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Celsion Announces FDA Clearance of the OVATION II Study for the Evaluation of GEN-1 Immunotherapy to Treat Newly Diagnosed Stage III/IV Ovarian Cancer

GEN-1 to Enter the Clinic in Mid-2018 Following a Phase IB Trial Which Demonstrated 100% Disease Control, 86% Objective Response Rate and 86% R0 & R1 Surgical Resection Rate in All Patients Treated

Compelling Progression-Free Survival Data from Phase IB Trial Supports Development of GEN-1 as a Novel First Line Neoadjuvant Therapy

LAWRENCEVILLE, N.J., Jan. 04, 2018 (GLOBE NEWSWIRE) -- Celsion Corporation (NASDAQ: CLSN), an oncology drug development company, today announced that the U.S. Food and Drug Administration (FDA), following the customary 30 day review period, has accepted its submission without comment, providing clearance for the OVATION II Study, the Company's planned Phase I/II clinical trial of GEN-1, its DNA-based immunotherapy for the localized treatment of ovarian cancer. The Phase I/II trial was developed with extensive input from the Company's Medical Advisory Board. The OVATION II Study builds on the highly promising clinical and translational research data from the Phase IB dose-escalating OVATION Study where 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, in combination with neoadjuvant chemotherapy, followed by interval debulking surgery.

This next Phase I/II study is designed with a single dose escalation phase to 100 mg/m² to identify a safe and tolerable dose of GEN-1 while maximizing an immune response, followed by a continuation at the selected dose in Phase II in an open label, 1:1 randomized design up to 90 patients with Stage III/IV ovarian cancer at up to fifteen U.S. centers. The study is powered to show a 33% improvement in the primary endpoint, progression-free survival (PFS), when comparing GEN-1 with neoadjuvant chemotherapy versus neoadjuvant chemotherapy alone.

Progression-free survival for patients treated per protocol in the Phase IB OVATION Study continues to be followed. Of the thirteen patients who received GEN-1 treatment in all four dose escalating cohorts, only four patients' cancer has progressed to-date. 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. Summarized below are the latest PFS results for all patients treated per protocol in the Phase IB OVATION Study:

- Cohort 1 (36 mg/m²) - All patients have progressed; Average PFS was 19.25 months; Longest progression-free patient in 1st cohort was 24.8 months.
- Cohort 2 (47 mg/m²) - No patients have progressed after 21 months.
- Cohort 3 (61 mg/m²) - One patient has progressed after 14 months; Two other patients in 3rd cohort are progression free over 17 months.
- Cohort 4 (79 mg/m²) - No patients have progressed; Average PFS for these five patients in 4th cohort is 14 months.

"In previous clinical studies performed to date, GEN-1 has demonstrated excellent safety and impressive clinical activity supported with dose dependent, pro-immune improvement in the tumor micro environment. A onetime dose escalation may prove to be even more impressive," stated Dr. Nicholas Borys, Celsion's senior vice president and chief medical officer. "As we continue to follow patients, the latest PFS analysis from the OVATION Study is showing a median of at least 15.4 months in the as-treated group which compares favorably to a historical control of 12 months. Our highest dose cohort has not demonstrated any progressions at our current 14 month follow up. This same cohort also had a 100% R0 surgical resection rate. One of our patients in the OVATION Study even had a complete pathological response."

The Company expects to initiate enrollment of the Phase I portion of the OVATION II Study in the first half of 2018. The Company expects to have 25% of the study 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 for tremendous promise as a cancer treatment in the rapidly emerging area of immunotherapy. This new trial will evaluate GEN-1's 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," said Michael H. Tardugno, Celsion's chairman, president and chief executive officer. "Designed in consultation with leading medical experts, 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 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.

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