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Celsion Expands Clinical Development Plan for GEN-1 IL-12 Immunotherapy Program in Ovarian Cancer

Combination GEN-1 with Avastin® in Platinum-Resistant Ovarian Cancer to be Initiated in the Second Half of 2015

Preclinical Data Demonstrate Synergistic Anti-Cancer Effects in Combination with Avastin®

Enrollment in Phase 1 Dose Escalating Trial Combining GEN-1 with NeoAdjuvant Therapies in Newly Diagnosed Ovarian Cancer Patients on Track to Begin in the Third Quarter

LAWRENCEVILLE, N.J., April 29, 2015 /PRNewswire/ --Â Celsion Corporation (NASDAQ: CLSN), a fully-integrated oncology company focused on the development of a portfolio of innovative cancer treatments, including directed chemotherapies, immunotherapies and RNA- or DNA-based therapies for the treatment of cancer and other difficult-to-treat diseases, announced today an update on its clinical development plans for GEN-1, the Company's DNA-based immunotherapy for the localized treatment of cancer, in ovarian cancer.Â GEN-1 has demonstrated promising clinical activity and tolerability in platinum-resistant and recurrent ovarian cancer patients, as well as synergistic anti-cancer effects in combination with bevacizumab (Avastin®) in preclinical models.Â The Company announced plans today to expand its ovarian cancer development program to include a Phase 1 dose escalating trial evaluating GEN-1 in combination with Avastin® and Doxil® in platinum-resistant ovarian cancer patients, expected to begin in the second half of 2015. As previously reported, Celsion intends to commence a Phase 1b dose escalating trial in newly diagnosed ovarian cancer patients in the third quarter of this year.Â

"We have demonstrated in our preclinical models that adding GEN-1 to Avastin® can result in a powerful immunotherapy combination for cancer patients.Â The mechanisms of GEN-1 and Avastin® complement each other and may prove to be an effective therapy in choking off cancer growth in this aggressive cancer," stated Nicholas Borys, M.D., Senior Vice President and Chief Medical Officer of Celsion. "GEN-1 has already demonstrated activity in platinum-resistant cancer patients when combined with Doxil® and recurrent ovarian cancer patients, two patient populations which historically have had limited responses to new treatment options. These data, together with the remarkable synergies observed when combining GEN-1 with Avastin® in two recent animal studies, provide a strong rationale for continued development in platinum-resistant patients and reflects evolving clinical practice following the approval of Avastin® in this indication."

The new combination study in platinum-resistant ovarian cancer is supported by two preclinical studies demonstrating that the combination of GEN-1 with Avastin® may result in significant clinical benefit with a favorable safety profile, as well as a prior Phase 1b trial of GEN-1 plus Doxil® in platinum resistant ovarian cancer patients.Â Specifically:

-  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 Additionally, it was demonstrated that GEN-1 treatment alone resulted in anti-tumor activity that was as good as or better than Avastin® treatment alone.
-  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-g) 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.
-  In a 16-patient Phase 1b study of GEN-1 in combination study in platinum-resistant ovarian cancer, there were no overlapping toxicities between GEN-1 and pegylated doxorubicin (Doxil®). Â Biological activity and clinical efficacy results, including disease control rates, translational data and survival rates, have been submitted for presentation at theÂ American Society of Clinical Oncologist (ASCO) Annual Meeting.

Celsion intends to conduct additional preclinical studies to support an Investigational New Drug filing with the U.S. Food and

Drug Administration for the planned Phase 1 combination study.Â The study will be designed to optimize the dosing regimen for GEN-1 in combination with Avastin® and is expected to enroll approximately 12 to 18 patients.Â

"As an IL-12 immunotherapy, GEN-1 has broad potential in multiple tumor types, and our clinical strategy is designed to accelerate its development, establish its clinical utility in various indications and drive it toward the market," saidÂ Michael H. Tardugno,Â Celsion'sÂ chairman, president and chief executive officer. Â "In addition to evaluating GEN-1 in first-line ovarian cancer, with Avastin's recent approval for platinum resistant patients, we now have an opportunity to study how it may work synergistically with Avastin®, one of the most widely used cancer treatments with 2014 revenues of \$7.4 billion, to improve efficacy while enhancing tolerability.Â The results of this important trial may therefore highlight additional therapeutic opportunities for GEN-1 and help guide how our development program evolves over the long term. We look forward to launching our study in first line ovarian cancer this year, followed by the launch of this combination trial, and then moving into clinical studies in a second tumor type, glioblastoma multiforme where Avastin® is currently used."

About GEN-1 Immunotherapy

GEN-1, designed usingÂ Celsion'sÂ 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.Â 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. The pipeline also includes EGEN-001, a DNA-based immunotherapy for the localized treatment of ovarian and brain cancers.Â Celsion 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 on Celsion, visit our website: <http://www.celsion.com>.

Avastin® (bevacizumab) is the registered trademark of Genentech.Â Genentech is not a collaborator with Celsion Corporation.Â

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; HEAT Study data is subject to further verification and review by the HEAT Study Data Management Committee; the need for Celsion to evaluate its future development plans; possible acquisitions or licenses of other technologies, assets or businesses or the possible failure to make such acquisitions or licenses; 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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