Celsion Corporation Provides Clinical Update on Phase I/II OVATION 2 Study with GEN-1 in Advanced Ovarian Cancer Including Encouraging Interim Resection Scores

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Of 27 patients who completed interval debulking surgery, 80% of those treated with GEN-1 had an R0 resection compared with 58% of control patients, a 38% improvement

To date 34 patients, or approximately one-third of the total, have been enrolled at 22 sites, including 20 patients in the treatment arm and 14 patients in the control arm

LAWRENCEVILLE, N.J., Feb. 25, 2021 (GLOBE NEWSWIRE) -- Celsion Corporation (NASDAQ: CLSN), a clinical-stage development company focused on DNA-based immunotherapy and next-generation vaccines, today provided an update on its Phase I/II OVATION 2 Study with GEN-1 in patients with advanced ovarian cancer, including interim observations. GEN-1 is Celsion's DNA-mediated interleukin-12 (IL-12) immunotherapy designed using TheraPlas, its proprietary, synthetic, non-viral nanoparticle delivery system platform.

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 cancer as much as possible for optimal surgical removal after three cycles of chemotherapy. Following NACT, patients undergo interval debulking surgery, followed by three adjuvant cycles of chemotherapy and up to nine additional weekly GEN-1 treatments, the goal of which is to delay progression and improve overall survival. 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 (standard of care + GEN-1) with the control arm (standard of care alone).

To date, the Company has enrolled approximately one-third, or 34 patients, of the anticipated 110 patients to be enrolled into the OVATION 2 Study, of which 20 are in the treatment arm and 14 are in the control. Currently, 27 patients have had their interval debulking surgery with the following results:

- 12 of 15, or 80%, of patients treated with GEN-1 had a R0 resection, which indicates a microscopically margin-negative complete resection in which no gross or microscopic tumor remains in the tumor bed.
- 7 of 12 patients, or 58%, of patients in the control arm had an R0 resection.
- This interim data represents a 38% improvement in R0 resection rates for GEN-1- patients compared with control arm patients and is consistent with the reported improvement in resection scores noted in the encouraging Phase I OVATION I Study, the manuscript of which has been submitted for peer review publication.

"As the goal for surgical debulking is to eliminate microscopic disease, more ovarian cancer patients require neoadjuvant chemotherapy. However, little progress has been made in adding additional efficacious immunotherapy agents to standard neoadjuvant chemotherapy," said Premal H. Thaker, M.D., MSc., Professor in Gynecologic Oncology and Director of Gynecologic Oncology Clinical Research at Washington University School of Medicine in St. Louis and lead Principal Investigator for the OVATION 2 Study. "The results seen to date in the OVATION 2 Study are exciting and impactful for ovarian cancer patients."

The Company further reports that 22 clinical sites in the U.S. and Canada have been initiated, with three more sites expected to be added by the end of the first quarter. Clinical investigators met in early February in a virtual meeting and expressed excitement about the potential for GEN-1 to treat advanced ovarian cancer and, despite the challenges and earlier delays posed by the COVID-19 pandemic, they remain committed to completing enrollment in the study during the second half of 2021.

Commenting on the interim patient reports, Dr. Nick Borys, chief medical officer of Celsion, said, "We are gratified that such a high proportion of GEN-1 patients had no residual disease at the time of their debulking surgery. These results are consistent with what we observed in our Phase I (OVATION I) study. This is great news for the patients and the surgeons in our study as a R0 resection suggests a good clinical outcome. We are following our patients carefully to see how well they do long term. The OVATION 2 investigators remain enthusiastic about the potential of GEN-1 to treat late-stage ovarian cancer, which currently has few treatment options."

Celsion announced earlier this week that GEN-1 had received Fast Track designation from the U.S. Food and Drug Administration (FDA). This designation is intended to facilitate the development and expedite the regulatory review of drugs to treat serious conditions and fill an unmet medical need. According to the FDA, a Fast Track Drug must show some advantage over available therapy, including:

- Showing superior effectiveness, effect on serious outcomes or improved effect on serious outcomes
- Avoiding serious side effects of an available therapy
- Decreasing a clinically significant toxicity of an available therapy that is common and causes discontinuation of treatment

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 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-CoV2. 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 feasibility stage 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

Forward-looking statements in this news release are made pursuant to the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995. These statements are subject to a number of risks and uncertainties, many of which are difficult to predict, including, unforeseen changes in the course of research and development activities and in clinical trials; the uncertainties of and difficulties in analyzing interim clinical data, particularly in small subgroups that are not statistically significant; FDA and regulatory uncertainties and risks; 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 or regulatory authorities; and other risks detailed from time to time in the Celsion's periodic filings 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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