxP3 -62.5%; IDO-1 -60%; PD-1 -62.5%; PD-L1 -37.5%). Reductions were also observed in patients administered the lower doses of GEN-1 (n=4) for all but one of the four key biomarkers (FoxP3 -40%; IDO-1 -40%; PD-1 +25%; PD-L1 -37.5%). The ratio of CD8+ cells to the four key immunosuppressive cell signals increased following treatment in 60 - 80% of patients.

Dose-limiting toxicity was not reached in the OVATION I Study. The most common adverse events attributed to GEN-1 in the OVATION I Study were nausea, abdominal pain/cramping, fatigue, vomiting, diarrhea and neutropenia.

The presentation titled, "Phase I study of the safety and activity of formulated IL-12 plasmid administered intraperitoneally in combination with neoadjuvant chemotherapy in patients with newly diagnosed advanced stage ovarian cancer" was presented as part of Oral Abstract Session C on March 2 , 2019 and may be accessed on Celsion's corporate website.

About GEN-1

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.

The OVATION 2 Phase I/II study in patients newly diagnosed with Stage III/IV ovarian cancer, was initiated in September 2018 and is 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. The OVATION 2 Study will evaluate the effect of initial and maintenance dosing of GEN-1 on PFS in up to 130 patients.

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 and in Phase II development for the treatment of recurrent chest wall breast 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: 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, 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; 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. 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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