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Celsion Announces Impressive Preclinical Data for its GEN-1 IL-12 Immunotherapy in Combination with Avastin® and Doxil® for Ovarian Cancer

Preclinical Data Demonstrates Significant Synergistic Anti-Cancer Effects when GEN-1 is combined with Avastin® and Doxil®
Data from Comprehensive Studies Confirm GEN-1's Synergy with Avastin and Supports the IND Filing for Phase 1/2 Trial Evaluating the Combination in Ovarian Cancer

LAWRENCEVILLE, N.J., Oct. 12, 2015 /PRNewswire/ -- Celsion Corporation (NASDAQ: CLSN), an oncology drug development company, today reported data from a large preclinical study of the Company's GEN-1 IL-12 immunotherapy in combination with Avastin® and Doxil® for the treatment of ovarian cancer. Results from the comprehensive studies confirmed remarkable initial GEN-1 + Avastin findings and show convincingly that GEN-1 when combined with Avastin® and Doxil®, standard of care for platinum resistant patients, demonstrated a greater than 98% reduction in tumor burden when compared to the untreated control group. Â 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.

"The immune stimulating nature of GEN-1 in combination with Avastin® and Doxil® 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 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."

The study was designed to evaluate in a mouse model of disseminated ovarian cancer, the efficacy of a combined treatment regimen that consisted of weekly administrations of GEN-1 with therapeutically relevant doses of Doxil® and Avastin®.Â In the study, the combination of GEN-1 with Avastin® and Doxil® demonstrated a robust anti-tumor advantage compared to untreated animals as well as a statistically significant improvement over the combination of Avastin® and Doxil® as summarized below:

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	Reduction in Mean Tumor Burden vs. Untreated Control	Percentage of Animals with No Visible Tumors
GEN-1 ImmunotherapyÂ	84%	50%
Avastin® + LD Doxil®Â Â Â	77%	12%
Avastin® + HD Doxil®Â Â	88%	50%
Avastin® + LD Doxil® + GEN-1Â Â Â	> 98%Â Â	75%
Avastin® + HD Doxil® + GEN-1Â Â	> 98%Â Â Â	75%

LD - Low Dose; HD - High Dose

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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.

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. GEN-1 has already demonstrated encouraging safety and efficacy clinical data in combination with PEGylated doxorubicin (Doxil®) in patients with platinum-resistant ovarian cancer, with a clinical response rate (CR+PD+SD) of 86% at the highest GEN-1 dose cohort.Â 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. Additionally, the data show that GEN-1 treatment alone resulted in anti-tumor

activity that was as good as or better than Avastin® treatment alone.

"The biology of GEN-1 continues to demonstrate a strong anti-tumor effect when combined with Avastin® and Doxil®, two of the most widely used cancer therapies," said Michael H. Tardugno, Celsion's chairman, president and chief executive officer. "In addition to evaluating GEN-1 in first-line ovarian cancers, with Avastin's recent approval for platinum resistant ovarian cancer patients, we now have an opportunity to study how our IL-12 immunotherapy may work in a clinical setting with Avastin®, one of the most widely used cancer treatments with 2014 revenues of over $7 billion, to improve efficacy while enhancing tolerability.Â Confirmation of our initial findings now provides substantial evidence for a clinical program that includes Doxil® and Avastin®. Â We look forward to completing enrollment of the OVATION Study, next year, followed by the launch of this combination trial later in 2016."

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. Â Â

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.Â The pipeline also includes GEN-1, a DNA-based immunotherapy for the localized treatment of ovarian and brain cancers.Â 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™.Â 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.Â 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.Â 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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