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Celsion Files Immunotherapy Clinical Protocol for the Evaluation of GEN-1 to Treat Newly Diagnosed Ovarian Cancer

Expert Advisory Board Endorses Randomized Phase I/II Trial in Newly Diagnosed Stage III and IV Ovarian Cancer

GEN-1 Immunotherapy to Enter Phase I/II Clinical Study in the First Half of 2018 Following a Phase IB Trial Demonstrating 100% Disease Control, 86% Objective Response Rate and 86% R0 & R1 Surgical Resection Rate in All Patients Treated

LAWRENCEVILLE, N.J., Nov. 13, 2017 (GLOBE NEWSWIRE) -- Celsion Corporation (NASDAQ:CLSN), an oncology drug development company, today announced the submission of its Phase I/II clinical trial protocol to the U.S. Food and Drug Administration (FDA) for GEN-1, the Company's DNA-based immunotherapy for the localized treatment of ovarian cancer. The protocol, developed in conjunction with guidance from the Company's Medical Advisory Board, is designed with a single dose escalation to evaluate the safety and biological activity of GEN-1 at 100mg/m² in newly diagnosed Stage III/IV ovarian cancer patients, followed by a continuation at the selected dose in Phase II in a 90 patient 1 to 1 randomized study. GEN-1 has demonstrated encouraging safety and efficacy data in a recently completed dose escalating Phase IB trial in combination with neoadjuvant chemotherapy, the standard of care for patients newly diagnosed with ovarian cancer. Concurrently with neoadjuvant chemotherapy, enrolled patients received escalating weekly doses of GEN-1, from levels beginning at 36mg/m², to 47mg/m², 61mg/m² and 79mg/m² weekly for 8 treatments in total, followed by interval debulking surgery.

"GEN-1 is designed to locally activate IL-12 production which can recruit and stimulate the patient's immune system to attack and destroy cancer," stated Dr. Nicolas Borys, Celsion's senior vice president and chief medical officer. "In preclinical and multiple Phase I clinical studies performed to date, GEN-1 has demonstrated good safety and impressive immune system stimulation and clinical activity. This trial will evaluate its value as an adjuvant to current standard of care in newly diagnosed Stage III/IV ovarian cancer patients with a relatively healthy immune system. We look forward to initiating the study in the first half of 2018."

The Phase I/II study builds on the highly promising clinical and translational research data for the recently completed Phase IB dose-escalating OVATION Study. This next Phase I/II study will have a dose escalating phase to 100 mg/m² to identify a safe and tolerable dose of GEN-1 while maximizing an immune response. The study protocol was unanimously supported by an expert medical advisory board and lead investigators from the Phase IB OVATION Study and is summarized below:

- Open label, 1:1 randomized design
- Enrollment up to 90 patients with Stage III/IV ovarian cancer patients at ten U.S. centers
- Primary endpoint of improvement in progression-free survival (PFS) comparing GEN-1 with neoadjuvant chemotherapy versus neoadjuvant chemotherapy alone.
- PFS for patients treated per protocol in the Phase IB OVATION Study continues to be followed. Of the eight patients who received GEN-1 treatment over one year ago (cohort 1 - 3) and are being followed, only [two] patients' cancer has progressed. This compares favorably to the historical median progression-free survival of 12 months for newly-diagnosed patients with Stage III and IV ovarian cancer that undergo neoadjuvant chemotherapy followed by interval debulking surgery. Of the remaining six patients who have been on the OVATION Study for over one year, their average PFS as of October 31, 2017 is [18] months with the longest progression-free patient at 24 months.

The protocol has been submitted to the FDA for its 30 day review and comment period. Pending this review, the Company expects to initiate enrollment of the Phase I portion of the study in the first half of 2018. The Company expects to have the study 50% enrolled by the end of 2018. Due to the open label design, clinical data will be disclosed throughout the execution of the trial as it is released by the study's investigators.

"GEN-1 holds the potential of tremendous promise as a cancer 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 leading thought leaders, this Phase I/II trial is expected to define an optimal dose, demonstrate GEN-1's clinical benefit when compared with current standard of care, and provide

insights on powering for a registration program as the candidate progresses through development."

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.

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 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. For more information on Celsion, visit our website: http://www.celsion.com. (CLSN-G1 CLSN-OV)

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 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.

Celsion Investor Contact

Jeffrey W. Church
Sr. Vice President and CFO
609-482-2455
jchurch@celsion.com

Source: Celsion Corporation