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Celsion Updates Clinical Data from the OVATION Study in Newly Diagnosed Advanced Ovarian Cancer Patients

Patients in First Four Cohorts Show Clinically Meaningful Responses in the Evaluation of GEN-1, A Novel IL-12 DNA-based Immunotherapy, in Combination with the Standard of Care

LAWRENCEVILLE, N.J., May 04, 2017 (GLOBE NEWSWIRE) -- Celsion Corporation (NASDAQ:CLSN) today announced updated additional clinical and 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. Of the five evaluable patients in the first two cohorts who have been on the study for over one year, only one patient's cancer has progressed after 11.7 months. This compares quite favorably to the historical median progression free survival (PFS) of 12 months for newly-diagnosed patients with Stage III and IV ovarian cancer who undergo neoadjuvant chemotherapy (NACT) followed by interval debulking surgery. Of the remaining four patients in the first two cohorts, their average PFS is 15.1 months with the longest progression-free patient at 19.1 months. None of the patients in the third or fourth dosing cohorts have progressed to date.

"This new data on progression-free survival adds to the impressive clinical findings seen across a number of meaningful measures used to assess ovarian cancer like a 75% objective tumor response rate and a greater than 50% R0 (margin-negative) surgical resection rate," said Dr. Nicholas Borys, M.D., Celsion's chief medical officer. "The consistency and robust nature of the data across all four cohorts and the encouraging clinical responses underscore the potential of GEN-1 to serve as an effective, safe IL-12 immunotherapy in ovarian cancer."

The Company also reported preliminary translational research findings from the first four patient cohorts. 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 significant dose dependent increases in IL-12 levels and immune system activity and 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.

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 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.

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

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 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.

Celsion Investor Contact

Jeffrey W. Church

Sr. Vice President and CFO

609-482-2455

jchurch@celsion.com

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