June 5, 2017

Celsion Announces Presentation of OVATION Study Findings at the ASCO 2017 Annual Meeting

100% disease control rate and 86% objective response rate reported

All patients at the highest dose demonstrated an objective response rate - partial (80%) or complete (20%) response rate

At the highest dose, 100% of patients achieved a R0, margin-negative, resection

LAWRENCEVILLE, N.J., June 05, 2017 (GLOBE NEWSWIRE) -- Celsion Corporation (NASDAQ:CLSN), an oncology drug development company, today provided an update on 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 at the tumor site.

The Company announced the latest clinical and translational data from the OVATION Study in a poster presentation at the American Society of Clinical Oncology (ASCO) 2017 Annual Meeting at McCormick Place in Chicago, IL. The poster presentation, entitled "Phase 1 study of the safety and activity of formulated IL-12 plasmid administered intraperitoneally in combination with neoadjuvant chemotherapy in patients with newly diagnosed advanced stage ovarian cancer," was presented on Saturday, June 3rd from 1:15 PM to 4:45 PM by Dr. Premal H. Thaker, Associate Professor, Obstetrics and Gynecology Division of Gynecologic Oncology, Washington University in St. Louis School of Medicine. The presentation summarized clinical findings and available translational data from all fourteen patients treated in the trial to-date.

"The OVATION study has accrued patients from four major research cancer centers. We have seen highly promising clinical findings including a patient with a complete pathological response along with a very high rate of R0 at time of debulking surgery. The translational research data in the poster presentation demonstrates that GEN-1 is producing beneficial cytokines and positively impacting T-cells in the tumor," said Dr. Premal Thaker. "This is strong early data and we believe that GEN-1 may be stimulating the immune system to improve tumor control in these patients. I am looking forward to continuing our clinical evaluation of GEN-1 in subsequent ovarian cancer studies."

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

- Of the fourteen patients treated to date 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. Of the five patients treated at the highest dose cohort, all five patients (100%) experienced a R0 surgical resection.
- One patient demonstrated a pathological complete response (pCR). pCRs are typically seen in less than 7% of patients receiving neoadjuvant chemotherapy followed by surgical resection, and have been associated with a median overall survival (OS) of 72 months, which is more than three years longer than those who do not experience a pCR.
- 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.

Celsion also reported supportive translational research data from the first four patient cohorts who have completed treatment in the OVATION Study. The translational data provides further insight into GEN-1's mechanism of action through

the evaluation of dose-related changes in the tumor and peritoneal immune cell population, as well as through the peritoneal cytokine levels.

Treatment-Related Changes in IL-12 and Cytokine Levels in Peritoneal Fluid

- The analysis of peritoneal fluid and blood samples collected immediately before and 24 hours after IP administration of multiple doses of GEN-1 (36, 47, 61, 79 mg/m2) and standard NACT (carboplatin every 21 days and Taxol weekly) shows clear evidence of IL-12 gene transfer and biological response following GEN-1 treatment on a dose-dependent basis.
- The translational data also demonstrated significant increases in IFN-gamma and decreases in VEGF levels. The treatment-related changes in immune activating cytokines and pro-tumor VEGF levels followed a dose-dependent trend and were predominantly in the peritoneal fluid compartment with little to no changes observed in the patients' systemic blood stream.

Treatment-Related Changes in the Density of Various T-cells in Tumors

- The immuno-histochemical (IHC) analysis of tumor tissue collected before treatment (laparoscopy) and after completion of eight GEN-1 weekly treatments showed increased infiltration of CD3+, CD4+ CD8+ T-cells into tumor tissue of several patients. The most pronounced effects observed in the IHC analysis were decreases in the density of immunosuppressive T-cell signals (FoxP3+, PD-1+, PDL-1+, IDO-1+) in the tumor microenvironment. The ratio of CD8+ cells to immunosuppressive T-cells was increased in 60-80% of patients suggesting an overall shift in the immune environment to pro-immune stimulatory following treatment with GEN-1.
- An intriguing effect of the treatment on tumor microenvironment is a substantial reduction in the immunosuppressive T-cell subsets and an overall shift in the T-cell environment to favoring immune stimulation.

"Now having completed enrollment, per protocol, of our OVATION Study, we are impressed with GEN-1's apparent activity in combination with standard chemotherapy in newly diagnosed patients with stage III and IV ovarian cancer. These data appear to correlate with the notable, unexpected surgical outcomes among all patients completing the prescribed eight weekly treatments and reinforce our confidence in the promise of GEN-1's ability to work safely and effectively in advanced ovarian cancer," said Michael H. Tardugno, Celsion's chairman, president and CEO. "Given these encouraging findings, in addition to our plans to evaluate GEN-1 in combination with Avastin® in 2 nd line, the Company will consider continuing our clinical trials in the underserved newly diagnosed patient population."

OVATION Study Design

The Phase Ib trial evaluated 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 received 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, followed by interval debulking surgery. The regimen is primarily being 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 and in Phase II development for the treatment of recurrent chest wall breast 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 OVATION Study 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, particularly for Phase I trials such as the OVATION Study; 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 the 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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Source: Celsion Corporation

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