Celsion Announces DSMB Recommendation to Continue GEN-1 at 100mg/m² Dose to Complete the Phase I Portion of OVATION 2 Study in Ovarian Cancer

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GEN-1 Manufacturing Technology Transfer Successfully Produces High-Quality Affordable Investigational Product for Use in Clinical Trials

LAWRENCEVILLE, N.J., Nov. 05, 2019 (GLOBE NEWSWIRE) -- Celsion Corporation (NASDAQ: CLSN) today announced that the independent Data Safety Monitoring Board (DSMB) has completed its safety review of data from the first eight patients enrolled in the ongoing Phase I/II OVATION 2 Study. Based on the DSMB's recommendation, the study will continue as planned and the Company will proceed with completing enrollment in the Phase I portion of the trial. The OVATION 2 Study combines GEN-1, the Company's IL-12 gene-mediated immunotherapy, with the standard of care for the treatment of newly diagnosed patients with Stage III and IV ovarian cancer who will undergo standard neoadjuvant chemotherapy (NACT) followed by interval debulking surgery (IDS).

The OVATION 2 Study is a randomized Phase I/II study designed to evaluate the safety of 100 mg/m² of GEN-1 in the Phase I portion, followed by a continuation at the safe dose in the Phase II portion in an open-label, 1:1 randomized design. GEN-1, designed using Celsion's proprietary TheraPlas platform technology, is an interleukin-12 (IL-12) DNA plasmid vector encased in a non-viral nanoparticle delivery system, which enables cell transfection followed by persistent, local secretion of the IL-12 protein.

In the OVATION 2 Study, patients in the GEN-1 treatment arm will receive GEN-1 plus chemotherapy pre- and post-interval debulking surgery. The OVATION 2 Study will enroll up to 130 patients with Stage III/IV ovarian cancer, with 12 to 15 patients in the Phase I portion and up to 118 patients in the Phase II portion. The study is powered to show a 33% improvement in progression-free survival (PFS), the primary endpoint, when comparing GEN-1 with NACT versus NACT alone. The PFS primary analysis will be conducted after at least 80 events (or deaths) have been observed, or after all patients have been followed for at least 16 months, whichever is later.

Developed with extensive input from the Company's Medical Advisory Board, the OVATION 2 Study builds on promising clinical and translational research data from the Phase IB dose-escalation OVATION I Study, in which enrolled patients received escalating weekly doses of GEN-1 up to 79 mg/m² for a total of eight treatments in combination with NACT, followed by IDS. In addition to exploring a higher dose of GEN-1 in the OVATION 2 study, patients will continue to receive GEN-1 after their IDS in combination with adjuvant chemotherapy.

"This latest DSMB review of GEN-1 at 100 mg/m² confirmed that there were no dose limiting toxicities detected in any of the five patients dosed with GEN-1 and that intraperitoneal administration is well tolerated even when given with standard NACT," said Nicholas Borys, M.D., executive vice president and chief medical officer of Celsion. “Of the eight patients treated in the Phase I portion of the OVATION 2 Study, five patients were treated with GEN-1 plus NACT and three patients were treated with NACT only. We look forward to presenting surgical results, overall response rates, and translational data as it becomes available later this quarter.”

Dr. Borys concluded, “OVATION 2 is designed to define the optimal dose of GEN-1 and provide important insights into GEN-1's clinical benefit as an adjuvant therapy both before and after debulking surgery with the potential to stimulate an anticancer immune response, compared to the current standard of care alone."

In the prior Phase Ib OVATION I Study, Celsion reported promising clinical findings including objective responses (complete response + partial response) in all patients at the two highest dose cohorts, along with an 87.5% rate of R0 (margin-negative) resections in the two highest dose cohorts and a 100% rate of R0 resections in the highest dose cohort at time of debulking surgery. Additionally, translational research data demonstrates that GEN-1 is biologically active, producing beneficial cytokines and positively impacting T-cell population in the tumor.

“We are very excited to advance our ovarian cancer research, which is based on the known and highly potent anti-cancer agent IL-12. We believe GEN-1, our novel, gene-mediated formulation, has the potential to effectively harness IL-12’s antitumor activity for cancer patients with a dimension of safety not found in the free, recombinant form,” said Michael H. Tardugno, Celsion's chairman, president and chief executive officer.

Manufacturing Technology Transfer for GEN-1

In order to support the future clinical development and global market strategy of GEN-1 in ovarian cancer, the Company is finalizing technology transfer initiatives with two premier global manufacturers in China, Zhejiang Hisun Pharmaceutical Co. Ltd. and Hainan Poly Pharm Co., Ltd. The Company has completed several important technology transfer activities relating to the manufacture of GEN-1, including studies required by National Medical Products Administration (NMPA), the China regulatory agency, for site approval. These important initiatives are designed to pursue an expanded partnership for the technology transfer relating to the clinical and commercial manufacture and supply of GEN-1 for the greater China territory, with the option to expand into other countries in the rest of the world after all necessary regulatory approvals are in effect.

Key provisions of the technology transfer initiatives are as follows:

- To provide Celsion with a high-quality, affordable, cost-effective supply for all global markets.
- To target unit costs for clinical supplies of GEN-1 that are substantially competitive with the Company's current suppliers.
- Once an approved drug, the cost structure for GEN-1 is expected to support rapid market adoption and significant gross margins across global markets.

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 cancer. 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; 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.

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