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Celsion Announces Latest Translational Data from the OVATION Study in Newly Diagnosed Advanced Ovarian Cancer Patients

Patients in All Cohorts Show Convincing Evidence of IL-12 Gene Transfer and Immune System Activity

LAWRENCEVILLE, N.J., Aug. 02, 2017 (GLOBE NEWSWIRE) -- Celsion Corporation (NASDAQ:CLSN) today announced findings from the translational research data from its Phase Ib dose escalating clinical trial (the OVATION Study) combining GEN-1, the Company's IL-12 gene-mediated immunotherapy, with the standard of care for the treatment of newly-diagnosed patients with Stage III and IV ovarian cancer who will undergo neoadjuvant chemotherapy (NACT) followed by interval debulking surgery.

Translational research data was reviewed with leading immuno-oncology experts from the Roswell Park Cancer Institute. 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, 72 mg/m2) and standard NACT (carboplatin every 21 days and Taxol weekly) shows clear evidence of IL-12 gene transfer by dose dependent increases in IL-12 levels and immune system activity and significant increases in interferon-gamma (IFN- γ) 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.

Key translational research findings from the first 12 of 15 patients[1] enrolled in four patient cohorts are summarized below:

- The treatment-related changes in immune activating cytokines and pro-tumor VEGF and IFN- γ levels followed a dose-dependent trend and were predominantly in the peritoneal fluid compartment with little to no changes observed in the patients' systemic circulation. The observed immunological changes are consistent with an IL-12 based mechanism.
- 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.

"These translational research findings demonstrate that GEN-1 in ovarian cancer patients is biologically active and creates a shift in the tumor microenvironment in the peritoneal cavity in a dose-dependent manner and promotes a pro-immune T-cell population dynamic in the tumor microenvironment," said Dr. Khursheed Anwer, Celsion's executive vice president and chief science officer. "These distinct immunological changes in the local disease environment appear 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. 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."

The Company previously announced the latest clinical findings from the OVATION Study in a poster presentation at the American Society of Clinical Oncology (ASCO) 2017 Annual Meeting in June 2017. The presentation summarized clinical findings for all fourteen patients treated in the trial to-date.

- Of the fourteen patients treated to date, 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 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. Seven out of eight (87%) patients in the highest two dose cohorts experienced a R0 surgical resection.
- Of the seven patients who have received GEN-1 treatment over one year ago and are being followed, only one

patient's cancer has progressed after 11.7 months. 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[2]. Of the remaining six patients who have been on the study for over one year, their average PFS is 16.4 months with the longest progression-free patient at over 22 months.

"The impressive early trends in tumor response, surgical resections and progression-free survival are consistent with the dose dependent increases in IFN- γ levels, decreases in VEGF levels and immune system activity observed in the translational data," said Michael H. Tardugno, Celsion's chairman, president and chief executive officer. "Ovarian cancer patients have a very poor prognosis. These data along with other published, pre-clinical data, underscore the potential of GEN-1 to serve as an effective, safe IL-12 immunotherapy in this underserved population."

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 gene-mediated 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 anticancer DNA or RNA therapies, including TheraPlas™ and TheraSilence™. 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 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.

[1] Tissue samples are being collected and translational data from the final three patients will be available in late September 2017.

[2] Wright AA, Bohlke K, Armstrong DK, et al: Neoadjuvant Chemotherapy for Newly Diagnosed, Advanced Ovarian Cancer: Society of Gynecologic Oncology and American Society of Clinical Oncology Clinical Practice Guideline. J Clin Oncol 34, 2016.

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