

## **Celsion Presents Two Posters on its GEN-1 IL-12 Gene-Mediated Immunotherapy at the ASCO-SITC Clinical Immuno-Oncology Symposium**

*OVATION Study Fully Enrolled, Final Patient Enrolled in the Fourth Cohort*

*Complete Clinical and Translational Research Data to be Announced During the Second Quarter*

LAWRENCEVILLE, N.J., Feb. 27, 2017 (GLOBE NEWSWIRE) -- Celsion Corporation (NASDAQ:CLSN) today announced that Khursheed Anwer, Ph.D., Celsion's executive vice president and chief science officer, presented two posters on February 23, 2017 at the American Society of Clinical Oncology (ASCO) - Society for Immunotherapy of Cancer (SITC) Clinical Immuno-Oncology Symposium held from February 23 - 25, 2017 in Orlando, FL. The ASCO-SITC Clinical Immuno-Oncology Symposium focused on the latest clinical and translational research in immuno-oncology and the implications for clinical care.

The first poster (#155) entitled "*Phase I study and activity of formulated IL-12 plasmid administered intraperitoneally in combination with standard neoadjuvant chemotherapy in patients with newly diagnosed advanced stage ovarian cancer*" reported the latest clinical results from the 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 followed by interval debulking surgery.

In the first twelve patients dosed in the OVATION Study, GEN-1 plus standard chemotherapy produced impressive clinical results, with no dose limiting toxicities and highly promising efficacy signals in this difficult to treat cancer.

- | Of the first twelve patients dosed, one patient (8%) demonstrated a complete response (CR), eight patients (67%) demonstrated a partial response (PR) and three patients (25%) demonstrated stable disease (SD), as measured by RECIST criteria. This translates to a 100% disease control rate (DCR), and 75% objective response rate (ORR).
- | Eleven of twelve patients had successful resections of their tumors, with six patients having an optimal R0 resection, which indicates a microscopically margin-negative resection in which no gross or microscopic tumor remains in the tumor bed, and four 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 eleven surgically treated and evaluable patients, one patient demonstrated a complete pathological response (cPR), five patients demonstrated a micro pathological response (microPR), and five 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<sup>1</sup>.
- | All eleven 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.

The second poster (#156) entitled "*Immunological changes following intraperitoneal administration of a formulated IL-12 plasmid in combination with standard neoadjuvant chemotherapy in patients with newly diagnosed advanced stage ovarian cancer*" reported preliminary translational data from the OVATION Study focusing primarily on the treatment-related changes in immune activating and immune suppressive T-cell populations in tumor tissue and in the levels of relevant cytokines in tumor ascites.

- | GEN-1 plus neoadjuvant chemotherapy resulted in dose-dependent increases in IFN-g levels and decreases in VEGF levels in peritoneal fluid, which is consistent with the results obtained from recurrent ovarian cancer patient population treated with GEN-1 in combination with standard chemotherapy in a previous clinical trial or in preclinical models of

ovarian cancer.

- Immuno-histochemical analysis of tumor tissue for various T-cell populations showed reduction in immunosuppressive T-cell phenotypes in most patients. The ratio of cytotoxic CD8<sup>+</sup> T cells to immunosuppressive FoxP3, IDO1 and PD-1 expressing cells was also increased in a majority of patients.

"Our hypothesis is that GEN-1 plus neoadjuvant chemotherapy treatment will reprogram the tumor immune microenvironment towards a potent antitumor immune response," said Dr. Anwer. "The available data demonstrate highly relevant immunological changes in the tumor immune environment, which supports the immune activating role of GEN-1 in this patient population. We are currently analyzing the tissue samples for additional immune cell populations and immune cytokines, and look forward to sharing a complete set of the clinical and translational results with the scientific and medical community."

The OVATION Study is designed to enroll three to six patients per dose cohort with the goal of identifying a safe, tolerable and immunologically active dose of GEN-1 by recruiting and maximizing an immune response. Enrollment in the fourth and final cohort is ongoing with the final three patients currently on study. Celsion expects to complete the enrollment and treatment phase of the OVATION Study early in the second quarter and report final data, including translational data for all patients, by the end of the second quarter of 2017.

"We are very encouraged, as have been our Investigators, by the findings to-date in this difficult-to-treat patient population," said Michael H. Tardugno, Celsion's chairman, president and CEO. "Over the past year, we have demonstrated the potential of our GEN-1 program, in both first and second-line ovarian cancer, and we look forward to reporting final clinical and translational data from this important study in the second quarter of 2017."

The two poster presentations will be available on Celsion's website under "News & Investors - Scientific Presentations."

## 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. 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.*

<sup>1</sup> 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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