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Celsion Announces Positive Data from the OVATION Study - An Immunotherapy Study of Newly Diagnosed Ovarian Cancer Patients

Second Cohort of Stage III and IV Patients Continues to 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., July 25, 2016 (GLOBE NEWSWIRE) -- Celsion Corporation (NASDAQ:CLSN) today announced data from the second cohort of patients in its Phase Ib dose escalating clinical trial (the OVATION Study) combining GEN-1, the Company's DNA-based immunotherapy, with the standard of care for the treatment of newly-diagnosed patients with advanced ovarian cancer who will undergo neoadjuvant chemotherapy followed by interval debulking surgery. In the first six patients dosed, GEN-1 plus standard chemotherapy produced impressive results, with no dose limiting toxicities and highly promising efficacy signals in this difficult to treat cancer.

"The totality of study data available to date suggests that GEN-1 holds great potential to serve as an effective, safe IL-12 immunotherapy in ovarian cancer," said Dr. Premal Thaker, Associate Professor in Gynecologic Oncology, Washington University School of Medicine and OVATION Study Investigator. "Notably, we have seen dramatic decreases of 95% or greater in CA-125 protein levels, which serve as a key indicator of the presence of ovarian cancer cells, as well as impressive pathological response data, which is associated with prolonged survival. We look forward to the completion of this study, and to learning more about how GEN-1 performs in this patient population."

The OVATION Study is designed to enroll three to six patients per dose cohort, and will continue into 2016 at higher doses of GEN-1 with the goal to identify a safe, tolerable and therapeutically active dose of GEN-1 by recruiting and maximizing an immune response. The first two cohorts each enrolled three patients. Enrollment in the third cohort is ongoing, and Celsion expects to complete the OVATION Study this year. Future studies of GEN-1 will include a Phase I/II study combining GEN-1 with Avastin® and Doxil®.

OVATION Study - Results to Date

- Of the first six patients dosed, one patient demonstrated a complete response (CR), two patients demonstrated partial response (PR) and three patients demonstrated stable disease (SD), as measured by RECIST criteria.
- Five patients had successful resections of their tumors, with two patients having an R0 resection, which indicates a microscopically margin-negative resection in which no gross or microscopic tumor remains in the tumor bed and three patients with a R1 resection, indicating microscopic residual tumor. One patient in the second cohort is currently ineligible for debulking surgery due to a medical complication unrelated to the study or the study drug.
- Of the five surgically treated and evaluable patients, one patient demonstrated a pathological complete response (pCR), two patients (40%) demonstrated a micro pathological response (microPR), and two patients (40%) demonstrated a macroPR. These data compare favorably to historical data, which indicate that pCRs are typically seen in less than 7% of patients receiving neoadjuvant chemotherapy followed by surgical resection. pCRs have been associated with a median overall survival of 72 months, which is more than three years longer than those who do not experience a pCR. In addition, microPRs are seen in approximately 30% of patients, and are associated with a median overall survival of 38 months[1].

"GEN-1 continues to demonstrate impressive activity in patients with advanced Stage III and IV ovarian cancer, a population clearly in need of effective therapies," said Nicholas Borys, M.D., Celsion's chief medical officer. "We anticipate completion of enrollment in the third patient cohort in the coming weeks, and will continue to assess a potential accelerated clinical development path for GEN-1. In parallel, we are currently evaluating translational data from the study, which we expect to report before the end of the third quarter."

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 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 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] Petrillo M, Zannoni GF, Tortorella L, et al. Prognostic role and predictors of complete pathologic response to neoadjuvant chemotherapy in primary unresectable ovarian cancer. American Journal of Obstetrics & Gynecology 2014

Celsion Investor Contact

Jeffrey W. Church

Sr. Vice President and CFO

609-482-2455

jchurch@celsion.com

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