Celsion Corporation Highlights Pipeline Progress in Its Lead Development Candidates

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PLACCINE DNA-based Vaccine in proof-of-concept non-Human Primate Studies

Phase II study of GEN-1 in ovarian cancer 85% enrolled with full enrollment expected in the third quarter of 2022

FDA Allows GEN-1 + Avastin Phase II study

LAWRENCEVILLE, N.J., May 10, 2022 (GLOBE NEWSWIRE) -- Celsion Corporation (NASDAQ: CLSN), a clinical-stage company focused on DNA-based immunotherapy and next-generation vaccines, today provided an update on the progress made in the Company's two lead development programs.

"We continue to make important progress in both of our lead development programs, and I am very pleased by the encouraging results to date," said Michael H. Tardugno, chairman, president and chief executive officer of Celsion. "Our PLACCINE DNA-based vaccine platform was recently highlighted at the 2022 World Vaccine Congress and is demonstrating its potential for rapid design and capability for targeting two or more different COVID variants in one vaccine. We have demonstrated a proof-of-concept utilizing a standard mouse model showing that PLACCINE can target two variants and produce robust levels of IgG, neutralizing antibodies, and t-cell responses. This proof-of-concept data is comparing favorably to commercial vaccines in mouse models with this data recently reported at the World Vaccine Congress. A vaccine that targets multiple strains at once and designed to provide long lasting immunity, is important in a future COVID-19 vaccination strategy. We are moving this program forward quickly and anticipate confirming our proof-of-concept in non-human primates over the next several months, with durability results later this year."

Mr. Tardugno continued, "OVATION 2, the Phase II study of our GEN-1 immunotherapy in ovarian cancer is 85% enrolled. In spite of all of the challenges presented by COVID 19, we are hopeful to complete enrollment in the third quarter of this year. Preclinical and clinical data gives us every reason to believe in GEN-1's promise for ovarian cancer patients along with the support from leading medical researchers of the Gynecological Oncology Group (GOG). The GOG's interest in forging a partnership to develop GEN-1 in ovarian cancer will assist Celsion in its plans for an accelerated registrational program. Meanwhile, FDA has approved our protocol for a second Phase II clinical trial to evaluate GEN-1 in combination with Avastin® (bevacizumab) in patients with advanced ovarian cancer. Our preclinical tumor inhibition data provides a convincing basis for this study. We look forward to initiating this study at major comprehensive cancer hospitals later this year."

About PLACCINE

PLACCINE is a first in class DNA vaccine platform that can target multiple antigens and be administered with a standard intramuscular injection. PLACCINE was derived from the Company's proprietary TheraPlas platform.

About GEN-1

GEN-1, an IL-12 DNA plasmid vector formulated into nanoparticles with a lipopolymeric delivery system, is the first product designed via the TheraPlas platform technology. GEN-1 may prove to be a safe and effective immunotherapy for treating various types of tumors by producing high levels of interleukin-12 (IL-12) at the site of tumors. IL-12 is one of the most active cytokines for stimulating an immune response against cancer. However, when administered as a recombinant protein requiring systemic administration, the pharmacokinetics of IL-12 requires that it be given by frequent, large bolus injections, resulting in serious toxicities that limit its use. GEN-1 addresses the toxicity issues associated with systemic IL-12. GEN-1's nanoparticle design enables local administration (into the abdominal cavity) and cell transfection followed by persistent, local secretion of IL-12 at therapeutic levels, while avoiding the toxicities associated with recombinant IL-12.

About Celsion Corporation

Celsion is a fully integrated, clinical stage biotechnology company focused on advancing a portfolio of innovative cancer treatments, including immunotherapies and DNA-based therapies; and a platform for the development of nucleic acid vaccines currently focused on SARS-CoV2. The company's product pipeline includes GEN-1, a DNA-based immunotherapy for the localized treatment of ovarian cancer. Celsion's wholly owned subsidiary, Celsion GmbH, is managing ThermoDox®, a proprietary heat-activated liposomal encapsulation of doxorubicin, which is under investigator-sponsored development for several cancer indications. For more information on Celsion, visit www.celsion.com and www.celsiongmbh.com.

Forward-Looking Statements

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; 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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