Celsion Reports Data Safety Monitoring Board Recommendation to Proceed to Phase II of the OVATION 2 Study in Advanced Ovarian Cancer

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Excellent Surgical Response Noted at the Higher, 100 mg/m^2 Dose

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

LAWRENCEVILLE, N.J., May 29, 2020 (GLOBE NEWSWIRE) -- Celsion Corporation (NASDAQ: CLSN), a leading oncology drug development company, today announced the final recommendations of the Data Safety Monitoring Board (DSMB) following completion of the Phase I dose-finding and tolerance portion of the Phase I/II OVATION 2 Study with GEN-1 in advanced (Stage III/IV) ovarian cancer. Based on favorable safety data from 15 randomized patients, the DSMB has recommended that the Phase II portion of the OVATION Study proceed 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 (IDS), followed by three additional cycles of chemotherapy in order to treat any remaining tumor after the surgery.

The OVATION 2 Study is an open-label, 1-to-1 randomized trial, 80% powered to show the equivalent of a 33% improvement in progression-free survival (PFS) (HR=0.75), 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, which incorporates DNA plasmids coded for the inflammatory protein interleukin-12 (IL-12). Cell transfection is followed by persistent, local secretion of the IL-12 protein at therapeutic levels.

In March 2020, the Company announced the following clinical data from these first 15 patients enrolled in the OVATION 2 Study:

- Of the 15 patients treated in the Phase I portion of the OVATION 2 Study:
  - Nine were treated with GEN-1 at a dose of 100 mg/m² plus NACT,
  - Six were treated with NACT only,
  - All 15 had successful resections of their tumors, with seven out of nine patients (78%) in the GEN-1 treatment arm 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
  - Only three out of six patients (50%) in the NACT only treatment arm had an R0 resection.
- 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 the current standard of care NACT:

		% Patients with R0 Resections
0, 36, 47 mg/m² of GEN-1 plus NACT	n=12	42%
61, 79, 100 mg/m² of GEN-1 plus NACT	n=17	82%

- The objective response rate (ORR) as measured by Response Evaluation Criteria in Solid Tumors (RECIST) criteria for the 0, 36, 47 mg/m² dose GEN-1 patients were comparable, as expected, to the 61, 79, 100 mg/m² higher dose GEN-1 patients, with both groups demonstrating an approximate 80% ORR.

The Company also engaged Medidata, a Dassault Systèmes company, to examine matched patient data provided by Medidata in a synthetic control arm (SCA) with results from the Company's completed Phase Ib dose-escalation OVATION 1 Study. The results were announced in March 2020, and showed positive data in PFS as follows:

GEN-1 Population	**PFS Hazard Ratio (Confidence Interval)**
Intent-to-treat, n=15	0.53 (95% CI 0.16, 1.73); log-rank p=0.29
Per-protocol, n=14	0.33 (95% CI 0.08, 1.37); log-rank p=0.11

Patients in the GEN-1 arm virtually demonstrated a doubling of control of their cancer compared with the SCA. Findings are not statistically significant due to the small number of patients.

"These findings show a consistent dose dependent clinical response in both surgical outcome and tumor response. This is further supported by a series of translational data of the tumor microenvironment," noted Dr. Nicholas Borys, Celsion's executive vice president and chief medical officer. "Continuing our clinical research program at the higher, 100mg/m^2 dose, in this advance stage ovarian cancer population, holds promise and is

strongly encouraged by our study investigators and medical advisors. We look forward to initiating enrollment as quickly as possible."

"We are excited to be moving into the Phase II portion of the OVATION 2 Study, and thank the DSMB for their work and advice," said Michael H. Tardugno, Celsion's chairman, president and chief executive officer. "The recommendation to proceed at the highest dose and the fact patients were able to tolerate 17 doses bode well for study success, particularly in light of the body of positive data we have generated for GEN-1 in the advanced ovarian cancer indication. With no good treatment options available, we are hopeful GEN-1 will make a meaningful difference in the lives of these women. As previously announced, we plan to begin the Phase II study in the fourth quarter of this year."

In March 2020, the Company announced that GEN-1 has received Orphan Drug Designation from the European Medicines Agency. Celsion plans to consult with the U.S. Food and Drug to request Fast Track review and potential Breakthrough Therapy designation for GEN-1 based on this encouraging clinical data.

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 has previously reported positive safety and encouraging Phase I results with GEN-1 given as monotherapy in patients with peritoneally metastasized ovarian cancer, and recently completed a Phase Ib trial of GEN-1 in combination with PEGylated doxorubicin in patients with platinum-resistant ovarian cancer.

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)

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