July 5, 2017

Celsion Announces Completion of OVATION Study and Provides Update on its Immunotherapy Trial in Advanced Stage III and IV Ovarian Cancer

86% Objective Response Rate (ORR) in Phase IB Dose Escalating Study

100% ORR and 100% R0 (Margin Negative) Surgical Resection Rate at Highest Dose Cohort

Increased Ratio of CD8+ Cells to Immunosuppressive T-cells Observed in 75% of Patients Indicating a Shift to a Pro-Immune Stimulatory Environment

LAWRENCEVILLE, N.J., July 05, 2017 (GLOBE NEWSWIRE) -- Celsion Corporation (NASDAQ:CLSN) today provided an update on its Phase Ib dose escalating clinical trial (the OVATION Study) combining GEN-1, the Company's IL-12 gene-mediated immunotherapy, with neoadjuvant chemotherapy for the treatment of newly-diagnosed patients with Stage III and IV ovarian cancer followed by interval debulking surgery.

Enrollment Complete in the OVATION Study. The last patient in the 4th dose cohort has completed their GEN-1 treatment which allows for a safety evaluation by the Company's Data Safety Monitoring Board (DSMB) in mid-July. The Company recently announced the latest clinical findings from the OVATION Study in a poster presentation at the American Society of Clinical Oncology (ASCO) 2017 Annual Meeting. The presentation summarized clinical findings and translational data from all fourteen patients treated in the trial to-date.

- Of the fourteen patients treated to date, two (2) patients demonstrated a complete response, ten (10) patients demonstrated a partial response and two (2) patients demonstrated stable disease, as measured by RECIST criteria. This translates to a 100% disease control rate (DCR) and an 86% objective response rate (ORR).
- Of the five patients treated in the highest dose cohort, there was a 100% objective response rate with one (1) complete response and four (4) partial responses.
- Fourteen patients had successful resections of their tumors, with nine (9) patients (64%) having an R0 resection, which indicates a margin-negative resection in which no gross or microscopic tumor remains in the tumor bed.
- Of the five patients treated at the highest dose cohort, all five patients (100%) experienced a R0 surgical resection.

"We have seen promising clinical findings including objective responses (CR and PR) in all patients at the highest dose cohort 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 presented at ASCO demonstrates that GEN-1 is biologically active, producing beneficial cytokines and positively impacting T-cell population in the tumor," said Dr. Nicolas Borys, Celsion's senior vice president and chief medical officer. "We believe that GEN-1 may be stimulating the immune system to improve tumor control in these patients. We are currently evaluating the most cost-effective development program to continue our clinical evaluation of GEN-1 in subsequent ovarian cancer studies."

Final translational research data for all patients on the study is being collected and will be available in the third quarter for evaluation by the Company's Scientific Advisory Committee and leading experts from Roswell Park, Vanderbilt University, Washington University School of Medicine in St. Louis, University of Alabama, Medical College of Wisconsin and the University of Oklahoma. Previously reported preliminary translational research findings from the first four patient cohorts are summarized below:

- The analysis of peritoneal fluid and blood samples collected immediately before and 24 hours after IP administration of multiple doses of GEN-1 (36, 47, 61, 79 mg/m^2) and standard NACT (carboplatin every 21 days and Taxol weekly) shows clear evidence of IL-12 gene transfer by significant dose dependent increases in IL-12 levels and significant increases in IFN-gamma and decreases in VEGF levels.
- The treatment-related changes in immune activating cytokines and pro-tumor VEGF levels followed a dose-dependent trend and were predominantly in the peritoneal fluid compartment with little to no changes observed in the patients' systemic circulation.
- The immuno-histochemical (IHC) analysis of tumor tissue collected before treatment (laparoscopy) and at debulking surgery after completion of eight GEN-1 weekly treatments showed increased infiltration of CD3+, CD4+ CD8+ T-cells into tumor tissue of several patients. The most pronounced effects observed in the IHC analysis were decreases in

the density of immunosuppressive T-cell signals (FoxP3, PD-1, PDL-1, IDO-1) in the tumor microenvironment. The ratio of CD8+ cells to immunosuppressive cells was increased in approximately 75% of patients suggesting an overall shift in the immune environment to pro-immune stimulatory following treatment with GEN-1. An increase in CD8+ to immunosuppressive T-cell populations is believed to be a good predictor of better overall survival.

"These translational research findings demonstrate that GEN-1 in ovarian cancer patients is biologically active and creates an immuno-stimulatory cytokine milieu in the peritoneal cavity in a dose-dependent manner and promotes a pro-immune T-cell population dynamic in the tumor micro-environment," said Dr. Khursheed Anwer, Celsion's executive vice president and chief science officer. "These distinct immunological changes in local disease environment appear to translate into clinical benefit and warrant the continued development of our GEN-1 IL-12 immunotherapy as a potential adjuvant, in both first and second-line ovarian cancer."

Progression Free Survival Update. Of the seven patients who have received GEN-1 treatment over one year ago and are being followed, only one patient's cancer has progressed after 11.7 months. This compares favorably to the historical median progression free survival (PFS) of 12 months for newly-diagnosed patients with Stage III and IV ovarian cancer who undergo neoadjuvant chemotherapy followed by interval debulking surgery[1]. Of the remaining six patients who have been on the study for over one year, their average PFS is 15 months with the longest progression-free patient at 21 months. None of the patients in the third or fourth dose cohorts have progressed to date.

"This progression-free survival trend adds to the impressive clinical findings seen across a number of meaningful measures used to assess ovarian cancer like an overall 86% objective tumor response rate and a greater than 60% R0 (margin-negative) surgical resection rate," said Michael H. Tardugno, Celsion's chairman, president and chief executive officer. "The consistency and robust nature of the data across all four cohorts and the encouraging clinical responses underscore the potential of GEN-1 to serve as an effective, safe IL-12 immunotherapy in ovarian cancer."

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 initiated a Technology Transfer, Manufacturing and Commercial Supply Agreement (the "GEN-1 Agreement") with a premier, global API manufacturer, Zhejiang Hisun Pharmaceutical Co. Ltd. (Hisun), in the second half of 2016. Hisun and Celsion have completed several important technology transfer activities relating to the manufacture of GEN-1, including studies required by CFDA for site approval. The GEN-1 Agreement was initiated 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. The GEN-1 Agreement will help to support supply for both ongoing and planned clinical studies.

Key provisions of the GEN-1 Agreement are as follows:

- The GEN-1 Agreement has targeted unit costs for clinical supplies of GEN-1 that are substantially competitive with the Company's current suppliers.
- Once approved, the cost structure for GEN-1 will support rapid market adoption and significant gross margins across global markets.

This strategy provides the Company with a high quality, affordable, cost effective supply for all global markets.

Publication Accepted. The Company also reported that the manuscript for a previously completed trial conducted by the Gynecologic Oncology Group in recurrent ovarian cancer using Doxil® and GEN-1 has been accepted for publication in *Gynecologic Oncology*. The manuscript describes positive clinical results from this study as summarized below:

- This study enrolled 16 patients with platinum-resistant ovarian cancer and evaluated the safety, tolerability, biological activity and efficacy of weekly intraperitoneal GEN-1 administered in combination with Doxil®. Patients received Doxil® on day 1 and GEN-1 on days 1, 8, 15 and 22. Cycles were repeated every 28 days until unacceptable toxicity or disease progression.
- GEN-1 was well tolerated, with no dose limiting toxicities and no overlapping toxicities between GEN-1 and Doxil®.
- The clinical findings 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 86%.

Recurrent, platinum resistant ovarian cancer patients have a poor prognosis. With these data along with other published, pre-clinical data, the Company considers this group to be a promising future population for a study of GEN-1 in combination with Avastin® and Doxil®.

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. 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)

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[1] Wright AA, Bohlke K, Armstrong DK, et al: Neoadjuvant Chemotherapy for Newly Diagnosed, Advanced Ovarian Cancer: Society of Gynecologic Oncology and American Society of Clinical Oncology Clinical Practice Guideline. J Clin Oncol 34, 2016.

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Source: Celsion Corporation