Celsion Reports Data Safety Monitoring Board Recommendation to Continue Dosing Patients in the Phase II Portion of the OVATION 2 Study with GEN-1 in Advanced Ovarian Cancer

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OVATION 2 Study is 50% Enrolled; Excellent R0 Surgical Resection Noted

Novel Gene-Mediated Immunotherapy is Safe and Demonstrates an Acceptable Risk/Benefit When Administered Over a Six-Month Period with Up to 17 Doses

LAWRENCEVILLE, N.J., July 19, 2021 (GLOBE NEWSWIRE) -- Celsion Corporation (NASDAQ: CLSN), a clinical-stage company focused on DNA-based immunotherapy and next-generation vaccines, today announced that following a pre-planned interim safety review of 55 as treated patients randomized in the Phase I/II OVATION 2 Study with GEN-1 in advanced (Stage III/IV) ovarian cancer, the Data Safety Monitoring Board (DSMB) has unanimously recommended that the OVATION 2 Study continue treating patients with the dose of 100 mg/m^2. The DSMB also determined that safety is satisfactory with an acceptable risk/benefit, and that patients tolerate up to 17 doses of GEN-1 during a course of treatment that lasts up to six months. No dose-limiting toxicities were reported.

The OVATION 2 Study combines GEN-1, the Company's IL-12 gene-mediated immunotherapy, with standard-of-care neoadjuvant chemotherapy (NACT) in patients newly diagnosed with Stage III/IV ovarian cancer. NACT is designed to shrink the cancer as much as possible for optimal surgical removal after three cycles of chemotherapy. Following NACT, patients undergo interval debulking surgery, followed by three additional cycles of chemotherapy to treat any residual tumor.

The OVATION 2 Study is designed with an 80% confidence interval for an observed Progression Free Survival (PFS) Hazard Ratio of 0.75, which would mean an approximate 33% improvement in risk for cancer progression when comparing the treatment arm (NACT + GEN-1) with the control arm (NACT only). GEN-1 is an immunotherapy that produces safe and durable local levels of IL-12, a pluripotent cytokine associated with the stimulation of innate and adaptive immune response against cancer. The GEN-1 nanoparticle comprises a DNA plasmid encoding IL-12 gene and a synthetic polymer facilitating plasmid delivery vector. Cell transfection is followed by persistent, local secretion of the IL-12 protein at therapeutic levels.

The Company also announced that more than 50% of the projected 110 patients have been enrolled in the OVATION 2 Study. Interim clinical data from the first 36 patients who have undergone interval debulking surgery are as follows:

- Of the 36 patients who have undergone interval debulking surgery in the OVATION 2 Study:
  - 20 patients were treated with GEN-1 at a dose of 100 mg/m² plus NACT, with 16 out of 20 patients (80%) having a complete tumor resection (R0), which indicates a microscopically margin-negative resection in which no gross or microscopic tumor remains in the tumor bed; and
  - 16 patients were treated with NACT only, with 9 out of 16 patients (56%) having R0 resections.

- When combining these results with the surgical resection rates observed in the Company's prior Phase Ib dose-escalation trial (the OVATION 1 Study), a population of patients with inclusion criteria identical to the OVATION 2 Study, the data reflect the strong dose-dependent efficacy of adding GEN-1 to NACT:

		% Patients with R0 Resections
0, 36, 47 mg/m² of GEN-1 plus NACT	n=22	50%
61, 79, 100 mg/m² of GEN-1 plus NACT	n=28	82%

- The objective response rate (ORR) as measured by Response Evaluation Criteria in Solid Tumors (RECIST) criteria for the 16 patients treated with NACT only were comparable, as expected, to the 20 patients treated with GEN-1 at a dose of 100 mg/m² plus NACT, with both groups demonstrating an approximate 80% ORR.

"These findings show a consistent dose-dependent clinical response in both surgical outcome and tumor response, which is further supported by translational data of the tumor microenvironment," noted Nicholas Borys, M.D., Celsion's executive vice president and chief medical officer. "Continuing our clinical research program at the 100 mg/m^2 dose in patients with advanced-stage ovarian cancer holds promise and is strongly encouraged by our study investigators and medical advisors."

"We thank the DSMB members for their work and advice," said Michael H. Tardugno, Celsion's chairman, president and chief executive officer. "We are encouraged by the current rate of patient recruitment and expect to complete enrollment around the end of this year. FDA Fast Track and Orphan Drug Designations for GEN-1 in advanced ovarian cancer are important for our future commercialization efforts. In addition, under the Biologics Price Competition and Innovation Act of 2009, sponsors of new, licensed biological products like GEN-1 that are approved through a Biologics License

Application receive 12 years of market exclusivity. The FDA cannot license any 351(k) application for a biosimilar or interchangeable product that relies on the previously approved product as a reference for biosimilarity during this 12-year period."

In February 2021, the Company announced that GEN-1 received FDA Fast Track Designation in advanced ovarian cancer. Celsion plans to request FDA Breakthrough Therapy Designation for GEN-1 based on the encouraging clinical data announced today.

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 previously reported positive safety and encouraging Phase I results with GEN-1 given as monotherapy or a combination therapy in patients with advanced peritoneally metastasized primary or recurrent ovarian cancer, and recently completed a Phase Ib dose-escalation trial (OVATION 1 Study) of GEN-1 in combination with carboplatin and paclitaxel in patients with newly diagnosed ovarian cancer.

About Celsion Corporation

Celsion is a fully integrated, clinical-stage biotechnology company focused on advancing a portfolio of innovative cancer treatments, including immunotherapies and DNA-based therapies; and a platform for the development of nucleic acid vaccines currently focused on SARS-CoV-2. The company's product pipeline includes GEN-1, a DNA-based immunotherapy for the localized treatment of ovarian cancer. ThermoDox ®, a proprietary heat-activated liposomal encapsulation of doxorubicin, is under investigator-sponsored development for several cancer indications. Celsion also has two platform technologies for the development of novel nucleic acid-based immunotherapies and other anticancer DNA or RNA therapies. Both are novel synthetic, non-viral vectors with demonstrated capability in nucleic acid cellular transfection. For more information on Celsion, visit www.celsion.com.

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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