Celsion Corporation Issues Letter to Stockholders

February 11, 2021

Discusses Broad-based DNA Vaccine Initiative, OVATION 2 Study,
and Phase III OPTIMA Study Conclusions

LAWRENCEVILLE, N.J., Feb. 11, 2021 (GLOBE NEWSWIRE) -- Celsion Corporation (NASDAQ: CLSN), an oncology drug development company, today announced that Michael H. Tardugno, the company's chairman, president and chief executive officer, issued a letter to stockholders providing:

- Further details on the Company's vaccine initiative using its PLACCINE DNA vaccine platform technology for preventing or treating infectious agents that have the potential for global pandemics, including the SARS-CoV-2 virus and its variations;
- Expectations for clinical development programs with GEN-1, the company's DNA-mediated IL-12 immunotherapy currently in Phase II development for the treatment of advanced ovarian cancer;
- An update on the status of the Phase III OPTIMA Study with ThermoDox® plus radiofrequency ablation (RFA) in patients newly diagnosed with primary liver cancer, or hepatocellular carcinoma (HCC) and the decision to stop following patients in the Study; and
- A review of the company's strong financial condition and three-year operating runway.

The full text of the letter follows.

To My Fellow Stockholders:

Celsion enjoys a broad base of technologies and competencies. Although 2020 was a challenging year in terms of the OPTIMA Study findings and the impact of COVID-19, we are, in fact, positioned for a future of broader development and exciting prospects. My message to you today is that a single disappointing study, OPTIMA, is not going to diminish the prospects of Celsion and its potential to bring exciting medicines to market.

Let me explain why, starting with TheraPlas and its adaptation to the PLACCINE platform.

Through its first investigational product GEN-1, Celsion's TheraPlas technology has demonstrated it can safely and effectively deliver and activate a DNA plasmid in patients. More than 90 patients have been treated in our oncology program with results demonstrating excellent safety, and with data clearly showing the activation of an immune response. We now believe that an adaption of the TheraPlas technology can do the same as a much-needed vaccine for the near future. We are calling this version of our proprietary plasmid and DNA delivery technology the PLACCINE platform. PLACCINE is the subject of our recently filed provisional patent that was announced on January 28, 2021.

Focus on Immunotherapies and Infectious Disease Vaccines

Future vaccine technology will need to address viral mutations and the challenges of efficient manufacturing, distribution, and storage. We believe an adaptation of our TheraPlas technology, PLACCINE, has the potential to meet these challenges, and perhaps more. Our approach is described in our provisional patent filing and is summarized as a DNA vaccine technology platform characterized by a single plasmid DNA with multiple coding regions. The plasmid vector is designed to express multiple pathogen antigens along with a potent immune modifier. It is delivered via a synthetic delivery system and has the potential to be easily modified to create vaccines against a multitude of infectious diseases, addressing:

- **Viral Mutations**: PLACCINE may offer broad-spectrum and mutational resistance (variants) by targeting multiple antigens on a single plasmid vector.
- **Enhanced Efficacy**: The potent immune modifier IL-12 may improve humoral and cellular responses to viral antigens and can be incorporated in the plasmid.
- **Durable Efficacy**: PLACCINE delivers a DNA plasmid-based antigen that can result in durable antigen exposure and a robust vaccine response to viral antigens.
- **Storage & Distribution**: PLACCINE allows for stability that is compatible with manageable vaccine storage and distribution.
- **Simple Dosing & Administration**: PLACCINE is a synthetic delivery system that should require a simple injection that does not require viruses or special equipment to deliver its payload.

We are conducting preliminary research associated with our recently announced proprietary DNA vaccine platform provisional patent filing. At the same time, we are redoubling our efforts and R&D resources in the immuno-oncology program.

GEN-1, OVATION 2 and Immunotherapy

The Phase II OVATION 2 Study with GEN-1, our DNA-mediated IL-12 immunotherapy, is the first product designed using the Company's TheraPlas platform technology. 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 and eight weekly cycles of GEN-1, patients undergo interval debulking surgery, which is then followed by three

adjuvant cycles of chemotherapy and up to nine additional weekly GEN-1 treatments. The goal of our treatment strategy is to delay progression and improve overall survival (OS). 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).

We have enrolled one-third of the study patients with advanced ovarian cancer at 19 active centers. I am proud to say that by the end of the first quarter, we expect that all 25 clinical sites in the U.S. and Canada will be up and running. This has been no easy task given the impact the COVID -19 pandemic has had on hospital resources and personnel availability. Patient enrollment is expected to be completed sometime during the second half of 2021, unless the pandemic continues to interfere with clinical trials. We expect to release overall response rate (ORR) and surgical resection scores as they become available during the course of 2021. The study's primary endpoint is expected to be announced during the fourth quarter of 2022.

As a reminder, based on favorable safety data from 15 randomized patients in the Phase I portion of the OVATION 2 Study, in June 2020 the Data Safety Monitoring Board (DSMB) recommended that the Phase II portion proceed with the dose of 100 mg/m^2. Of these 15 patients, nine were treated with GEN-1 at a dose of 100 mg/m² plus NACT and six were treated with NACT only. All 15 had successful resections of their tumors, with eight out of nine patients (88%) in the GEN-1 treatment arm having an R0 resection, which indicates a microscopically margin-negative resection in which no gross or microscopic tumor remains in the tumor bed. In comparison, only three out of six patients (50%) in the standard-of-care arm had an R0 resection. Additionally, a manuscript detailing the results of our Phase 1 OVATION 1 Study has been submitted for publication. Translational and clinical data from this dose-escalating study support GEN-1's continued development. I look forward to announcing acceptance of this manuscript by a peer-reviewed publication in the near future.

OPTIMA Study Analyses and ThermoDox® Status

Since the surprising and incredibly disappointing second interim analysis results of the Phase III OPTIMA Study in HCC announced on July 9, 2020, in which the independent Data Monitoring Committee (DMC) found that the interim findings suggested futility, we have continued to follow patients for OS. Independent analyses conducted by a global biometrics contract research organization, and by the National Institutes of Health (NIH), did not find any evidence of significance or factors that would justify continuing to follow patients for OS. Therefore, the Company will be notifying all clinical sites to discontinue following patients. The OPTIMA Study database of 556 patients will now be frozen at 185 patient deaths.

As a reminder, we had previously stated that it would be highly unlikely the DMC's recommendation would be reversed by subsequent data analyses. And while the analyses did identify certain patient subgroups that appear to have had a clinical benefit, we concluded that it would not be in our best interest to pursue these retrospective findings as the regulatory hurdles supporting further discussion will be significant.

A single disappointing study does not mean an end to the future of ThermoDox®. Celsion continues working closely and supporting investigations by others throughout the world in breast cancer, pancreatic cancer and in solid tumors in children. Following inquiries from the NIH, we intend to renew our Cooperative Research and Development Agreement (CRADA) with the Institute at a nominal cost, one goal of which is to pursue their interest in a study of ThermoDox® to treat patients with bladder cancer. Importantly, Celsion is developing a business model to support these investigator-sponsored studies in a manner that will not interfere with the Company's focus on our GEN-1 programs and our vaccine development initiative.

Strong Balance Sheet

Celsion is fortunate to be in an excellent financial position to fund the achievement of our near-term milestones, with an anticipated cash runway of nearly three years. Including the $35 million equity financing announced in January 2021, we currently have approximately $58 million in cash and cash equivalents on our balance sheet. In conjunction with the registered direct common stock only financing in January 2021, we terminated our Common Stock Purchase Agreement with Lincoln Park Capital. During the third quarter of 2020, the Company restructured its venture debt facility with Horizon Technology Finance Corporation, thereby reducing our outstanding debt obligation from $10 million to $5 million.

Furthermore, we were pleased in early February to have received written notice from the Listing Qualifications Staff of The Nasdaq Stock Market notifying us that we had regained compliance with the minimum bid price listing requirement set forth under Listing Rule 5550(a)(2). As such, shares of our common stock continue to trade on The Nasdaq Stock Market without interruption.

In Conclusion

While 2020 brought the challenges of navigating the COVID-19 pandemic, we are heartened by the promise of our platform technologies to improve the lives of patients. We look forward to an active and potentially highly rewarding future, and to updating you on our progress.

On behalf of all our employees, I thank our stockholders for their continued support.

Sincerely,

Michael H. Tardugno
Chairman, President and Chief Executive Officer
February 11, 2021

About Celsion Corporation

Celsion is a fully integrated, clinical stage biotechnology company focused on advancing a portfolio of innovative cancer treatments, including immunotherapies, DNA-based therapies and directed chemotherapies through clinical trials and eventual commercialization. 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 based upon current beliefs, expectation, and assumptions and include statements regarding the platform having the potential to provide broad protection against coronavirus disease 2019 (COVID-19), and possible future mutations of SARS-CoV-2 or other coronaviruses. These statements are subject to a number of risks and uncertainties, many of which are difficult to predict, including the ability of the Company's platform to provide broad protection against COVID-19, and possible future mutations of SARS-CoV-2 or other coronaviruses, the issuance of a patent to the Company for use of its technology platform for treating or preventing infection with the SARS-CoV-2 virus that causes COVID-19, 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.

Celsion Investor Contact
Jeffrey W. Church
Executive Vice President and CFO
609-482-2455
jchurch@celsion.com

LHA Investor Relations
Kim Sutton Golodetz
212-838-3777
kgolodetz@lhai.com

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