



## Novavax and Serum Institute of India to Develop and Commercialize Malaria Vaccine Candidate

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- Novavax' proprietary Matrix-M vaccine adjuvant enhances immune response of malaria antigen developed at Jenner Institute at Oxford University
- Phase 2b clinical efficacy study of experimental malaria vaccine with Matrix-M nearing completion in Burkina Faso

GAITHERSBURG, Md., March 11, 2020 (GLOBE NEWSWIRE) -- Novavax, Inc. (NASDAQ: NVAX), a late-stage biotechnology company developing next-generation vaccines for serious infectious diseases, and Serum Institute of India (SII) today announced a commercial license agreement for the use of Novavax' proprietary Matrix-M™ vaccine adjuvant with SII's malaria vaccine candidate. SII licensed the R21 malaria vaccine, which targets the most severe *Plasmodium falciparum*-induced malaria disease, from the Jenner Institute at Oxford University in 2017. Matrix-M is a key component in the malaria vaccine candidate, currently in a Phase 2b clinical trial sponsored by the Jenner Institute, with top-line data expected to be reported in the second quarter of 2020.

Under the terms of the agreement, SII is granted 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. Matrix-M will be manufactured and supplied to SII by Novavax AB, a wholly-owned subsidiary of Novavax based in Uppsala, Sweden.

In addition, as part of the arrangement, Novavax has gained the rights to sell and distribute the SII-manufactured vaccine in high-income countries, primarily in the travelers and military vaccine markets.

Dr. Adrian Hill, director of the Jenner Institute, is leading the clinical studies of the experimental vaccine, which was created using the R21 malaria antigen combined with Matrix-M. He commented, "It has proven very challenging to develop a vaccine against malaria and many different approaches have been tested. After a thorough evaluation of several adjuvants pre-clinically many years ago, we selected Matrix-M for this program based on the strong immune responses elicited in those preclinical studies. Multiple clinical trials sponsored by the Jenner Institute have now confirmed these immunogenicity results. The current Phase 2b efficacy trial represents an important opportunity to test the efficacy of a malaria vaccine using the potent Matrix-M adjuvant in infants in an endemic setting."

"Novavax' next-generation adjuvant, Matrix-M, is an impressive and critical component in this much-needed malaria vaccine," said Adar Poonawalla, Chief Executive Officer of Serum Institute of India. "This will be an important long-term partnership in advancing an innovative potential malaria vaccine and while we have much work to do, this marks a key step forward."

"As the world's largest vaccine producer in terms of doses delivered, Serum Institute of India is the ideal partner to ensure that an improved malaria vaccine ultimately reaches the many millions of individuals at risk in areas where malaria is endemic," said Stanley C. Erck, President and Chief Executive Officer of Novavax. "This agreement highlights our mutual confidence in Matrix-M's ability to induce a strong immune response that will ultimately increase vaccine effectiveness."

### About Malaria

Malaria is a serious and sometimes fatal disease caused by at least four different parasites that are found on certain types of mosquitos. *Plasmodium falciparum*, the most severe of these parasites, causes the type of malaria that is most likely to result in severe infections and, if not promptly treated, can lead to death. There are approximately 2,000 annual cases of malaria diagnosed in the U.S.; the vast majority of which are in travelers and immigrants returning from endemic parts of the world where malaria transmission occurs.

Globally, the World Health Organization estimated that in 2018, over 200 million clinical cases of malaria occurred, resulting in over 400,000 deaths, mostly children in Africa.<sup>1</sup> Globally, malaria is the one of the leading causes of death in children younger than age five years.

### About Matrix-M™

Matrix-M™ is Novavax' next-generation saponin-based adjuvant, powered by a novel formulation that provides a potent and well-tolerated adjuvant effect. Saponins are steroid or triterpenoid glycosides, which occur in many plant species. In Matrix-M, purified saponin fractions are mixed with synthetic cholesterol and a phospholipid to form stable particles than can be readily formulated with a variety of vaccine antigens. Saponin-based adjuvants act in part by stimulating the entry of antigen-presenting cells into the injection site and enhancing antigen presentation in the local lymph nodes. Matrix-M has the ability to stimulate cell-mediated immunity as well as to enhance antibody production; and importantly, when facing rapidly emerging diseases such as those caused by coronaviruses, Ebola virus or pandemic influenza, they can allow immune responses to be achieved with much lower doses of antigen, known as "dose-sparing." Matrix-M also increases the opportunity for longer-lasting immunity, which may reduce the number of vaccinations needed to gain optimal protection.

Novavax' past experience with saponin-based adjuvants in both animals and humans indicates that, like all adjuvants, they increase the local reaction at the injection site. However, those local reactions are transient and there is no evidence of longer-term adverse effects. Matrix-M has been evaluated in several Novavax vaccine candidates, including Novavax' Phase 3 NanoFlu™ vaccine for influenza in older adults, and is expected to be included in Novavax' COVID-19 vaccine candidate, which is expected to go into clinical trials in spring of 2020.

<sup>1</sup> WHO 2019 World Malaria Report <https://www.who.int/publications-detail/world-malaria-report-2019>

## About Novavax

Novavax, Inc. (Nasdaq:NVAX), is a late-stage biotechnology company that promotes improved health globally through the discovery, development, and commercialization of innovative vaccines to prevent serious infectious diseases. NanoFlu™, its quadrivalent influenza nanoparticle vaccine, is currently in a pivotal Phase 3 clinical trial to address key factors that can lead to the poor effectiveness of currently approved flu vaccines. ResVa x™, its RSV vaccine for infants via maternal immunization, is the only vaccine to demonstrate efficacy in a Phase 3 clinical trial. Novavax recently initiated development of a vaccine program against COVID-19. Novavax is a leading innovator of recombinant vaccines; its proprietary recombinant technology platform combines the power and speed of genetic engineering to efficiently produce a new class of highly immunogenic nanoparticles addressing urgent global health needs.

For more information, visit [www.novavax.com](http://www.novavax.com) and connect with us on [Twitter](#) and [LinkedIn](#).

## About Serum Institute of India

Serum Institute of India Pvt. Ltd. was founded in 1966 by Dr. Cyrus Poonawalla with a mission of manufacturing life-saving immuno-biologics. Serum is the world's largest vaccine manufacturer by number of doses produced and sold globally (more than 1.3 billion doses). It is estimated that about 65% of the children in the world receive at least one vaccine manufactured by Serum Institute. Vaccines manufactured by Serum are accredited by the World Health Organization, Geneva and are being used in approximately 170 countries across the globe.

Serum is ranked as India's No. 1 biotechnology company, manufacturing highly specialized lifesaving biologics like vaccines using cutting edge genetic and cell-based technologies, antisera and other medical specialties.

The philanthropic philosophy of Serum continues with its work on newer vaccines and biologicals.

Learn more about Serum Institute of India at <https://www.seruminstitute.com/>.

## 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, 2018, and Quarterly Report on Form 10-Q for the period ended September 30, 2019, as filed with the Securities and Exchange Commission (SEC). We caution investors not to place considerable reliance on the forward-looking statements contained in this press release. You are encouraged to read our filings with the SEC, available at [sec.gov](http://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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