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Celsion Corporation Announces Positive Data from the First Cohort of Patients in the OVATION Study

GEN-1 Immunotherapy Together with Standard Chemotherapy in First Line Ovarian Cancer Patients Demonstrates Impressive Outcomes
One Patient of the First Three with Advanced Ovarian Cancer Had a Complete Pathological Response

LAWRENCEVILLE, N.J., May 2, 2016 /PRNewswire/ -- Celsion Corporation (NASDAQ: CLSN), an oncology drug development company, today announced data from the first 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 three patients dosed, GEN-1 plus standard chemotherapy produced excellent results, with no dose limiting toxicities and highly promising efficacy signals leading to successful surgical outcomes. The three patients were treated at the University of Alabama at Birmingham.

"These results, while early, are very impressive and speak to the potential of GEN-1 to improve patient outcomes in ovarian cancer," said Ronald D. Alvarez, M.D., Professor, Division of Gynecologic Oncology at the University of Alabama at Birmingham. "In particular, we see improvements across a number of important and meaningful measures used to assess ovarian cancer, which reinforce our confidence in this IL-12 immunotherapy approach and provide a strong rationale for continued development of GEN-1 for the treatment of ovarian cancer."

OVATION Study - First Cohort Results

- Of the three patients treated in the first cohort, two patients demonstrated stable disease (SD) and one patient demonstrated a complete response (CR), as measured by RECIST criteria.
- All 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 one patient with an optimal R1 resection.
- One patient demonstrated a pathological complete response (pCR). pCRs are typically seen in less than 7% of patients receiving neoadjuvant chemotherapy followed by surgical resection, and have been associated with a median overall survival (OS) of 72 months, which is more than three years longer than those who do not experience a pCR[1].
- All patients experienced a dramatic > 96% 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. All patients' CA-125 levels were below the standard cutoff level of 35 U/mL.

"These results build on the impressive clinical findings we observed in the GOG Study as well as the translational data from this same study reported earlier this year. As we move closer towards initiating a Phase I/II trial to evaluate the synergistic anti-cancer effects of GEN-1 together with Avastin® and Doxil®, these results also provide strong validation for the potential of GEN-1 in ovarian cancer," said Michael H. Tardugno, Celsion's chairman, president and chief executive officer. "We will continue to evaluate the maturing dataset from the OVATION study, and may evaluate ways to leverage insights from this trial to help accelerate the clinical development of this highly promising therapy and inform the design of future studies."

The OVATION Study 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. Celsion has initiated four clinical sites at the University of Alabama at Birmingham; Oklahoma University Medical Center; Washington University in St. Louis and the Medical College of Wisconsin. The trial is designed to enroll three to six patients per dose cohort and will evaluate safety and efficacy and attempt to define an optimal dose. Future studies of GEN-1 will include a Phase I/II study combining GEN-1 with Avastin® and Doxil®. With the second cohort fully enrolled, Celsion expects to complete the OVATION Study this year.

GOG Study - GEN-1 Data

Celsion also recently announced clinical data from a dose-escalation study evaluating GEN-1 plus Doxil® in platinum resistant ovarian cancer (the GOG Study). In the GOG Study, at the highest dose level, GEN-1 plus Doxil® produced an objective response rate (ORR) of 29%. This compares favorably to the data from the Phase 3 AURELIA trial in platinum-resistant ovarian cancer, which demonstrated that Avastin® plus chemotherapy produced an ORR of 27%. Historical data for trials evaluating Doxil® monotherapy in platinum resistant ovarian cancer suggest an ORR of only 8% to 12%.

Translational data from the GOG Study reported in January 2016 is highlighted below:

- Intraperitoneal administration of GEN-1 in platinum-resistant ovarian cancer patients resulted in a significant increase in IL-12 levels in peritoneal fluid samples. IL-12 levels were quantifiable in 91% of evaluable fluid samples collected post GEN-1 treatment. None of the evaluable pre-treatment peritoneal fluid samples had any detectable IL-12 levels.
- The IL-12 levels were detectable for at least seven days after GEN-1 treatment.
- In comparison to peritoneal fluid, the IL-12 levels in plasma samples (systemic exposure) following GEN-1 treatment were not detectable or were very low in quantity.
- Significant increases in levels of IFN-γ, a key downstream mediator of IL-12 action, were observed in peritoneal fluid but not in plasma samples. At least a 5-fold increase above pre-treatment level in IFN- γ was observed in most samples, with the highest increase observed at 120-fold. Similar results were observed with TNF-α levels, with the highest increase observed at 77-fold over pre-treatment control.

About GEN-1 Immunotherapy

GEN-1, designed using Celsion's proprietary TheraPlas™ platform technology, is an IL-12 DNA plasmid vector encased in a nanoparticle delivery system, which enables cell transfection followed by persistent, local secretion of the IL-12 protein. IL-12 is one of the most active cytokines for the induction of potent anti-cancer immunity acting through the induction of T-lymphocyte and natural killer (NK) cell proliferation. The Company has previously reported positive safety and encouraging Phase I results with GEN-1 given as monotherapy in patients with peritoneally metastasized ovarian cancer, and recently completed a Phase Ib trial of GEN-1 in combination with PEGylated doxorubicin in patients with platinum-resistant 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 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 anti-cancer 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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