



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

March 2, 2021

LAWRENCEVILLE, N.J., March 02, 2021 (GLOBE NEWSWIRE) -- [Celsion Corporation](#) (NASDAQ: CLSN), a clinical-stage development company focused on DNA-based immunotherapy and next-generation vaccines, today announced that a poster on the Company's Phase I/II OVATION 2 Study with GEN-1 in advanced ovarian cancer has been accepted for presentation at the Virtual Annual Meeting on Women's Cancer, sponsored by the Society of Gynecologic Oncology.

The conference is being held March 19-25, 2021. The OVATION 2 Study design is being presented as a poster entitled "A Phase I/II Study Evaluating Intraperitoneal GEN-1 in Combination with Neoadjuvant Chemotherapy in Patients with Newly Diagnosed Advanced Epithelial Ovarian Cancer (EOC)" in the "Trials in Progress" poster session from March 19 to 25 (8 pm to 11 pm each day). GEN-1 is Celsion's DNA-mediated interleukin-12 (IL-12) immunotherapy designed using TheraPlas, its proprietary, synthetic, non-viral nanoparticle delivery system platform. Poster authors are: P.H. Thaker, R.W. Holloway, L. Kuroki, S. E. DePasquale, W.H. Bradley, A. EINaggar, 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, C.A. Leath III and the poster will be available for virtual viewing during the meeting.

"We are delighted that the Society of Gynecologic Oncology has accepted this poster for presentation," said Michael H. Tardugno, Celsion's chairman, president and chief executive officer. "The poster authors, led by the Study Chair of the OVATION 2 Study Dr. Premal Thaker of Washington University School of Medicine in St. Louis, are a Who's Who of key opinion leaders in women's health. Celsion is grateful to have such luminaries represent our study to their peers."

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 poster will be available <https://investor.celsion.com/scientific-presentations> on March 19, 2021.

The Company recently announced that to date it 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, 28 patients have had their interval debulking surgery with the following results:

- 13 of 16, or 81%, 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 40% 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 peer review publication.

Celsion also announced last 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.

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.

Celsion Investor Contact

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

LHA Investor Relations

Kim Sutton Golodetz
212-838-3777
kgolodetz@lhai.com

###



Source: Celsion CORP