Celsion Reports Data Safety Monitoring Board Unanimous 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 Over 75% Enrolled; Full Enrollment Expected by Mid-2022

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

LAWRENCEVILLE, N.J., Feb. 17, 2022 (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 81 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 75% of the projected 110 patients have been enrolled in the OVATION 2 Study. Interim clinical data from the first 39 patients who have undergone interval debulking surgery showed that the GEN-1 treatment arm is showing a 27% improvement in R0 surgical resection rate over the control arm. A complete tumor resection (R0) is a microscopically margin-negative resection in which no gross or microscopic tumor remains in the tumor bed.

“Findings from our OVATION I and OVATION 2 studies 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. “We are encouraged by the current rate of patient recruitment and expect to complete enrollment by mid-2022. The primary endpoint for the study is progression-free survival (PFS) which we expect to report approximately 12 months after patient enrollment is completed.”

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.

“We thank the DSMB members for their work and advice,” said Michael H. Tardugno, Celsion’s chairman, president and chief executive officer. “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.”

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 Epithelial Ovarian Cancer

Epithelial ovarian cancer (EOC) is the fifth deadliest malignancy among women in the United States. There are approximately 22,000 new cases of ovarian cancer every year and the majority (approximately 70%) are diagnosed in advanced stages III and IV. EOC is characterized by dissemination of tumor in the peritoneal cavity with a high risk of recurrence (75%, stage III and IV) after surgery and chemotherapy. Since the five-year survival rates of patients with stages III and IV disease at diagnosis are poor (41% and 20%, respectively), there remains a need for a therapy that not only reduces the recurrence rate but also improves overall survival. The peritoneal cavity of advanced ovarian cancer patients contains the primary tumor environment and is an attractive target for regional approach to immune modulation.

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-CoV2. The company's product pipeline includes GEN-1, a DNA-based immunotherapy for the localized treatment of ovarian cancer. Celsion also has two platform technologies for the development of novel nucleic acid-based immunotherapies and other anti-cancer 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.

Forward-Looking Statements

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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