Celsion Corporation Advances Proof of Concept to Non-human Primate Challenge Study Against SARS-CoV-2 with In-Process Vaccine Candidate

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Preclinical results demonstrate safe and efficient immune response with vaccine development showing promise of neutralizing activity for a range of variants

LAWRENCEVILLE, N.J., Jan. 31, 2022 (GLOBE NEWSWIRE) -- Celsion Corporation (NASDAQ: CLSN), a clinical-stage development company focused on DNA-based immunotherapy and next-generation DNA-based vaccines, announces it has engaged BIOQUAL, Inc., a preclinical testing contract research organization, to conduct a non-human primate (NHP) challenge study with Celsion's DNA-based approach for a SARS-CoV-2 vaccine. The NHP pilot study follows the generation of encouraging mouse data and will evaluate the Company's lead vaccine formulations for safety, immunogenicity and protection against SARS-CoV-2.

In completed preclinical studies, Celsion demonstrated safe and efficient immune responses including IgG response, neutralizing antibodies and T-cell responses that parallel the activity of commercial vaccines following intramuscular (IM) administration of novel vaccine compositions expressing a single viral antigen. In addition, vector development has shown promise of neutralizing activity against a range of SARS-CoV-2 variants. Celsion's novel DNA-based vaccines have been based on a simple intramuscular injection that does not require viral encapsulation or special equipment for administration.

"We are pleased to have engaged BIOQUAL to support the advancement of our PLACCINE platform research and look forward to beginning non-human primate challenge studies with the initial proof of concept based on a single variant antigen," said Michael H. Tardugno, chairman, president and chief executive officer of Celsion.

"Over the past 14 months, Celsion has substantially expanded its vaccine competencies, resources and capabilities, reinforced with the addition of several key scientists skilled in immunology and vaccine development. The acquisition of plasmid manufacturing capability and state-of-the-art equipment in vaccine research and our investments in vector design engineering, analytical methods, and vivarium capacity have allowed for the rapid evaluation of more than 35 plasmid vectors. Rapid turnaround of novel vaccine-expression systems leveraging in-house capabilities and strategic business collaborations have allowed us to refine and focus on promising formulations," continued Mr. Tardugno. "Importantly, we are protecting our novel know-how with additional patent applications."

Concluding his remarks, Mr. Tardugno noted, "Ongoing directional and technical guidance from our Vaccine Advisory Board, which is comprised of leaders in commercial vaccine development, virology, vector engineering and drug development, has been invaluable as we approach this critical advancement in our platform development program. We expect NHP studies to begin during the second quarter of 2022 with the goal of generating important data to inform human clinical studies."

About BIOQUAL, Inc.

BIOQUAL was established in 1991 and performs contract research services focused on in vivo models of human diseases including COVID-19, AIDS, influenza, RSV infection, Flavivirus infections including Zika and Dengue, malaria, hepatitis and cancer. BIOQUAL has laboratories and vivarium under both BSL-2 and BSL-3 containment. In addition, BIOQUAL maintains CDC-approved BSL-3 containment laboratories for studies associated with Select Agents including highly pathogenic avian influenza.

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 the option to include 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 option for including 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 delivers for stability that is compatible with manageable vaccine storage and distribution.
- **Dosing & Administration**: PLACCINE is a synthetic delivery system designed to require a simple injection and does not require viruses or special equipment for administration.

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-CoV-2. The Company's product pipeline includes GEN-1, a DNA-based immunotherapy for the localized treatment of ovarian cancer. Celsion also has two feasibility-stage platform technologies for the development of novel nucleic acid-based immunotherapies and other anticancer 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. [PLACCINE/VACCINE]

Celsion GmbH is Celsion's wholly owned, special purpose subsidiary based in Zug, Switzerland. Celsion GmbH is responsible for supporting studies of ThermoDox®, a proprietary heat-activated liposomal encapsulation of doxorubicin, is under investigator-sponsored development for several cancer indications. For more information on Celsion GmbH, visit www.celsiongmbh.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, expectations, 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 or biomarkers of other technologies, access 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.

CONTACTS:

Celsion Corporation
Jeffrey W. Church
Executive VP, President and CFO
609-482-2345
jchurch@celsion.com

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

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