Celsion Corporation Receives FDA Fast Track Designation for GEN-1 in Advanced Ovarian Cancer

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Celsion's Commitment to Promoting Immune System Solutions to Fight Life-Threatening Diseases Granted an Accelerated Development Pathway

Designation Provides Potential for an Expedited Regulatory Review.

LAWRENCEVILLE, N.J., Feb. 22, 2021 (GLOBE NEWSWIRE) -- Celsion Corporation (NASDAQ: CLSN), a clinical stage development company focused on DNA based immunotherapy and next generation vaccines, today announced that it has received Fast Track designation from the U.S. Food and Drug Administration (FDA) for GEN-1, its DNA-mediated interleukin-12 (IL-12) immunotherapy currently in Phase II development for the treatment of advanced ovarian cancer. GEN-1 was designed using TheraPlas, Celsion's proprietary, synthetic, non-viral nanoparticle delivery system platform.

Fast Track designation is intended to facilitate the development and expedite the regulatory review of drugs to treat serious conditions and fill an unmet medical need. According to the FDA, a Fast Track Drug must show some advantage over available therapy, including:

- Showing superior effectiveness, effect on serious outcomes or improved effect on serious outcomes
- Avoiding serious side effects of an available therapy
- Decreasing a clinical significant toxicity of an available therapy that is common and causes discontinuation of treatment

"Fast Track designation is an important step in developing GEN-1 for advanced ovarian cancer. Presuming the encouraging data we are generating in early clinical studies continues, this designation supports an expedited path to market," said Michael H. Tardugno, Celsion's chairman, president and chief executive officer. "Fast Track allows for more frequent communication with the FDA to discuss development plans and clinical trial design. In addition, should criteria be met, Fast Track-designated drugs are eligible for rolling review, a process whereby the drug's sponsor can separately submit sections of its New Drug Application to the FDA. They also are eligible for accelerated approval and priority review, under which drugs for serious conditions fulfilling an unmet medical need can be approved based on a surrogate endpoint. We are optimistic that GEN-1 represents a game-changer for women with advanced ovarian cancer who have limited treatment options."

GEN-1 is the subject of Celsion's Phase II OVATION 2 Study, which combines GEN-1 with standard-of-care neoadjuvant chemotherapy (NACT) in patients newly diagnosed with Stage III/IV ovarian cancer. NACT is designed to shrink the cancer as much as possible for optimal surgical removal after three cycles of chemotherapy. Following NACT, patients undergo interval debulking surgery, followed by three adjuvant cycles of chemotherapy and up to nine additional weekly GEN-1 treatments, the goal of which is to delay progression and improve overall survival. The OVATION 2 Study is an open-label, 1-to-1 randomized trial, 80% powered to show the equivalent of a 33% improvement in progression-free survival (PFS) (HR=0.75), the primary endpoint, when comparing the treatment arm (standard of care + GEN-1) with the control arm (standard of care alone).

As Celsion has previously announced, it has shared with the FDA data from the Phase I portion of the Phase I/II OVATION 2 Study that showed successful tumor resections, with seven out of eight patients (88%) in the GEN-1 treatment arm having a complete tumor resection (R0), which indicates a microscopically margin-negative resection in which no gross or microscopic tumor remains in the tumor bed. The NACT-only treatment arm had an R0 resection rate of 50%.

Patients in the Company's completed Phase 1b dose-escalation OVATION I Study showed compelling objective response rates, with 100% of patients in high-dose cohorts experiencing a complete or partial response, and 67% of patients in lower-dose cohorts experiencing a complete or partial response. Further, R0 resections in the high-dose cohorts was 88%, compared with 33% in the low-dose cohorts.

In addition, Celsion compared matched patient data in a synthetic control arm with results from the OVATION I Study. Patients in the GEN-1 arm virtually demonstrated a doubling of control of their cancer compared with the synthetic control arm. Findings are not statistically significant due to the small number of patients. This comparison showed positive data in progression-free survival (PFS) as follows:

GEN-1 Population	**PFS Hazard Ratio (Confidence Interval)**
Intent-to-treat, n=15	0.53 (95% CI 0.16, 1.73); log-rank p=0.29
Per-protocol, n=14	0.33 (95% CI 0.08, 1.37); log-rank p=0.11

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 or a combination therapy in patients with advanced peritoneally metastasized primary or recurrent ovarian cancer, and recently completed a Phase Ib dose-escalation trial (OVATION I Study) of GEN-1 in combination with carboplatin and paclitaxel in patients with newly diagnosed ovarian cancer.

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. ThermoDox ®, a proprietary heat-activated liposomal encapsulation of doxorubicin, is under investigator-sponsored development for several cancer indications. Celsion also has two feasibility stage platform technologies for the development of novel nucleic acid-based immunotherapies and other anti-cancer DNA or RNA therapies. Both are novel synthetic, non-viral vectors with demonstrated capability in nucleic acid cellular transfection. For more information on Celsion, visit www.celsion.com.

Forward-looking Statements

Forward-looking statements in this news release are made pursuant to the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995. These statements are subject to a number of risks and uncertainties, many of which are difficult to predict, including, 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 or regulatory authorities; and other risks detailed from time to time in the Celsion's periodic filings 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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