Celsion Corporation Initiates Phase II OVATION 2 Study of GEN-1 in Advanced Ovarian Cancer

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Promising Translational and Clinical Findings Support the Randomized Trial in Newly Diagnosed Patients

Non-Viral Nanoparticle Delivery System, TheraPlas Platform, Demonstrates Potential for Long-Term, Repeat Administration Up To 6 Months

LAWRENCEVILLE, N.J., July 27, 2020 (GLOBE NEWSWIRE) -- Celsion Corporation (NASDAQ: CLSN), an oncology focused drug-development company, today announced the randomization of the first two patients in the Phase II portion of the Phase I/II OVATION 2 Study with GEN-1 in advanced ovarian cancer. The Company anticipates completing enrollment of up to 118 patients in the third quarter of 2021. Because this is an open-label study, the Company intends to provide clinical updates throughout the course of treatment including response rates and surgical resection scores.

GEN-1 was designed using TheraPlas, Celsion's proprietary, synthetic, non-viral nanoparticle delivery system platform. It is an interleukin-12 (IL-12) DNA plasmid vector associated with a non-viral nanoparticle delivery system, which enables cell transfection followed by persistent, local secretion of the IL-12 protein.

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).

“During the first half of 2020, we reported data from the Phase I portion of the OVATION 2 Study that showed successful tumor resections, with seven out of eight patients (87.5%) 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. The NACT-only treatment arm had an R0 resection rate of 50%,” said Dr. Nicolas Borys, Celsion’s Chief Medical Officer. “The Company engaged Medidata/Acorn to independently evaluate our data using a propensity matched synthetic control arm (SCA) with results from the Company’s previously completed Phase I studies. The results suggested that GEN-1 nearly doubled progression-free survival (PFS) in these patients. These findings are not statistically significant, however, due to the small number of patients, but nonetheless are encouraging and supportive of our current Phase II study.”

“This past May we reported that the Data Safety Monitoring Board recommended that the Phase II portion of the OVATION 2 Study proceed with a GEN-1 dose of 100 mg/m²,” said Michael H. Tardugno, Chairman, President and Chief Executive Officer of Celsion. “Patients will undergo up to 6 months of immunostimulatory GEN-1 treatment. Based on results from earlier studies, we believe this regimen holds great potential to alter the current treatment paradigm, and in doing so improve survival for ovarian cancer patients, whose prognosis is generally poor. Our investigators are among the leading researchers in ovarian cancer. Together, we are delighted to have begun enrolling patients in the Study and look to achieve our goal of providing new novel therapeutic options to patients with this difficult-to-treat cancer.”

In March 2020 the Company announced the European Medicines Agency Committee for Orphan Medicinal Products recommended that GEN-1 be designated as an orphan medicinal product for the treatment of ovarian cancer. GEN-1 previously received orphan designation from the U.S. Food and Drug Administration for the treatment of ovarian cancer. This designation by the EMA provides 10 years of exclusivity once approved for marketing.

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 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 and in development for other cancer indications. The Company’s second product in its pipeline is GEN-1, a DNA-based immunotherapy for the localized treatment of late stage ovarian cancer. Celsion has two platform technologies for the development of novel nucleic acid-based immunotherapies and other anti-cancer DNA or RNA therapies.

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. Readers are cautioned that such forward-looking statements involve risks and uncertainties including, without limitation, 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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