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Celsion Corporation Presents Clinical and Preclinical Data for GEN-1 IL-12 Immunotherapy in Ovarian Cancer at the Molecular Medicine TRI-Conference

A Follow-On Combination Trial in First-Line Ovarian Cancer in the Neo-Adjuvant Setting Has Been Accepted by FDA

LAWRENCEVILLE, N.J., Feb. 20, 2015 /PRNewswire/ -- Celsion Corporation (NASDAQ: CLSN), a fully-integrated oncology company focused on the development of a high potential portfolio of innovative cancer treatments, today presented clinical and preclinical data demonstrating the safety, biological activity and clinical benefits of GEN-1, its DNA-based immunotherapy, as a single agent in advanced platinum-resistant and recurrent ovarian cancer patients, at the Molecular Medicine TRI-Conference in San Francisco. These data provide support for advancing GEN-1 into clinical development in the front-line setting. The Company also announced that the U.S. Food and Drug Administration (FDA) has accepted, without comment, its planned Phase 1 dose-escalation clinical trial of GEN-1 in combination with the standard of care in neo-adjuvant ovarian cancer, which is expected to commence in mid-2015 at five to six U.S. clinical centers.

"These important findings significantly strengthen our established clinical and preclinical data providing additional evidence of GEN-1's ability to effectively recruit a cellular immune system response, widely known for its anti-cancer activity. Evidence now in platinum-resistant and recurrent ovarian cancer patients, populations which historically have had little to no response to new investigational therapies, is highly encouraging," stated Khursheed Anwer, Ph.D., Executive Vice President and Chief Scientific Officer of Celsion. "Based on the level of activity observed in these advanced patient populations, we believe that GEN-1 has the potential to produce a robust response in the neo-adjuvant setting, where patients typically have healthier immune systems and no prior treatment with immunosuppressive drugs."

Today's presentation at the Molecular Medicine TRI-Conference included data from the recently completed Phase 1b dose-escalation combination study of GEN-1, as well as a review of previously reported data. The Phase 1b study enrolled 16 patients with platinum-resistant ovarian cancer and evaluated the safety, tolerability and efficacy of GEN-1 in combination with pegylated doxorubicin. Patients received pegylated liposomal doxorubicin on day 1 and GEN-1 intra-peritoneally (IP) over days 1, 8, 15 and 22. This treatment course was repeated every 28 days in the absence of disease progression or unacceptable toxicity. The findings demonstrated that there were no overlapping toxicities between GEN-1 and pegylated doxorubicin. Biological activity and clinical efficacy results from this Phase 1b study including disease control rates, translational data and survival rates among the three doses evaluated have been submitted for presentation at the American Society of Clinical Oncologist (ASCO) Conference in the second quarter of 2015 and will be publicly available following ASCO's normal publication schedule. Patients will be followed quarterly for up to one year following completion of study treatment.

The data from the Phase 1b study was consistent with previously reported data from two single-agent studies of GEN-1 in platinum-resistant recurrent ovarian cancer. In an earlier Phase 1 study, treatment with GEN-1 demonstrated a DCR of 31%, biological activity and median overall survival (OS) of 18 months. In the Phase 2 study, treatment with GEN-1 demonstrated a DCR of 45% and a median OS of 10 months. In both studies, GEN-1 was well tolerated and no maximum tolerated dose (MTD) was achieved.

"The data presented today highlights the potential value and promise of our IL-12 immunotherapy program and our expectations for the TheraPlas™ platform generally," said Michael H. Tardugno, Celsion's Chairman, President and Chief Executive Officer. "With results that pave the way for GEN-1 to provide a promising new approach for treating ovarian cancer, we are now focused on launching our upcoming combination trial, which is designed to help identify a maximum tolerated dose of GEN-1 and will inform the design of our planned Phase 2 study in the front line setting, where new therapies are desperately needed. We will collect translational data to better understand the relationship between higher doses of GEN-1 and the effect on stimulation of the patients' immune system."

The combination trial is designed to enroll three to six patients per dose level until a safe, tolerable and potentially therapeutically active dose is identified. The study will evaluate safety and efficacy and attempt to define an optimal dose to carry forward into a Phase 2 trial.

A copy of the presentation can be found on the Company's website under *Events & Presentations*.

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.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.Â A Phase Ib trial of GEN-1 in combination with PEGylated doxorubicin in patients with platinum-resistant ovarian cancer is currently ongoing. 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 EGEN-1, 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>.

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 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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