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Celsion Corporation Announces Positive DSMB Review of Phase 1b OVATION Study in Ovarian Cancer

Study to Continue to Fourth and Final Patient Cohort

LAWRENCEVILLE, N.J., Sept. 15, 2016 (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 three patient cohorts in the ongoing Phase Ib OVATION Study. Based on the DSMB's recommendation, the study will continue as planned and the Company will proceed with dosing in its fourth and final patient cohort at an escalated dose. The OVATION Study is a 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 ovarian cancer who will undergo neoadjuvant chemotherapy followed by interval debulking surgery.

"The DSMB's recommendation and the lack of any dose limiting toxicities in the trial to date underscore the improved tolerability of GEN-1 over recombinant IL-12 protein-based therapies," said Nicholas Borys, M.D., senior vice president and chief medical officer of Celsion. "The favorable safety profile we have seen thus far is consistent with the translational data that we reported earlier this year, which show that GEN-1 produces a sustained, localized secretion of IL-12 protein and avoids the high levels of systemic exposure which have limited the development of recombinant IL-12 therapies in the past."

"We could not be more excited to progress with the OVATION Study and look forward to reporting clinical findings from the third patient cohort, as well as translational data from the first two cohorts, early in the fourth quarter. Furthermore, we expect to report final data from this highly promising study in the first quarter of 2017," said Michael H. Tardugno, Celsion's chairman, CEO and president. "We have been encouraged, as have been our Investigators, by the findings to-date in this difficult-to-treat patient population. As we have previously reported, all six patients in the first two cohorts experienced a clinically meaningful response, ranging from stable disease to one pathologically confirmed complete response. In addition, we saw sustained decreases of 90% or greater of the prospective indicator of the presence of ovarian cancer cells, CA-125 protein, in all patients, as well as highly impressive pathologically responses, which is associated with prolonged survival."

The OVATION Study is designed to enroll three to six patients per dose cohort at escalating doses of GEN-1 with the goal to identify a safe, tolerable and therapeutically active dose of GEN-1 by recruiting and maximizing an immune response. The first three cohorts each enrolled three patients. Enrollment in the fourth and final cohort is underway, and Celsion expects to report full data from the OVATION Study by the first quarter of 2017. Future studies of GEN-1 will include a Phase I/II study combining GEN-1 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 anticancer DNA or RNA therapies, including TheraPlas™ and TheraSilence™.

For more information on Celsion, visit our website: http://www.celsion.com. (TheraPlas/GEN-1, Ovation Study/Ovarian Cancer)

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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