

# Celsion Completes Integration of EGEN and Outlines Clinical Development Plan for GEN-1 IL-12 Immunotherapy Program

# Company Strengthens Financial Profile with a 20 Percent Reduction in Headcount and a Leaner, More Efficient Product Development Organization Three Phase I Studies Anticipated for GEN-1 IL-12 Immunotherapy in 2015 - 2016

LAWRENCEVILLE, N.J., Sept. 9, 2015 /PRNewswire/ --Â Celsion Corporation (NASDAQ: CLSN), 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, announced today that the Company has completed the integration of its June 2014 acquisition of EGEN, Inc. and has provided an update on its clinical development plans for GEN-1, the Company's DNA-based immunotherapy for the localized treatment of ovarian and brain cancer. Â Â

Following the acquisition of EGEN, Celsion has consolidated all early stage and preclinical assets at its Huntsville, AL facility. All clinical development, commercialization (including its Early Access Programs for ThermoDox), business development and administrative functions are now located in Lawrenceville, NJ. From this reorganization, Celsion expects to realize a 15 to 20 percent reduction in personnel and related annual operational costs.

Additionally, the Company has evaluated opportunities to maximize efficiency in its GEN-1 IL-12-based immunotherapy and has structured its clinical development program to capitalize on previously established proof-of-concept clinical data. GEN-1 has demonstrated promising clinical activity and tolerability in platinum-resistant and recurrent ovarian cancer patients, as well as synergistic anti-cancer effects in combination with bevacizumab (Avastin®) in preclinical models.

- The Company's OVATION Study, a Phase 1b dose escalating trial combining GEN-1 with neo-adjuvant therapies in newly diagnosed ovarian cancer patients, is expected to commence enrollment in the second half of 2015. The first OVATION site at the University of Alabama at Birmingham has been initiated, with three additional sites expected to follow shortly. Data from this open label study is expected in the fourth quarter of 2015, and will continue into the first half of next year at higher doses of GEN-1. This trial will provide a starting dose for a follow-on Phase I/II study combining GEN-1 with Avastin and Doxil.
- The Company also expects to commence a second ovarian cancer development program with initiation of a Phase I/II dose escalating trial evaluating GEN-1 in combination with Avastin® and Doxil® in platinum-resistant ovarian cancer patients later this year. This new combination study in platinum-resistant ovarian cancer is supported by two preclinical studies demonstrating that the combination of GEN-1 with Avastin® may result in significant clinical benefit with a favorable safety profile, as well as a prior Phase 1b trial of GEN-1 plus Doxil® in platinum resistant breast cancer patients.
- The Company is now completing a comprehensive series of pre-clinical safety and efficacy studies, and plans to initiate a third Phase I trial combining GEN-1 with current standard of care to treat newly resected glioblastoma multiforme (GBM) brain cancer patients in 2016.

"Over the past 12 months, since our acquisition of EGEN, Inc., we have carefully evaluated our current organizational structure and collective management competencies to determine the most efficient path forward for our broad, diversified product pipeline. Our new organization will be both lean and focused on generating clinical data from our GEN-1 platform," said Michael H. Tardugno, Celsion's chairman, president and chief executive officer. Â "As an IL-12 immunotherapy, GEN-1 has broad potential in multiple tumor types, and our clinical strategy is designed to accelerate its development, establish its clinical utility in various indications and drive it toward the market."

## About GEN-1 Immunotherapy

GEN-1, designed using Celsion's proprietary TheraPlas<sup>™</sup> 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 Tlymphocyte 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. GEN-1 has also demonstrated preclinical activity in glioblastoma multiforme (brain cancer) and the Company plans to initiate a Phase I study in this indication in the second half of 2015.

### **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, including TheraPlas<sup>™</sup> and TheraSilence<sup>™</sup>. For more information on Celsion, visit our website: <a href="http://www.celsion.com">http://www.celsion.com</a>.

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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