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Celsion Announces Presentation of OVATION Study Findings at the Upcoming AACR Special Conference

Company to Report Final Clinical and Translational Research Data

LAWRENCEVILLE, N.J., Aug. 24, 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 to the tumor site.

The Company announced that an abstract for the OVATION Study has been accepted for presentation at the American Association for Cancer Research (AACR) Addressing Critical Questions in Ovarian Cancer Research and Treatment Special Conference, which will take place from October 1 - 4, 2017 at the Wyndham Grand Pittsburgh Downtown in Pittsburgh, PA.

- The abstract, entitled "Immunological changes following intraperitoneal administration of a formulated IL-12 plasmid in combination with neoadjuvant chemotherapy in newly diagnosed advanced ovarian cancer patients," will be presented in a poster presentation session by Dr. Khursheed Anwer, Celsion's executive vice president and chief scientific officer.

- The presentation will summarize clinical findings and translational data from all patients treated in the Phase Ib dose escalating clinical trial. 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.

Celsion previously 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 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. 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 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 this date is 17 months with the longest progression-free patient at 23 months.

"We have completed enrollment of our OVATION Study in newly diagnosed ovarian cancer patients, one goal of which is to determine GEN-1's activity in combination with standard chemotherapy. The remarkable surgical outcomes among all patients completing the prescribed eight weekly treatments 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. "We have scheduled an Advisory Board Meeting in late September 2017 with our clinical investigators and scientific experts from the Roswell Park Cancer Institute and M.D. Anderson Cancer Center to review the clinical and translational research 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, we fully expect to file a next phase protocol with FDA later this year."

OVATION Study Design

The Phase Ib trial will 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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