Malaria Vaccine Phase 2b Clinical Trial Results Published in Preprints with The Lancet

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GAITHERSBURG, Md., April 23, 2021 /PRNewswire/ -- Novavax, Inc. (Nasdaq: NVAX), a biotechnology company developing next-generation vaccines for serious infectious diseases, today announced the pre-print publication of data from a Phase 2b clinical trial in children demonstrating 77 percent efficacy for a malaria vaccine candidate, R21, created by the University of Oxford that includes Novavax' Matrix-M™ adjuvant and is licensed to Serum Institute of India (SII). Published online in *Preprints with The Lancet*, this vaccine's high levels of protective efficacy hold promise of becoming an important tool for global malaria eradication.

The Phase 2b randomized, controlled, double-blind trial was conducted at the Clinical Research Unit of Nanoro (CRUN) / Institut de Recherche en Sciences de la Santé (IRSS), Burkina Faso, and recruited 450 participants from the catchment area of Nanoro, a setting with highly seasonal malaria transmission.

In three study arms, participants aged 5-17 months received 5 mg of R21 with either 25 mg or 50 mg of Matrix-M, or a rabies vaccine as a control. The researchers reported a vaccine efficacy of 77 percent in the higher adjuvant dose group and 71 percent in the lower adjuvant dose group. The publication reports that both adjuvant dosage levels were well tolerated in young children with no reported severe reactions to the vaccine. In addition, participants vaccinated with R21/Matrix-M showed high titers of malaria-specific anti-N-acetylneuraminic acid phosphatase (NANP) antibodies 28 days after the third vaccination, which were almost doubled with the higher adjuvant dose. After a fourth dose, administered one year later, antibody levels were boosted to levels similar to the peak titers achieved following the primary series of vaccinations.

The Matrix-M component of the malaria vaccine will be manufactured and supplied to SII by Novavax. Under Novavax' agreement with Serum Institute, SII has rights to use Matrix-M in the vaccine in regions where the disease is endemic and will pay Novavax royalties on its market sales of the vaccine. Additionally, Novavax will have commercial rights to sell and distribute the SII-manufactured vaccine in certain countries, primarily in the travelers' and military vaccine markets.

"These significant results support our high expectations for the potential of this vaccine, which included reaching the WHO-stated goal for a malaria vaccine with at least 75 percent efficacy," said Adrian Hill, Lakshmi Mittal and Family Professorship of Vaccinology; Director of the Jenner Institute at the University of Oxford; Co-Director, Oxford Martin Programme on Vaccines, and co-author of the publication. "With the commitment by our commercial partner, Serum Institute of India, to manufacture at least 200 million doses annually in the coming years, we believe this vaccine could have a major public health impact."

There were an estimated 229 million cases of malaria worldwide in 2019, with an estimated 409,000 deaths. Children under the age of five are the most vulnerable, accounting for 67 percent of deaths worldwide in 2019. A Phase 3 trial of the vaccine has begun recruitment across five trial sites in four countries of differing malaria transmission rates and seasonality in Africa to study large-scale safety and efficacy.

"The team at Novavax is gratified to be a part of the collaboration that has led to today's important advance for this longstanding global health problem," said Gregory M. Glenn, M.D., President, Research and Development, Novavax. "Novavax' Matrix-M adjuvant used with the Oxford R21 antigen both minimizes the dose required and thereby increases the number of doses available, and stimulates a highly effective immune response that could protect the world's most vulnerable population, children."

"We are excited to be working with Oxford University and Novavax on the successful development of a malaria vaccine," said Dr. Cyrus Poonawalla, Chairman and Managing Director, Serum Institute of India. "We are committed to supplying 200 million doses of the vaccine annually after licensure at a very cost-effective price."

The results, detailed in, 'Efficacy of a low dose candidate malaria vaccine, R21 in adjuvant Matrix-M^{TM}, with seasonal administration to children in Burkina Faso: a randomized controlled trial,' are available online here.

About R21

R21 was produced by expressing recombinant HBsAg virus-like particles in Hansenula polymorpha, comprising the central repeat and the C-terminus of the circumsporozoite protein (CSP) fused to the N-terminal end of HBsAg10 and manufactured

by the Serum Institute of India Private Ltd (SIIPL). R21 was mixed immediately prior to administration with Matrix-M™, a saponin-based vaccine adjuvant produced by Novavax AB, Uppsala, Sweden.

Development of the R21/Matrix-M, vaccine which targets *P. falciparum* malaria, has been accelerated by a collaboration between the Jenner Institute at Oxford University, the Serum Institute of India Pvt Ltd. and Novavax, Inc. working with many clinical trial units in the UK and Africa.

About Matrix-M™

Novavax' patented saponin-based Matrix-M™ adjuvant has demonstrated a potent and well-tolerated effect by stimulating the entry of antigen presenting cells into the injection site and enhancing antigen presentation in local lymph nodes, boosting immune response.

About Novavax

Novavax, Inc.?(Nasdaq: NVAX) is a biotechnology company that promotes improved health globally through the discovery, development and commercialization of innovative vaccines to prevent serious infectious diseases. The company's proprietary recombinant technology platform combines the power and speed of genetic engineering to efficiently produce highly immunogenic nanoparticles designed to address urgent global health needs. Novavax?is conducting late-stage clinical trials for NVX-CoV2373, its vaccine candidate against SARS-CoV-2, the virus that causes COVID-19. NanoFlu™, its quadrivalent influenza nanoparticle vaccine, met all primary objectives in its pivotal Phase 3 clinical trial in older adults and will be advanced for regulatory submission. Both vaccine candidates incorporate Novavax' proprietary saponin-based Matrix-M™ adjuvant to enhance the immune response and stimulate high levels of neutralizing antibodies.

For more information, visit www.novavax.com and connect with us on Twitter and LinkedIn.

Novavax Forward Looking Statements

Statements herein relating to the future of Novavax and the ongoing development of its vaccine and adjuvant products are forward-looking statements. Novavax cautions that these forward-looking statements are subject to numerous risks and uncertainties, which could cause actual results to differ materially from those expressed or implied by such statements. These risks and uncertainties include those identified under the heading "Risk Factors" in the Novavax Annual Report on Form 10-K for the year ended December 31, 2020, as filed with the Securities and Exchange Commission (SEC). We caution investors not to place considerable reliance on forward-looking statements contained in this press release. You are encouraged to read our filings with the SEC, available at sec.gov, for a discussion of these and other risks and uncertainties. The forward-looking statements in this press release speak only as of the date of this document, and we undertake no obligation to update or revise any of the statements. Our business is subject to substantial risks and uncertainties, including those referenced above. Investors, potential investors, and others should give careful consideration to these risks and uncertainties.

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