Celsion Announces Common Stock Purchase Agreement with Lincoln Park Capital and Provides Updates on OVATION 2 Study

September 8, 2020

Agreement Includes 1 Million Shares Purchased at 28% Market Premium

LAWRENCEVILLE, N.J, Sept. 08, 2020 (GLOBE NEWSWIRE) -- Celsion Corporation (NASDAQ: CLSN), an oncology drug development company, today provided an update on the OVATION 2 Study with GEN-1 in advanced ovarian cancer patients. Celsion also announced it has entered into a common stock purchase agreement for the issuance and sale, from time to time, of up to $26 million of shares of common stock with Lincoln Park Capital Fund, LLC (LPC), a Chicago-based institutional investor.

Stock Purchase Agreement

In connection with the execution of the purchase agreement, LPC made an initial purchase of $1 million of common stock at $1.00 per share, representing a significant premium to the current market price.

Under the terms of the new purchase agreement with LPC, Celsion has the right at its sole discretion, but not the obligation, to sell to LPC up to $26 million worth of shares (including the $1 million initially purchased) over the 36-month term of the agreement, subject to certain conditions. There are no upper limits to the price per share LPC may pay to purchase the shares, and the purchase price of the shares will be based on the prevailing market prices at the time of each sale to LPC. Celsion controls the timing and amount of any future sales of its stock to LPC.

There are no warrants, derivatives, financial or business covenants associated with the agreement, and LPC has agreed not to cause or engage in any direct or indirect short selling or hedging of Celsion's common stock. Celsion may terminate the purchase agreement at any time, at its discretion, without any cost or penalty. In consideration for LPC entering into the purchase agreement, Celsion issued shares of its common stock to LPC as a fee for LPC's obligation to purchase shares at the Company's discretion.

"The LPC financing, along with the anticipated sale of New Jersey net operating losses later this year, the repayment and restructure of our long-term debt with Horizon announced last week and our current cash position of approximately $20 million, will help us reach a number of value-rich events including full enrollment of the OVATION 2 Study," said Michael H. Tardugno, Celsion's chairman, president and chief executive officer. "These funds will also allow us to complete the definitive analysis of the OPTIMA Study, our Phase III trial with ThermoDox™ in primary liver cancer. We continue to follow patients for overall survival, and to compile data and CT scans to submit to the National Institutes of Health for their review and perspective," Mr. Tardugno added.

Celsion intends to use any net proceeds from the sale of its common stock to LPC to advance its product pipeline and for general corporate purposes. Additional information regarding the purchase agreement with LPC is available in the Current Report on Form 8-K that Celsion will file with the Securities and Exchange Commission.

This press release shall not constitute an offer to sell or a solicitation of an offer to buy any shares of common stock, nor shall there be any sale of shares of common stock in any state or jurisdiction in which such an offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such state or other jurisdiction.

OPTIMA Study Update

Celsion continues to follow patients for overall survival (OS) in its Phase III study of ThermoDox for newly diagnosed hepatocellular carcinoma (HCC) patients, noting that the unexpected and marginally crossed futility boundary, suggested by the Kaplan-Meier analysis at the second interim analysis on July 9, 2020, may be associated with a data maturity issue. The Company has hired independent statisticians to further evaluate the trial data, the statistical plan, and the hypothesis generating data from the earlier HEAT Study, as well as, supplying data to the NIH for independent analysis and recommendation. The Company expects to announce its plans for the OPTIMA Study before year end.

OVATION 2 Study Update

Enrollment in the Phase II portion of the Phase I/II OVATION 2 Study has been accelerated with 22 patients enrolled thus far at 13 sites in the U.S. The Company expects 12 additional sites in the U.S. and Canada to begin enrolling patients by the end of the year, and now expects full enrollment of 118 patients to be completed by the end of the second quarter of 2021, a full quarter earlier than previously anticipated.

GEN-1 was designed using TheraPlas, Celsion's proprietary, synthetic, non-viral nanoparticle delivery system platform. It is an interleukin-12 (IL-12) DNA plasmid vector associated with a non-viral nanoparticle delivery system, which enables cell transfection followed by persistent, local secretion of the IL-12 protein.

The OVATION 2 Study 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). Celsion has received definite confirmation from the U.S. Food and Drug Administration (FDA) that PFS may be used as a surrogate endpoint for overall survival.

Because OVATION 2 is an open-label study, the Company intends to provide clinical updates throughout the course of treatment, including response rates and surgical resection scores.

Dr. Nicolas Borys, Celsion's chief medical officer, said, "We are pleased with the pace of enrollment in this trial, and attribute the high level of interest among investigators and patients to the impressive data generated from prior studies. In particular, data from the Phase I portion of the OVATION 2 Study that showed successful tumor resections, with seven out of eight patients (87.5%) 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%."

"In addition, investigators have expressed confidence in the role of IL-12 and GEN-1's safety profile. The Data Safety Monitoring Board recommended that the Phase II portion of the OVATION 2 Study proceed with a GEN-1 dose of 100 mg/m², and with more than 17 doses over more than six-months of treatment. We look forward to providing tumor response data and surgical results as they become available throughout the course of treatment. In addition, we believe that PFS as an endpoint bodes well for study success," Dr. Borys added.

About Lincoln Park Capital Fund, LLC

LPC is a long-only institutional investor headquartered in Chicago, Illinois. LPC's experienced professionals manage a portfolio of investments in public and private entities. These investments are in a wide range of companies and industries emphasizing life sciences and technology. LPC's investments range from multi-year financial commitments to fund growth to special situation financings to long-term strategic capital offering companies' flexibility and consistency. For more information, please visit www.lpcfunds.com.

About Celsion Corporation

Celsion is a fully integrated oncology company focused on developing a portfolio of innovative cancer treatments, including immunotherapies, DNA-based therapies and directed chemotherapies. The Company's product pipeline includes GEN-1, a DNA-based immunotherapy for the localized treatment of ovarian cancer and ThermoDox®, a proprietary heat-activated liposomal encapsulation of doxorubicin, currently in Phase III development for the treatment of primary liver cancer and in development for other cancer indications. Celsion 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: http://www.celsion.com. (CLSN-FIN).

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, Celsion's intended use of proceeds, the amount and prices of any such sales under the agreement, 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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