Celsion Corporation Announces DSMB has Confirmed Initial Safety of Weekly GEN-1 Dosing at 100 mg/m² in 15 Randomized Patients with Advanced Ovarian Cancer

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Phase 2 Portion Will Continue After Patients Have Completed Their Full Treatment Regimen of up to 17 doses of GEN-1 plus Standard Chemotherapy

LAWRENCEVILLE, N.J., Feb. 06, 2020 (GLOBE NEWSWIRE) -- Celsion Corporation (NASDAQ: CLSN) today announced that the independent Data Safety Monitoring Board (DSMB) has completed its initial safety review of data from the first fifteen patients treated with the first four neoadjuvant doses of GEN-1 at 100 mg/m² in the ongoing Phase I/II OVATION 2 Study. As requested by the U.S. Food and Drug Administration (FDA), a follow-on Phase 1 review by the DSMB will evaluate the safety of GEN-1 in up to 17 weekly doses before initiating the Phase 2 portion of the Study. The OVATION 2 Study combines GEN-1, the Company's IL-12 gene-mediated immunotherapy, with neoadjuvant chemotherapy (NACT), a standard of care for newly diagnosed patients with Stage III and IV ovarian cancer. Following NACT, patients undergo interval debulking surgery (IDS) followed by three additional cycles of chemotherapy.

The OVATION 2 Study is an open label, 130 patient, 1 to 1 randomized Phase II trial, 80% powered to show the equivalent of a 33% improvement in progression-free survival (PFS), the primary endpoint, when comparing the treatment arm (NACT + GEN-1) with the control arm (NACT alone). GEN-1, is a formulation of Celsion's proprietary, synthetic, non-viral cell transfection platform TheraPlas, incorporating, DNA plasmids coded for the inflammatory protein, interleukin-12 (IL-12). Cell transfection is followed by persistent, local secretion of the IL-12 protein, expected at therapeutic levels.

The OVATION 2 Study builds on promising clinical and translational research data from the Phase IB OVATION I Study, in which enrolled patients received escalating weekly doses of GEN-1 (from 36 mg/m² to 79 mg/m²) for a total of eight treatments in combination with NACT, followed by IDS. These data from the OVATION I Study were presented at the ASCO-SITC Clinical-Oncology Symposium by Dr. Premal H. Thaker, M.D., M.S. on May 4, 2019 and can be reviewed here. In addition to exploring a higher dose of GEN-1 in the OVATION 2 Study, patients will continue to receive GEN-1 after their IDS in combination with adjuvant chemotherapy.

"This latest DSMB review of GEN-1 at 100 mg/m² confirmed that there were no dose limiting toxicities detected in any of the six evaluable patients (those patients who received at least four doses of GEN-1) and that intraperitoneal GEN-1 administration is well tolerated even when given with standard NACT," said Nicholas Borys, M.D., executive vice president and chief medical officer of Celsion. “Of the fifteen patients treated in the Phase I portion of the OVATION 2 Study, nine patients were treated with GEN-1 plus NACT and six patients were treated with NACT only. After the final six patients in the Phase I portion of the Study have completed their interval debulking surgery, we will be reporting surgical results and overall tumor response rates for all fifteen patients from the Phase I portion of the trial later this quarter.”

Dr. Borys concluded, “We anticipate that the Phase II portion of the OVATION 2 Study will begin enrolling patients at more than 25 clinical sites in the U.S. and Canada beginning in the second quarter of 2020. As requested by the FDA, a follow-on safety review will be conducted by the DSMB after all the patients have concluded their chemotherapy dosing. The Study protocol allows for up to 17 doses of GEN-1. Our goal is to complete enrollment of all patients in the OVATION 2 Study by the first quarter of 2021."

The OVATION 2 Study is supported with promising clinical and translational data from the Company’s prior Phase Ib OVATION I Study. In addition to a 100% objective response rate (complete response + partial response) observed in all 9 patients at the two highest dose cohorts, translational research data demonstrates that GEN-1 is biologically active, producing therapeutic levels of IL-12 cytokines and positively impacting T-cell population in the tumor.

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 cancer. 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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