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Celsion Corporation Enrolls First Patient in the OVATION Study

First Line, Phase 1b Trial to Assess Immunotherapy Combining GEN-1 with Neo-Adjuvant Therapies in Newly Diagnosed Ovarian Cancer Patients

LAWRENCEVILLE, N.J., Sept. 30, 2015 /PRNewswire/ --Â Celsion Corporation (Celsion) (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, today announced the enrollment of the first patient in its Phase Ib dose escalating clinical trial (the OVATION Study) combiningÂ GEN-1, the Company's DNA-based immunotherapy, with the standard of care for the treatment of newly-diagnosed ovarian cancer patients who will undergo neoadjuvant chemotherapy. Â The first patient in the OVATION Study was enrolled at the University of Alabama at Birmingham (UAB).Â In addition to UAB, Oklahoma University Medical Center is now also recruiting patients in the OVATION Study.Â Celsion plans to initiate two additional sites in the coming months. Interim findings from this open label study are expected in the fourth quarter of 2015.Â The study will continue into the first half of next year at higher doses of GEN-1.

The OVATION Study will seek to identify a safe, tolerable and therapeutically active dose of GEN-1 by recruiting and maximizing an immune response.Â The trial is designed to enroll three to six patients per dose level and will evaluate safety and efficacy and attempt to define an optimal dose for a follow-on Phase I/II study combining GEN-1 with Avastin® and Doxil®.Â Â In addition, the OVATION Study establishes a unique opportunity to assess how cytokine-based compounds such as GEN-1, directly affects ovarian cancer cells and the tumor microenvironment in newly diagnosed patients. The study is designed to characterize the nature of the immune response triggered by GEN-1 at various levels of the patients' immune system, including:

- infiltration of cancer fighting T-cell lymphocytes into primary tumor and tumor microenvironment including peritoneal cavity, which is the primary site of metastasis of ovarian cancer;
- changes in local and systemic levels of immuno-stimulatory and immunosuppressive cytokines associated with tumor suppression and growth, respectively; andÂ
- expression profile of a comprehensive panel of immune related genes in pre-treatment and GEN-1-treated tumor tissue.Â

These extensive mechanistic studies will assist in the design of novel combination approaches with immunotherapies and other anti-cancer agents driven by potential synergistic action mechanisms, and define an enhanced patient population based on molecular characteristics inherent to tumor tissue or the immune system.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. GEN-1 has demonstrated encouraging safety and efficacy data in a Phase Ib trial in combination with PEGylated doxorubicin in patients with platinum-resistant ovarian cancer. The findings from this trial 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

"Developing more effective immunotherapy approaches for ovarian cancer is a high priority for those of us who care for the thousands of patients affected by advanced ovarian cancer. Â GEN-1 is a novel IL-12 expressing lipopolymer that has demonstrated promising activity in preclinical and early phase clinical trials in ovarian cancer," stated Premal H. Thaker, M.D., associate professor, Division of Gynecologic Oncology, Department of Obstetrics and Gynecology, Washington University School of Medicine.Â "In preclinical and clinical studies performed to date, GEN-1 has demonstrated good safety and impressive immune system stimulation and activity, and this trial will evaluate its value as an adjuvant to chemotherapy in patients with a relatively healthy immune system."

"GEN-1 is designed to locally activate IL-12 production, which can stimulate the patient's immune system to attack and destroy cancer," stated Dr. Nicolas Borys, Celsion's senior vice president and chief medical officer.Â "Increases in IL-12 concentrations at the tumor site could create a potent immune environment against tumor activity resulting in a more robust and durable antitumor response compared to chemotherapy alone.Â We are conducting this trial in newly diagnosed

patients with good immune systems in order to maximize the success of GEN-1's novel mechanism."

"GEN-1 holds tremendous promise as a potential treatment in the rapidly emerging area of immuno-oncology. Unlike the toxicities, poor tolerability, and poor pharmacokinetics of systemically administered recombinant IL-12, the beauty of GEN-1 is that it inspires secretion of highly-tolerable endogenous IL-12," said Michael H. Tardugno, Celsion's chairman, president and chief executive officer. "Designed in consultation with clinicians, this Phase I trial is expected to define an optimal dose and potentially an enhanced population.Â It will also provide insights on powering for a registration program as the candidate progresses through development."

About GEN-1 Immunotherapy

GEN-1, designed using the 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.Â 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 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 in combination with PEGylated doxorubicin in patients with platinum resistant ovarian cancer.Â 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.

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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