

CyanVac Receives BARDA-Funded Project NextGen Award to Evaluate its Intranasal COVID-19 Vaccine Candidate in a Phase 2b Study

6/13/2024

Award will support a 10,000-participant study comparing CyanVac's PIV5-based intranasal vaccine candidate CVXGA with a commercial COVID-19 vaccine under BARDA's Clinical Studies Network

ATHENS, Ga. & SAN JOSE, Calif.--(BUSINESS WIRE)-- CyanVac LLC, a clinical-stage biotechnology company developing intranasal vaccines using a transformational parainfluenza virus 5 (PIV5)-based vector, announced today that it received federal **Project NextGen** funding to support a comparative Phase 2b study of CVXGA, the company's PIV5-based vaccine candidate designed to protect against COVID-19.

Project NextGen is an initiative of the U.S. Department of Health and Human Services (HHS) to advance new, innovative vaccines and therapeutics providing broader and more durable protection for COVID-19. The award is one of the first made through the Rapid Response Partnership Vehicle, a consortium funded by the Biomedical Advanced Research and Development Authority (BARDA) part of the Administration for Strategic Preparedness and Response (ASPR) within HHS, to accelerate product and technology development.

The Phase 2b study of PIV-5-based CVXGA intranasal COVID-19 vaccine will be conducted through BARDA's clinical studies network.

"This award will accelerate the development of our PIV5-based intranasal COVID-19 vaccine, building on our very promising Phase 1 and preliminary Phase 2a clinical trial results," said Biao He, Ph.D., founder and CEO of CyanVac. "PIV5 is a novel intranasal vaccine vector that has been shown to replicate safely in humans in clinical trials and stimulates all three pillars of immunity – cellular, mucosal, and humoral – with minimal uncomfortable side effects.

The successful development of an intranasal COVID-19 vaccine using this new vector will demonstrate the capabilities of our PIV5 platform and benefit the development of PIV5-based vaccines for other emerging infectious diseases.”

Under the award, CyanVac will be the sponsor for a 10,000 participant, randomized double-blinded Phase 2b study that will compare the efficacy, safety and immunogenicity of CyanVac’s next-generation intranasal COVID-19 vaccine candidate to a U.S. Food and Drug Administration (FDA)-approved mRNA-based COVID-19 vaccine. The study will be conducted through BARDA's Clinical Studies Network and will evaluate the vaccine in a subset of participants at higher risk of severe disease. The study is expected to start in the fall of 2024 and will evaluate the efficacy of CVXGA in preventing not only severe COVID-19 infections, but also asymptomatic infections.

“Many vaccines including COVID-19 vaccines are quite effective at preventing serious illness and death, but there is a need for vaccines that can also block transmission of a pathogen to other people,” said Dr. Henry Radziewicz, Chief Medical Officer of CyanVac. “Our intranasal vaccine is delivered to mucosal surfaces, a key focus area for Project NextGen by BARDA because such vaccines have the potential to reduce the spread of disease.”

“We are excited to work with BARDA on this large-scale trial and are grateful for their support,” added Dr. He.

The project is being funded with federal funds from HHS, ASPR, BARDA, under Other Transaction (OT) number 75A50123D00005.

About CVXGA

CVXGA is a clinical-stage COVID-19 vaccine candidate based on a proprietary parainfluenza virus 5 (PIV5) vector that encodes the spike (S) protein of SARS-CoV-2. The PIV5 vector was developed at the University of Georgia and is based on a respiratory virus that is not known to cause disease in humans which has been commonly administered to dogs as part of combination distemper/kennel cough vaccines for decades. CyanVac and its affiliate, Blue Lake Biotechnology, are developing CVXGA as a single-dose, intranasal vaccine to prevent SARS-CoV-2 infection and serious complications associated with COVID-19. Preclinical studies have demonstrated that CVXGA is immunogenic and protective and prevents transmission of SARS-CoV-2. Phase 1 data has shown that subjects dosed with CVXGA showed robust mucosal, cellular and humoral immune responses with limited or no reactogenicity and no serious events assessed as related to the vaccine.

About CyanVac and Blue Lake Biotechnology

CyanVac LLC and its affiliate, Blue Lake Biotechnology, Inc., are developing intranasal vaccines that harness the full breadth of the immune system to keep people healthy, prevent serious infectious diseases, and protect the health

of vulnerable populations. Our platform uses a proprietary parainfluenza virus 5 vector into which a foreign gene from a targeted pathogen is inserted. We have generated a robust clinical-stage pipeline of best-in-class vaccines designed to overcome the limitations of existing vaccine technologies. Our lead product candidates have demonstrated potential for high efficacy and durability with few vaccine-related side effects.

Learn more at **CyanVac** and **Blue Lake Biotechnology**.

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Source: Blue Lake Biotechnology, Inc