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Celsion Announces Presentation of Preclinical Data for GEN-1 IL-12 Immunotherapy in Combination with Avastin® and Doxil® at the AACR Annual Meeting 2016

Preclinical Studies Demonstrate Statistically Significant Synergistic Anti-Cancer Effects when GEN-1 is combined with Avastin® and Doxil®

LAWRENCEVILLE, N.J., March 16, 2016 /PRNewswire/ -- Celsion Corporation (NASDAQ: CLSN), an oncology drug development company, today announced that its preclinical data for GEN-1 in combination with Avastin® and Doxil® for the treatment of ovarian cancer will be presented at the upcoming AACR Annual Meeting 2016 in New Orleans. The presentation will be held on Monday, April 18, 2016 (1:00 pm to 5:00 pm) and will summarize results from preclinical studies demonstrating significant synergistic anti-cancer effects when GEN-1 is combined with Avastin® and Doxil®, a current Standard of Care (SoC) for platinum resistant ovarian cancer patients. GEN-1 is an IL-12 DNA plasmid vector formulated into a nanoparticle with a non-viral delivery system to cause the sustained local production and secretion of the Interleukin-12 (IL-12) protein loco-regionally to the tumor site. These data will be used by the Company to support a comprehensive IND protocol filing for a Phase I/II clinical trial evaluating the combination in recurrent ovarian cancer later this year.

"The immune stimulating nature of GEN-1 in combination with Avastin® and Doxil®, two of the most widely used cancer therapies, makes for an ideal therapy, bolstering the anti-cancer effect beyond what has been observed when used alone," said Nicholas Borys, M.D., senior vice president and chief medical officer of Celsion. "Results from this important study are highly encouraging and suggest that when these therapies are combined, they offer the potential to significantly reduce tumor burden and disease progression in this highly aggressive cancer in patients who have failed first line platinum-based therapies."

Data is emerging on how SoC chemotherapy treatments influence the immune response in cancers that they are targeting. Chemotherapy stimulates the immune system by (i) making the dying tumor cells more visible to the body's immune system through the release of tumor antigens; (ii) destroying the immune suppression caused by the tumor; and (iii) directly or indirectly affecting immune cells and immune modulators.

Chemotherapy treatments may be a good candidate for combination with immune-mediating therapies like GEN-1. Doxorubicin increases not only T-cell and natural killer (NK) cell production, but also B cells (anti-tumor antibodies) in ovarian cancer. IL-12 is a highly active cytokine that can induce a potent anti-cancer immunity mediated through the activation of cytotoxic T-lymphocytes and NK cells and the inhibition of immune-suppressing regulatory T-cells.

Clinical data supporting the combination of GEN-1 with SoC chemotherapies

GEN-1 has already demonstrated encouraging safety and efficacy clinical data in combination with PEGylated liposomal doxorubicin (Doxil®) in patients with platinum-resistant ovarian cancer. Results from a Phase Ib clinical trial in platinum resistant ovarian cancer patients have shown that intraperitoneal delivery of GEN-1 in combination with Doxil® produced an overall clinical benefit of 57.1% (PR=21.4%; SD=35.7%) in patients with measurable disease. The highest percentage of PRs were found at the highest dose level (28.6%) along with the highest percentage of patients achieving SD (57.1%) producing an overall clinical response rate (CR+PD+SD) of 86% at the highest GEN-1 dose cohort, which, despite a small study size, is highly encouraging considering the poor outcome with Doxil alone in this patient population.

GEN-1 has also produced encouraging data in combination with Avastin® alone in earlier preclinical studies in a model of ovarian cancer, leading to a significant reduction in tumor burden and disease progression. The inhibition of VEGF by IL-12 through the secretion of interferon-gamma may help explain the impressive synergies between GEN-1 and SoC anti-angiogenic agents like Avastin. These findings open up an additional combination therapy of Avastin with an immune-based therapy like GEN-1.

Preclinical data supporting the combination of GEN-1 with SoC Chemotherapy + Avastin

Results from comprehensive studies confirmed remarkable, statistically significant initial GEN-1 + Avastin findings. Recent studies now show convincingly that GEN-1 when combined with Avastin® and Doxil® demonstrated a greater than 98% reduction in tumor burden when compared to the untreated control group. The findings represent a statistically significant

reduction in tumor burden and disease progression when compared to the combination of Avastin® and Doxil® in a SKOV3 human cell line implanted into immunocompromised (nude) mice. Analysis of serum chemistry and hematology suggested no overt toxicities associated with the combined treatments. The preclinical data are consistent with the mechanism of action for GEN-1, which exhibits certain anti-angiogenic properties in addition to its well-characterized immunomodulatory activities.

"We believe that the synergy provided to the tumor micro-environment by GEN-1 is responsible for our remarkable preclinical findings," said Michael Tardugno, chairman, chief executive officer and president of Celsion. "Local cellular production and secretion of highly-tolerable endogenous IL-12, a multi-mechanistic anti-cancer agent, both supports doxorubicin's immune system activating potential as well as reinforces the anti-angiogenic properties of one of the world's most prescribed anti-cancer biologics, Avastin. We are excited to move forward into clinical trials with the potential for a ground breaking therapeutic approach."

The Company is currently enrolling patients in the OVATION Study, a Phase 1b dose escalating trial combining GEN-1 with neo-adjuvant therapies in newly diagnosed ovarian cancer patients which will provide a starting dose for the follow-on Phase 1/2 study combining GEN-1 with Avastin® and Doxil®. The Phase 1/2 combination trial is expected to begin in mid-2016.

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

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>.

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.

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