Celsion Reports T-cell and B-cell Response from In Vivo Studies with its PLACCINE DNA Vaccine Platform

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Results Indicate Induction of Adaptive Immune Response Against SARS-CoV-2

Company Plans Additional Development Work to Further Optimize its Vaccine Platform Through Vector Compositions, Delivery Route, Dosing and Dosing Frequency, and Use of Molecular Adjuvant

LAWRENCEVILLE, N.J., Sept. 02, 2021 (GLOBE NEWSWIRE) -- Celsion Corporation (NASDAQ: CLSN), a clinical-stage company focused on DNA-based immunotherapy and next-generation vaccines, today announced results from preclinical *in vivo* studies showing production of antibodies and cytotoxic T-cell response specific to the spike antigen of SARS-CoV-2 when immunizing BALB/c mice with the Company's next-generation PLACCINE DNA vaccine platform. Moreover, the antibodies to SARS-CoV-2 spike antigen prevented the infection of cultured cells in a viral neutralization assay. The production of antibodies predicts the ability of PLACCINE to protect against SARS-CoV-2 exposure, and the elicitation of cytotoxic T-cell response shows the vaccine's potential to eradicate cells infected with SARS-CoV-2.

These findings demonstrate the potential immunogenicity of Celsion's PLACCINE DNA vaccine, which is intended to provide broad-spectrum protection and resistance against variants by incorporating multiple viral antigens, to improve vaccine stability at storage temperatures of 4^{o} C and above, and to facilitate cheaper and easier manufacturing. Celsion expects to report these data at the International Vaccines Conference to be held on October 19 – 21, 2021.

"In an effort to establish a suite of platform technologies, we have produced and characterized a family of DNA vaccine vectors expressing one or more SARS-CoV-2 surface antigens or proteins with or without immune modifiers or agents to improve vaccine quality," said Khursheed Anwer, PhD, Celsion's Executive Vice President and Chief Science Officer. "In addition, we are developing an intramuscular vaccine based on a specialized synthetic delivery system that yields high levels of viral proteins to generate the desired immune response. This formulation does not require a separate delivery device, such as electroporation, for administration. We are pleased with the immunogenicity data from our recent preclinical studies and plan to continue to share progress from ongoing *in vivo* studies intended to further optimize the PLACCINE DNA vaccine activity through vector design, delivery route, dose levels and dosing frequency, as well as adjuvant quality. If successful, our immediate goal is to validate our program with IND-enabling studies."

Michael H. Tardugno, Celsion's Chairman, President and Chief Executive Officer, said, "Our DNA-based vaccine is designed to improve the breadth of immune response by targeting multiple antigens of a pathogen or multiple mutants of the same antigen. The findings we are reporting today are encouraging and demonstrate that the immune response to the PLACCINE DNA vaccine is consistent with our vaccine design goals. We look forward to sharing our progress as we conduct further studies to optimize vector design, dosing and delivery with the goal of filing an Investigational New Drug application with the U.S. Food and Drug Administration early next year.

"Importantly, based on our experience with GEN-1, our DNA plasmid immunotherapy, we fully expect that our platform will be both cost-effective and scalable, allowing for stability across a reasonable and readily achievable temperature range that addresses global vaccine storage and distribution needs. A successful proof of concept using mRNA vaccines as a standard will provide Celsion with the scientific basis to launch a vaccine program to address a range of unaddressed serious infectious diseases," Mr. Tardugno added.

About the PLACCINE platform

PLACCINE is Celsion's proprietary plasmid and DNA delivery technology and the subject of a provisional patent application that covers a broad range of next-generation DNA vaccines. An adaptation of the Company's TheraPlas technology, PLACCINE is 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 modifiers such as cytokines and chemokines 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.
- **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.

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 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. Readers are cautioned that such forward-looking statements involve risks and uncertainties including, without limitation, statements relating to the offering and the use of proceeds therefrom, 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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