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Celsion Presents GEN-1 Immunotherapy Phase 1b Results in Recurrent Ovarian Cancer at ASCO 2015

Significant Clinical Benefit Observed at Highest Dose of GEN-1 in Platinum Resistant Ovarian Cancer

LAWRENCEVILLE, N.J., June 1, 2015 /PRNewswire/ -- Celsion Corporation (NASDAQ: CLSN), a fully integrated oncology drug development company, announced the presentation of clinical results from its Phase IB trial for GEN-1 in platinum-resistant ovarian cancer in a poster session by Dr. Premal H. Thaker, M.D., associate professorÂ at Washington University and Siteman Cancer Center in St. Louis, on Saturday, May 30th at the 2015 American Society of Clinical Oncology (ASCO) Meeting in Chicago. Â GEN-1 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.Â The poster presentation is available onÂ Celsion's website atÂ http://www.celsion.com.

The Phase 1B dose escalating study enrolled 16 patients with platinum-resistant ovarian cancer and evaluated the safety, tolerability and efficacy of GEN-1 in combination with pegylated doxorubicin as well as the effect of intraperitoneal injection of GEN-1 on IL-12 and tumor cytokine levels. Patients received pegylated liposomal doxorubicin on day 1 and GEN-1 on days 1, 8, 15 and 22. This treatment regimen was repeated every 28 days in the absence of disease progression or toxicity.Â

The clinical findings demonstrated an overall clinical benefit of 57% for all treatment arms, with a partial response (PR) rate of 21% and a stable disease (SD) rate of 36%. The overall clinical benefit observed at the highest dose cohort in this difficult-to-treat patient population was 100% (PR=33% and SD=67%) in all six evaluable patients. GEN-1 was well tolerated, with no dose limiting toxicities and no overlapping toxicities between GEN-1 and pegylated doxorubicin.Â

"These clinical results are very encouraging, especially given the fact that patients suffering from advancedÂ relapsedÂ ovarian cancer have typically failed previous treatments and have limited treatment options for this aggressive cancer.Â GEN-1 is a novel immunotherapy designed to enhance the patient's immune system to help the body treat and fight cancer," said Dr. Thaker. "I am pleased to be part of this important study and look forward to continuing my involvement with future trials of GEN-1 IL-12 immunotherapy in this underserved patient population."

Additional translational data measuring cytokine levels (IFN-gamma and TNF-alpha) at increased doses of GEN-1 will be available after the ASCO Meeting.Â Since the maximum tolerated dose was not reached in this study, Celsion plans to evaluate GEN-1 in a Phase 1 dose escalating trial in first line neoadjuvant ovarian cancer. Â Based on the significant clinical benefit observed in the Phase 1B study coupled with compelling preclinical data, the Company also plans to initiate a Phase 1B dose escalating trial evaluating GEN-1 plus Avastin® and Doxil® in platinum-resistant ovarian cancer patients, a combination which has the potential to significantly improve treatment outcomes for these patients.

In two preclinical studies using an animal model of disseminated ovarian cancer, GEN-1 in combination with Avastin® led to a significant reduction in tumor burden and disease progression.Â The effectiveness of the combined treatment was seen when GEN-1 was combined with various dose levels of Avastin® (low-medium-high).Â The preclinical studies indicated that no obvious overt toxicities were associated with the combined treatments.Â

The preclinical data are also consistent with the mechanism of action for GEN-1, which exhibits certain anti-angiogenic properties and suggests that combining GEN-1 with lower doses of Avastin® may enhance efficacy and help reduce the known toxicities associated with this anti-VEGF drug.

The distinct biological activities of GEN-1 (immune stimulation) and Avastin® (inhibition of tumor blood vessel formation) makes a sound scientific rationale for this combination approach.Â Additionally, the anti-angiogenic activity of GEN-1 mediated through up regulation of the interferon gamma (IFN-gamma) pathway may help to explain the remarkable synergy between GEN-1 and Avastin® and potentially addresses the VEGF escape mechanisms associated with resistance to Avastin® therapy.

"This impressive body of clinical and preclinical data warrants the continued development with escalating doses of GEN-1 and underscores the potential clinical utility of this immunotherapy in difficult-to-treat diseases like recurrent ovarian

cancer," said Michael H. Tardugno, Celsion's chairman, president and chief executive officer.

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. GEN-1 has also demonstrated preclinical activity in glioblastoma multiforme (brain cancer) and the Company plans to initiate a Phase I study in this indication in the second half of 2015.

About Celsion Corporation

CelsionÂ 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.Â The pipeline also includes GEN-1, a DNA-based immunotherapy for the localized treatment of ovarian and brain cancers.Â Â CelsionÂ has three platform technologies for the development of novel nucleic acid-based immunotherapies and other anti-cancer DNA or RNA therapies, including TheraPlas™, TheraSilence™ and RAST™.Â For more information onÂ Celsion, visit our website:Â http://www.celsion.com.

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