Poster on Celsion Corporation's Phase I/II OVATION 2 Study Presented at the Society of Gynecologic Oncology Virtual Annual Meeting on Women's Cancer

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Company reports further strengthening of R0 resection results in patients treated with GEN-1

LAWRENCEVILLE, N.J., April 01, 2021 (GLOBE NEWSWIRE) -- Celsion Corporation (NASDAQ: CLSN), a clinical-stage company focused on DNA-based immunotherapy and next-generation vaccines, today announced that a poster highlighting the Company's ongoing Phase I/II OVATION 2 Study with GEN-1 in advanced ovarian cancer was presented last week at the Virtual Annual Meeting on Women's Cancer, sponsored by the Society of Gynecologic Oncology. The poster, titled "A Phase I/II Study Evaluating Intraperitoneal GEN-1 in Combination with Neoadjuvant Chemotherapy [NACT] in Patients with Newly Diagnosed Advanced Epithelial Ovarian Cancer (EOC)," can be viewed here.

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 poster was presented by Premal Thaker, MD, Study Chair of the OVATION 2 Study and Professor of Obstetrics and Gynecology, Director of Gynecological Oncology Clinical Research, Division of Gynecologic Oncology, Washington University School of Medicine. Additional authors were R.W. Holloway, L. Kuroki, S. E. DePasquale, W.H. Bradley, A. ElNaggar, M.C. Bell, R.P. Rocconi, A. Bregar, M.D. Indermaur, C. Gunderson, B. Pothuri, R. Agajanian, D. Warshal, D. Provencher, M. McHale, V. John, M. Bergman, S. Lau, L. Musso, K. Anwer, N. Borys and C.A. Leath III.

"Currently advanced ovarian cancer has a low survival rate and a lack of effective therapies. PARP inhibitors have made an important contribution in a subset of patients. For the majority of patients there is hope that an immunotherapy such as GEN-1 will provide a valuable new treatment option to improve both the quality of life and the life expectancy for these women," commented Dr. Thaker. "OVATION 2 Study data now show R0 resections in 14 of 17 patients, or 82%, in the GEN-1 + NACT arm, compared with seven of 12 patients, or 58%, in the NACT alone arm. We view R0 resections as a good predictor of survival, and R0 resections in the GEN-1 + NACT arm are encouraging thus far," Dr. Thaker added.

The poster describes the OVATION 2 Study, which 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).

The Company recently announced that it has enrolled approximately 40% of the anticipated 110 patients to be enrolled into the OVATION 2 Study. To date, 29 patients have had their interval debulking surgery with the following results:

- 14 of 17, or 82%, 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 41% 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 1 Study, the manuscript of which has been submitted for publication in a peer-reviewed journal.

Celsion also recently announced 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.

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 the Virtual Annual Meeting on Women's Cancer

The Society of Gynecologic Oncology (SGO) 2021 Annual Meeting on Women's Cancer will be a fully virtual meeting, allowing participants to access high-quality content and engage remotely from around the world in a platform that will be designed explicitly for this meeting. SGO is working hard to provide a great virtual experience with the latest gynecologic cancer research and education you have come to expect at the Annual Meeting on Women's Cancer. All education sessions will be recorded and available through the virtual platform for attendees who register for the meeting by March 25, 2021.

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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