Celsion Announces Highly Encouraging Initial Clinical Results from the Phase I Portion of the Phase I/II OVATION 2 Study with GEN-1 in Patients with Advanced Ovarian Cancer

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R0 (Complete) Surgical Resection Rates for Patients Randomized to GEN-1 Treatment Arm Compare Favorably to Patients Receiving Neoadjuvant Chemotherapy Only

Company to Proceed with Phase II Portion of the OVATION 2 Study After All Phase I Patients Have Completed Their Full Treatment Regimen (up to 17 doses of GEN-1)

LAWRENCEVILLE, N.J., March 19, 2020 (GLOBE NEWSWIRE) -- Celsion Corporation (NASDAQ: CLSN), an oncology drug development company, today announced highly encouraging initial clinical data from the first 15 patients enrolled in the ongoing Phase I/II OVATION 2 Study for patients newly diagnosed with Stage III and IV ovarian cancer. The OVATION 2 Study combines GEN-1, the Company's IL-12 gene-mediated immunotherapy, with standard-of-care neoadjuvant chemotherapy (NACT). Following NACT, patients undergo interval debulking surgery (IDS), followed by three additional cycles of chemotherapy.

GEN-1 plus standard NACT produced positive dose-dependent efficacy results, with no dose-limiting toxicities, which correlates well with successful surgical outcomes as summarized below:

- Of the 15 patients treated in the Phase I portion of the OVATION 2 Study, nine patients were treated with GEN-1 at a dose of 100 mg/m² plus NACT and six patients were treated with NACT only. All 15 patients had successful resections of their tumors, with seven out of nine patients (78%) in the GEN-1 treatment arm having an R0 resection, which indicates a microscopically margin-negative resection in which no gross or microscopic tumor remains in the tumor bed. Only three out of six patients (50%) in the NACT only treatment arm had a 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:

		% of 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 higher (61, 79, 100 mg/m²) dose GEN-1 patients, with both groups demonstrating an approximate 80% ORR.

As previously reported, the independent Data Safety Monitoring Board (DSMB) for the OVATION 2 Study completed its initial safety review of data from the first 15 patients treated with the first four weekly doses of GEN-1 at 100 mg/m², and confirmed that there were no apparent dose-limiting toxicities in any of the six evaluable patients (those patients who received at least four weekly doses of GEN-1) and that intraperitoneal administration of GEN-1 is well tolerated even when given with standard NACT.

The OVATION 2 Study is an open-label, 130-patient, 1-to-1 randomized Phase I/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, 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.

The OVATION 2 Study builds on encouraging clinical and translational research data from the Phase Ib OVATION 1 Study, in which enrolled patients received escalating weekly doses of GEN-1 up to 79 mg/m² for a total of eight treatments in combination with NACT, followed by IDS. These data from the OVATION 1 Study were presented at the ASCO-SITC Clinical-Oncology Symposium by Dr. Premal H. Thaker 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.

“Of the nine patients treated with GEN-1 at 100 mg/m² plus NACT in the Phase I portion of the OVATION 2 Study, seven patients had an R0 resection at the time of their interval debulking surgery. A recent article published in the *European Journal of Obstetrics & Gynecology and Reproductive Biology*[1] confirms the importance of complete tumor resection to improved survival outcome,” said Nicholas Borys, M.D., executive vice president and chief medical officer of Celsion. "The combined data from our previous Phase Ib dose-escalating trial (OVATION 1 Study) plus this latest data from the Phase I portion of the OVATION 2 Study further confirms the encouraging dose-dependent efficacy of GEN-1 plus NACT. The clinical data at the three highest doses of GEN-1 showed an 82% R0 resection rate, compared with a 50% R0 resection rate for the NACT only control arm of the OVATION 2 Study. Historical levels of R0 resections after interval debulking surgery range from 40% to 60%."

[1] *219 (2017) 100-105*

“These data provide an early, but highly encouraging trend in both Phase I studies, and even more so when the study populations are combined to provide a larger ‘n’,” stated Michael H. Tardugno, Celsion’s chairman, president and chief executive officer. “Confirmation that the 100 mg/m² dose is effective as a treatment for newly diagnosed ovarian cancer will be determined in the Phase II portion of the OVATION 2 Study, which is expected to begin enrollment in the 2nd half of 2020. As an open label randomized trial, we expect to report patient data and trends over the course of 2021, as it becomes available, with final PFS data expected to be reported 12 months following full patient enrollment.”

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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