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Celsion Announces Continuing Positive Data from the OVATION Study - An Immunotherapy Study of Newly Diagnosed Stage III and IV Ovarian Cancer Patients

Third Cohort of 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

Top Line Translational Data from First Two Cohorts Demonstrates Potential Immune Activation

LAWRENCEVILLE, N.J., Nov. 10, 2016 (GLOBE NEWSWIRE) -- Celsion Corporation (NASDAQ:CLSN) today announced data from the third 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 nine 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.

"While the patient number in this trial may be small, the consistency and robust nature of the data across all three cohorts and the encouraging clinical responses underscore the potential of GEN-1 to serve as an effective, safe IL-12 immunotherapy in ovarian cancer," said Nicholas Borys, M.D., Celsion's chief medical officer. "I am particularly impressed with the pathological response data, which is known to be associated with prolonged survival in this patient population. The data generated support continued evaluation of GEN-1 in ovarian cancer, and we look forward to seeing how GEN-1 performs in the fourth and final study cohort."

The OVATION Study is designed to enroll three to six patients per dose cohort with the goal of identifying a safe, tolerable and therapeutically active dose of GEN-1 by recruiting and maximizing an immune response. The first three cohorts each enrolled three patients. Enrollment in the fourth cohort is ongoing, and Celsion expects to complete the OVATION Study this year and report data in early 2017. Future studies of GEN-1 will include a Phase I/II study combining GEN-1 with Avastin® and Doxil®.

OVATION Study - Totality of Results in the First Three Cohorts

- Of the first nine patients dosed, one patient demonstrated a complete response (CR), five patients demonstrated partial response (PR) and three patients demonstrated stable disease (SD), as measured by RECIST criteria. This translates to a 100% disease control rate (DCR), and 66% objective response rate (ORR).
- Eight patients had successful resections of their tumors, with four 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 had an R2, indicating macroscopic residual tumor. One patient in the second cohort was ineligible for debulking surgery due to a medical complication unrelated to the study or the study drug.
- Of the eight surgically treated and evaluable patients, one patient demonstrated a complete pathological response (cPR), three patients demonstrated a micro pathological response (microPR), and four patients demonstrated a macroPR. These data compare favorably to historical data, which indicate that cPRs are typically seen in less than 7% of patients receiving neoadjuvant chemotherapy followed by surgical resection. cPRs 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 cPR. In addition, microPRs are seen in approximately 30% of patients, and are associated with a median overall survival of 38 months[1].
- Seven patients who completed treatment follow-up experienced a dramatic (greater than 90%) drop 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. A 50% reduction in CA-125 levels is considered meaningful. Six patients maintained CA-125 levels below the standard cutoff level of 35 U/mL.

OVATION Study - Top Line Translational Data from First Two Cohorts

Celsion also reported initial translational data from the first two cohorts of the OVATION study. Tumor and blood samples collected before the start of the neoadjuvant chemotherapy (NACT) and after the completion of GEN-1 treatment at

debulking surgery are being analyzed for immune cell populations. Top line data demonstrates intriguing immunological changes in the tumor that are consistent with the activation of the immune system. Specifically,

- In tumor tissue, there was an increase in cytotoxic CD8+ T-cell density in three out of four evaluable patients at debulking surgery. There was a decrease in immunosuppressive FoxP3+ T-cells in two out of those 4 patients. The ratio of CD8+/FoxP3+ cells was increased in all four evaluable patients. High tumor infiltrating CD8+ T-cell density, low FoxP3+ T-cell density or high CD8+/FoxP3+ ratio demonstrate a potential shift in tumor environment to favoring immune stimulation following NACT + GEN-1 therapy. For the remaining two patients the post-treatment tumor tissue was not available. In one of those two patients there was complete pathological response hence no tumor tissue was present to provide a post-treatment comparison. In the other patient the debulking surgery was not performed due to disease related complications.
- In plasma samples, there appeared to be no significant change in T-cell density following the treatment. The density of myeloid derived suppressor cells that are associated with immunosuppression in ovarian cancer were either decreased or did not increase in post-treatment samples.

Additional immune analysis of biological tissue including cytokine ELISA from the first two patient cohorts and a complete analysis of the two higher dose cohorts is in progress.

"The clinical and translational data generated to date are meaningful and reinforce our confidence in the potential of GEN-1 to address advanced Stage III and IV ovarian cancer, a population clearly in need of effective therapies," said Dr. Khursheed Anwer, Ph.D., MBA, Celsion's chief scientific officer. "We anticipate completion of enrollment in the fourth 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 fourth 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 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] 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

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