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Celsion Reports Translational Research Data from its Phase 1b Study of GEN-1 Immunotherapy in Recurrent Ovarian Cancer

Treatment with GEN-1 Results in Sustained, Targeted Production of Immunologically Active IL-12 Cytokine Activation to GEN-1 Immunotherapy is Limited to Targeted Area in the Peritoneum of Patients Exciting Development Shows Potential for Significant Advantages over Recombinant IL-12 Dosage Options

LAWRENCEVILLE, N.J., Jan. 7, 2016 /PRNewswire/ --Â Celsion Corporation (NASDAQ: CLSN), today announced new translational data from its Phase 1b study of GEN-1 in patients with platinum-resistant ovarian cancer. GEN-1 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.Â The new data demonstrate that intraperitoneally-administered GEN-1 produces an immunologically distinct IL-12 protein that is localized at the tumor site and lasts for up to one week after a single treatment.Â Furthermore, concomitant increases in IFN-γÂ and TNF- αÂ indicate that the IL-12 produced following treatment with GEN-1 treatment is immunologically active.Â Celsion Corporation is a fully integrated oncology company focused on the development of a portfolio of innovative cancer treatments, including directed chemotherapies, immunotherapies and RNA- or DNA-based therapies for the treatment of cancer and other difficult-to-treat diseases.Â

"We now have clear clinical evidence that treatment of platinum-resistant ovarian cancer with GEN-1 produces a sustained, localized immune response, which then translates to the compelling activity and tolerability profile we have seen in early clinical studies," said Khursheed Anwer, Ph.D., executive vice president and chief scientific officer of Celsion. "These data also provide additional evidence of GEN-1's ability to overcome the limitations associated with recombinant IL-12, which has a very short half-life and results in high systemic levels of IL-12, leading to potentially severe toxicities.Â We plan to build on these data and advance our understanding of GEN-1's mechanism of action further with additional translational research as part of our ongoing OVATION Study."

The Phase 1B dose escalating study enrolled 16 patients with platinum-resistant ovarian cancer and evaluated the safety, tolerability and efficacy of GEN-1 in combination with pegylated doxorubicin as well as the effect of intraperitoneal injection of GEN-1 on IL-12 and tumor cytokine levels. Patients received pegylated liposomal doxorubicin on day 1 and GEN-1 on days 1, 8, 15 and 22. This treatment regimen was repeated every 28 days in the absence of disease progression or toxicity.Â

Celsion reported clinical findings from the Phase 1b study at the 2015Â American Society of Clinical Oncology (ASCO) Meeting in June 2015 demonstrating an overall clinical benefit of 57% for all treatment arms.Â The overall clinical benefit observed at the highest dose cohort in this difficult-to-treat patient population was 100% (PR=33% and SD=67%) in all six evaluable patients.Â A maximum tolerated dose was not reached and studies evaluating higher doses of GEN-1 are currently underway.

The new translational data reported today is highlighted below:

- Intraperitoneal administration of GEN-1 in platinum-resistant ovarian cancer patients resulted in a significant increase in IL-12 levels in peritoneal fluid samples.Â IL-12 levels were quantifiable in 91% of evaluable fluid samples collected post GEN-1 treatment. None of the evaluable pre-treatment peritoneal fluid samples had any detectable IL-12 levels.Â
- The IL-12 levels were detectable for at least seven days after GEN-1 treatment.Â
- In comparison to peritoneal fluid, the IL-12 levels in plasma samples (systemic exposure) following GEN-1 treatment were not detectable or were very low in quantity.
- Significant increases in levels of IFN-γ, a key downstream mediator of IL-12 action, were observed in peritoneal fluid but not in plasma samples.Â At least a 5-fold increase above pre-treatment level in IFN- γÂ was observed in most samples, with the highest increase observed at 120-fold.Â Similar results were observed with TNF-α levels, with the highest increase observed at 77-fold over pre-treatment control.
- A publication of this data is being prepared for submission for major scientific review which will detail all cytokine levels observed in this study.Â

Celsion intends to collect additional translational data, including cellular responses in primary tumor tissue and peritoneal ascites, in its ongoing OVATION Study, a Phase I dose escalation study in newly diagnosed ovarian cancer patients in the neoadjuvant setting.

"With these remarkable findings we feel confident that the data we expect to collect from the OVATION Study will provide further evidence that GEN-1, our gene-mediated immunotherapy, has significant potential in oncology generally and in ovarian cancer specifically," noted Michael H. Tardugno, Celsion's chairman, CEO and president.Â "Our clinical development program for ovarian cancer is now well positioned with compelling clinical and biological data, fully supporting our thesis for combining GEN-1 with Doxil® and Avastin® to treat platinum-resistant ovarian cancer patients in a study we expect to launch later this year."

About Celsion Corporation

CelsionÂ 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.Â Â Celsion'sÂ pipeline also includes GEN-1, a DNA-based immunotherapy for the localized treatment of ovarian and brain cancers.Â Â CelsionÂ has two platform technologies for the development of novel nucleic acid-based immunotherapies and other anti-cancer DNA or RNA therapies, including TheraPlas™ and TheraSilence™.Â For more information onÂ Celsion, visit our website:Â http://www.celsion.com.

CelsionÂ 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.Â 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;Â FDAÂ and regulatory uncertainties and risks; the significant expense, time, and risk of failure of conducting clinical trials; possible acquisitions or licenses of other technologies, assets or businesses; possible actions by suppliers, competitors, regulatory authorities; and other risks detailed from time to time in theÂ Celsion'sÂ periodic reports and prospectuses filed with theÂ Securities and Exchange Commission.Â Â CelsionÂ 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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