Celsion Completes Enrollment of the Phase I/II OVATION 2 Study with GEN-1 in Advanced Ovarian Cancer

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110 Patients Enrolled in Study Comparing Novel Gene-Mediated Immunotherapy plus Neoadjuvant Chemotherapy versus Neoadjuvant Chemotherapy Alone

LAWRENCEVILLE, N.J., Sept. 15, 2022 (GLOBE NEWSWIRE) -- Celsion Corporation (NASDAQ: CLSN), a clinical-stage company focused on DNA-based immunotherapy and next-generation vaccines, today announced that its Phase I/II OVATION 2 Study with GEN-1 in advanced ovarian cancer has completed enrollment with 110 patients. GEN-1 is the Company's IL-12 gene-mediated immunotherapy. Topline results are expected in the second half of 2023.

The OVATION 2 Study combines GEN-1 with standard-of-care neoadjuvant chemotherapy (NACT) in patients newly diagnosed with Stage III/IV ovarian cancer. NACT is designed to shrink the tumors 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 study is designed with an 80% confidence interval to show an approximate 33% improvement in progression-free survival when comparing the treatment arm (NACT + GEN-1) with the control arm (NACT only).

IL-12 is 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.

"We are delighted to reach this important milestone of completing enrollment in our Phase I/II OVATION 2 Study with GEN-1 and are optimistic the study will show our technology's ability to deliver the powerful immune-modulating agent IL-12," said Corinne Le Goff, Ph.D., president and chief executive officer of Celsion Corporation. "Preliminary interim data in this study are very promising, showing both safety and activity. We look forward to completing the study and reporting top line results, in the second half of 2023."

The Company announced in June 2022 that following a pre-planned interim safety review of 87 patients (46 in the experimental arm and 41 in the control arm), the Data Safety Monitoring Board (DSMB) 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. No dose-limiting toxicities were reported.

In June, the Company also announced that interim clinical data from 70 patients who underwent interval debulking surgery showed that those in the GEN-1 treatment arm had improvement in R0 surgical resection rates and CRS 3 chemotherapy response scores versus 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. The chemotherapy response score is a three-tier standardized scoring system for histological tumor regression into complete/near complete (CRS 3), partial (CRS 2) and no/minimal (CRS 1) response based on omental examination.

In February 2021, the FDA awarded fast track designation to GEN-1 in advanced ovarian cancer. Celsion plans to request FDA breakthrough therapy designation for GEN-1 based on the encouraging clinical data.

About GEN-1 Immunotherapy

Designed using Celsion's proprietary TheraPlas platform technology, GEN-1 is an IL-12 DNA plasmid vector encased in a nanoparticle delivery system that 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 cell proliferation. The Company previously reported positive safety and encouraging Phase I results with GEN-1 administered as monotherapy or as combination therapy in patients with advanced peritoneally metastasized primary or recurrent ovarian cancer and completed a Phase Ib dose-escalation trial (the 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 a 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-CoV-2. 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.

Contact:

Jeffrey W. Church
Executive Vice President, CFO and Corporate Secretary
609-482-2455
jchurch@celsion.com

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