October 3, 2017

Celsion Announces Final Clinical and Translational Research Data from its OVATION Study at the AACR Special Conference on Ovarian Cancer

100% Disease Control; 86% Objective Response Rate and 86% R0 & R1 Surgical Resection Rate in All Patients Treated in Four Dose-Escalating Cohorts

Clear Evidence of Biological Activity Including Dose Dependent Increases in Inflammatory Cytokines (IL-12 and IFN-g*), Decreases in VEGF Levels and No Dose Limiting Toxicities*

Expert Advisory Board Endorses Randomized Phase II in Newly Diagnosed Stage III and IV Ovarian Cancer

LAWRENCEVILLE, N.J., Oct. 03, 2017 (GLOBE NEWSWIRE) -- Celsion Corporation (NASDAQ:CLSN), an oncology drug development company, today announced final clinical and translational research data from its OVATION Study, a Phase Ib dose escalating clinical trial combining GEN-1, the Company's DNA-based immunotherapy, with the standard of care for the treatment of newly-diagnosed patients with advanced Stage III/IV ovarian cancer who will undergo neoadjuvant chemotherapy followed by interval debulking surgery. GEN-1 is an IL-12 DNA plasmid vector formulated as a nanoparticle in a non-viral delivery system to cause the sustained local production and secretion of the Interleukin-12 (IL-12) protein loco-regionally to the tumor site.

The Company updated the translational data from the OVATION Study in a poster presentation at the American Association of Cancer Research (AACR) Special Conference entitled "Addressing Critical Questions in Ovarian Cancer Research and Treatment" at the Wyndham Grand Pittsburgh Downtown in Pittsburgh, PA. The poster entitled "Immunological changes following intraperitoneal administration of a formulated IL-12 plasmid in combination with neoadjuvant chemotherapy in newly diagnosed advanced ovarian cancer patients," was presented by Dr. Khursheed Anwer, Celsion's executive vice president and chief scientific officer in a poster session on Monday, October 2, 2017 from 6:00 PM to 8:30 PM.

The Company also held an Advisory Board Meeting on September 27, 2017 with the clinical investigators and scientific experts including those from Roswell Park Cancer Institute, Vanderbilt University Medical School, and M.D. Anderson Cancer Center to review and finalize clinical, translational research and safety data from the OVATION Study in order to determine the next steps forward for this exciting new immunotherapy. With the endorsement and recommendations from the Advisory Board, the Company expects to file a next phase protocol with FDA later this year.

Translational Research Data

Key translational research findings from all evaluable patients are consistent with the earlier reports from partial analysis of the data and are summarized below:

- The intraperitoneal treatment of GEN-1 in conjunction with neoadjuvant chemotherapy resulted in dose dependent increases in IL-12 and Interferon-gamma (IFN-g) levels that were predominantly in the peritoneal fluid compartment with little to no changes observed in the patients' systemic circulation. These and other post-treatment changes including decreases in VEGF levels in peritoneal fluid are consistent with an IL-12 based immune mechanism.
- Consistent with the previous partial reports, the effects observed in the IHC analysis were pronounced decreases in the density of immunosuppressive T-cell signals (Foxp3, PD-1, PDL-1, IDO-1) and increases in CD8+ cells in the tumor microenvironment.
- The ratio of CD8+ cells to immunosuppressive cells was increased in approximately 75% of patients suggesting an overall shift in the tumor microenvironment from immunosuppressive to pro-immune stimulatory following treatment with GEN-1. An increase in CD8+ to immunosuppressive T-cell populations is a leading indicator and believed to be a good predictor of improved overall survival.
- Analysis of peritoneal fluid by cell sorting, not reported before, shows treatment-related decrease in the percentage of immunosuppressive T-cell (Foxp3+), which is consistent with the reduction of Foxp3+ T-cells in the primary tumor tissue, and a shift in tumor naïve CD8+ cell population to more efficient tumor killing memory effector CD8+ cells.

These translational research findings demonstrate that GEN-1 in ovarian cancer patients is biologically active and creates a shift in the primary tumor and in the surrounding tumor environment in the peritoneal cavity that promotes a pro-immune T-cell population dynamic and conversion of tumor naïve T-cell into cytotoxic effector T-cells in the tumor microenvironment.

"These distinct immunological changes in the local disease environment are likely to translate into clinical benefit and warrant the continued development of our GEN-1 IL-12 immunotherapy as a potential adjuvant, in both first and second-line ovarian cancer," said Dr. Kunle Odunsi, Deputy Director, Chair of Gynecologic Oncology and Center for Immunotherapy Executive Director at Roswell Park Cancer Institute. "Furthermore, pro-immune changes in the tumor microenvironment appear to support research combining GEN-1 with other exciting immuno-oncology therapies including adaptive T-cell and check point inhibitors."

Clinical Data

Celsion also reported highly encouraging clinical data from the first fourteen patients who have completed treatment in the OVATION Study. GEN-1 plus standard chemotherapy produced positive clinical results, with no dose limiting toxicities and promising dose dependent efficacy signals which correlate well with successful surgical outcomes as summarized below:

- Of the fourteen patients treated in the entire study, two (2) patients demonstrated a complete response, ten (10) patients demonstrated a partial response and two (2) patients demonstrated stable disease, as measured by RECIST criteria. This translates to a 100% disease control rate ("DCR") and an 86% objective response rate ("ORR"). Of the five patients treated in the highest dose cohort, there was a 100% objective response rate with one (1) complete response and four (4) partial responses.
- Fourteen patients had successful resections of their tumors, with nine (9) patients (64%) having an R0 resection, which indicates a microscopically margin-negative resection in which no gross or microscopic tumor remains in the tumor bed. Seven out of eight (87%) patients in the highest two dose cohorts experienced a R0 surgical resection. All five patients treated at the highest dose cohort experienced a R0 surgical resection.
- All patients experienced a clinically significant decrease in their CA-125 protein levels as of their most recent study visit. CA-125 is used to monitor certain cancers during and after treatment. CA-125 is present in greater concentrations in ovarian cancer cells than in other cells.
- Of the eight patients who have received GEN-1 treatment over one year ago (cohort 1 - 3) and are being followed; only two patients' cancer has progressed. This compares favorably to the historical median progression free survival (PFS) of 12 months for newly-diagnosed patients with Stage III and IV ovarian cancer that undergo neoadjuvant chemotherapy followed by interval debulking surgery. Of the remaining six patients who have been on the study for over one year, their average PFS as of September 30, 2017 is 18 months with the longest progression-free patient at 24 months.

"We have completed enrollment of our Phase Ib OVATION Study in newly diagnosed ovarian cancer patients to determine GEN-1's clinical and biological activity in combination with standard chemotherapy. The remarkable surgical outcomes for all patients completing the prescribed eight weekly treatments of GEN-1 reinforce our belief in the promise of GEN-1's ability to work safely and effectively in advanced ovarian cancer," said Dr. Nicholas Borys, Celsion's senior vice president and chief medical officer. "The Advisory Board Meetings held in late September 2017 with our clinical investigators and scientific experts in immuno-oncology provided an important endorsement of our development program for this innovative immunotherapy for first line ovarian cancer."

The poster presentation will be available on Celsion's website under "*News & Investors - Scientific Presentations.*"

OVATION Study Design

The Phase Ib trial was designed to evaluate weekly intraperitoneal dosing of GEN-1 in combination with neoadjuvant chemotherapy, the standard of care for patients newly diagnosed with ovarian cancer. Concurrently with neoadjuvant chemotherapy, enrolled patients will receive escalating weekly doses of GEN-1, from levels beginning at 36mg/m², to 47mg/m², 61mg/m² and 79mg/m² weekly for 8 treatments in total, with interval debulking surgery to follow. The regimen will primarily be evaluated for its safety and tolerability.

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 and brain cancers. 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)

Celsion wishes to inform readers that forward-looking statements in this 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, regulatory authorities; and other risks detailed from time to time in Celsion's periodic reports and prospectuses filed 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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