Celsion and Medidata to Present Findings on Use of Synthetic Control Arm to Estimate Treatment Effect in Ovarian Cancer Trial

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Phase Ib dose-escalating OVATION I Study with GEN-1 in advanced ovarian cancer patients to be presented at 2022 AACR Annual Meeting being held April 8-13 in New Orleans, LA

LAWRENCEVILLE, N.J., April 06, 2022 (GLOBE NEWSWIRE) -- Celsion Corporation (NASDAQ: CLSN) a clinical-stage company focused on DNA-based immunotherapy and next generation vaccines and Medidata, a Dassault Systèmes company, today announced that they will be presenting their findings on the use of a Synthetic Control Arm® (SCA) in a completed Phase Ib dose-escalating study of GEN-1 in the neoadjuvant treatment of patients with Stage III/IV ovarian cancer (the OVATION 1 Study) at the Annual Meeting of the American Association for Cancer Research (AACR) being held on April 8-13, 2022 in New Orleans, LA.

In a poster presentation entitled "Phase IB trial efficacy estimates via a clinical trial synthetic control arm", taking place on Monday April 11th 2022 from 9 AM through 12:00 PM EST , Dr. Elizabeth Lamont will present the research team's findings that demonstrate how comparing patients from a single-arm trial can help enhance understanding of treatment effects in advance of randomized trials, inform drug development and trial design, and increase the scientific value of early phase trials.

The Phase Ib OVATION I Study evaluated escalating doses of GEN-1 (36 mg/m^2, 47 mg/m^2, 61 mg/m^2 and 79 mg/m^2) administered intraperitoneally in combination with three cycles of neoadjuvant chemotherapy (NACT) prior to interval debulking surgery, followed by three cycles of NACT in the treatment of newly diagnosed patients with Stage III/IV ovarian cancer. GEN-1, designed using Celsion's proprietary TheraPlas platform technology, is an interleukin-12 (IL-12) DNA plasmid vector encased in a non-viral nanoparticle delivery system, which enables cell transfection followed by persistent, local secretion of the IL-12 protein.

"The Medidata Synthetic Control Arm provided reliable estimates of the efficacy endpoints, which allowed for a decrease in the number of patients needed to participate in the subsequent randomized Phase II trial. In addition to decreasing the burden on patients, this helped to accelerate trial timelines and decrease costs," said Dr. Nicholas Borys, Chief Medical Officer at Celsion. "This truly important progress will lead to further insights and advancements in future trials and, in the end, help bring treatments to patients faster."

A Synthetic Control Arm is a type of external control and is formed by carefully matching patients treated with a new investigational therapy to anonymized clinical trial patients from Medidata's extensive repository of historical clinical trials using baseline demographic and disease characteristics. Using this advanced statistical methodology, Celsion and Medidata found that progression-free survival was prolonged for the patients treated with the investigational therapy GEN-1 along with standard of care chemotherapy in the OVATION 1 Study compared to well-balanced historic control patients treated with the same standard of care chemotherapy alone (Hazard Ratio=0.53, 95% Confidence Interval (0.16, 1.73). This larger than expected effect size led to a decrease in the number of planned patients for Celsion's subsequent Phase II trial and was used in support of Fast Track Designation from the U.S. Food and Drug Administration (FDA) received in February 2021.

"Medidata Acorn AI is in a unique position to create fit-for-purpose synthetic controls because of access to a pool of more than eight million anonymized patients from 27,000+ previous clinical trials," said Ruthie Davi, Ph.D., vice president, Data Science at Medidata Acorn AI. "Our AACR presentation with Celsion will show how the SCA can provide a scientifically rigorous comparison in scenarios where a control group is not part of the study design or hard to recruit or retain. We are proud to be working to decrease the patient burden, enhance scientific value, and accelerate studies."

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 also has two 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

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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