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Celsion Announces Presentation of OVATION Study Findings at the Upcoming ASCO 2017 Annual Meeting

Study's Lead Investigator to Report Updated Translational Research Data

LAWRENCEVILLE, N.J., April 20, 2017 (GLOBE NEWSWIRE) -- Celsion Corporation (NASDAQ:CLSN), an oncology drug development company, today provided an update on its OVATION Study, a Phase Ib dose escalating clinical trial combining GEN-1, the Company's DNA-based immunotherapy, with the standard of care for the treatment of newly-diagnosed patients with advanced (stage III/IV) ovarian cancer who will undergo neoadjuvant chemotherapy followed by interval debulking surgery. GEN-1 is an IL-12 DNA plasmid vector formulated as a nanoparticle in a non-viral delivery system to cause the sustained local production and secretion of the Interleukin-12 (IL-12) protein loco-regionally to the tumor site.

The Company announced that an abstract for the OVATION Study has been accepted for presentation at the American Society of Clinical Oncology (ASCO) 2017 Annual Meeting, which will take place from June 2-6 at McCormick Place in Chicago, IL.

- The abstract, entitled "Phase 1 study of the safety and activity of formulated IL-12 plasmid administered intraperitoneally in combination with neoadjuvant chemotherapy in patients with newly diagnosed advanced stage ovarian cancer," will be presented in a poster presentation session on Saturday, June 3rd from 1:15 PM to 4:45 PM by Dr. Premal H. Thaker, Associate Professor, Obstetrics and Gynecology Division of Gynecologic Oncology, Washington University in St. Louis School of Medicine.
- The presentation will summarize clinical findings and translational data from all available patients treated in the trial. The translational data will provide further insight into GEN-1's mechanism of action through the evaluation of dose-related changes in the tumor and peritoneal immune cell population, as well as through the peritoneal cytokine levels.

Celsion has previously reported highly encouraging interim data from the first twelve patients who have completed treatment in the OVATION Study. GEN-1 plus standard chemotherapy produced excellent results, with no dose limiting toxicities and promising dose dependent efficacy signals which appear to correlate well with successful surgical outcomes as summarized below:

- Of the twelve patients treated, one patient demonstrated a complete response, eight (8) patients demonstrated a partial response and three (3) patients demonstrated stable disease, as measured by RECIST criteria. This translates to a 100% disease control rate ("DCR") and a 75% objective response rate ("ORR").
- Eleven patients had successful resections of their tumors, with six (6) patients (55%) having an R0 resection, which indicates a microscopically margin-negative resection in which no gross or microscopic tumor remains in the tumor bed, and four (4) patients (36%) having a R1 resection, indicating microscopic residual tumor.
- One patient demonstrated a pathological complete response (pCR). pCRs are typically seen in less than 7% of patients receiving neoadjuvant chemotherapy followed by surgical resection, and have been associated with a median overall survival (OS) of 72 months, which is more than three years longer than those who do not experience a pCR.
- All patients experienced a dramatic decrease in their CA-125 protein levels as of their most recent study visit. CA-125 is used to monitor certain cancers during and after treatment. CA-125 is present in greater concentrations in ovarian cancer cells than in other cells.

"We have now completed enrollment of our OVATION Study in newly diagnosed ovarian cancer patients, one goal of which is to determine GEN-1's activity in combination with standard chemotherapy. The previously reported remarkable, unexpected surgical outcomes among all patients completing the prescribed eight weekly treatments reinforce our confidence in the promise of GEN-1's ability to work safely and effectively in advanced ovarian cancer," said Michael H. Tardugno, Celsion's chairman, president and CEO. "We are looking forward to Dr. Thaker's report of comprehensive findings at the upcoming ASCO meeting and to learning more about the utility of our gene-based immunotherapy approach as this important study matures."

OVATION Study Design

The Phase Ib trial will evaluate weekly intraperitoneal dosing of GEN-1 in combination with neoadjuvant chemotherapy, the

standard of care for patients newly diagnosed with ovarian cancer. Concurrently with neoadjuvant chemotherapy, enrolled patients will receive 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, with interval debulking surgery to follow. The regimen will primarily be evaluated for its safety and tolerability.

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 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)

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 the 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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