



Moderna Receives FDA Fast Track Designation for Zika Vaccine mRNA-1893

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CAMBRIDGE, Mass.--(BUSINESS WIRE)--Aug. 19, 2019-- Moderna, Inc., (Nasdaq: MRNA) a clinical stage biotechnology company pioneering messenger RNA (mRNA) therapeutics and vaccines to create a new generation of transformative medicines for patients, today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation for its investigational Zika vaccine (mRNA-1893) currently being evaluated in a Phase 1 study for the prevention of Zika virus infection in healthy adults.

[Fast Track](#) is designed to facilitate the development and expedite the review of therapies and vaccines for serious conditions and fill an unmet medical need. Programs with Fast Track designation may benefit from early and frequent communication with the FDA, in addition to a rolling submission of the marketing application. Moderna previously received Fast Track designation for its methylmalonic acidemia (MMA) program (mRNA-3704), which is now recruiting patients for a Phase 1/2 clinical study.

"Protecting against Zika virus transmission, particularly in women during pregnancy, continues to be an area of high unmet need. Fast Track designation supports our belief in the clinical potential of mRNA-1893 and the importance of developing an effective vaccine that can be rapidly developed and deployed," said Tal Zaks, M.D., Ph.D., chief medical officer at Moderna. "Our Zika program is part of Moderna's broader commitment to improving global public health through developing mRNA vaccines to prevent the spread of infectious diseases."

mRNA-1893 contains an mRNA sequence encoding for the structural proteins of Zika virus and is designed to cause cells to secrete virus-like particles, mimicking the response of the cell after natural infection. Preclinical data published in [The Journal of Infectious Diseases](#) have shown that vaccination with mRNA-1893 protected against transmission of Zika virus during pregnancy in mice.¹ mRNA-1893 is currently in a Phase 1 study evaluating safety, pharmacokinetics and pharmacodynamics in healthy volunteers.

This project has been funded in whole or in part with Federal funds from the Department of Health and Human Services (HHS); Office of the Assistant Secretary for Preparedness and Response; Biomedical Advanced Research and Development Authority (BARDA), under Contract No. HHSO100201600029C.

About the Phase 1 Study

This randomized, observer-blind, placebo-controlled, dose-ranging study is designed to evaluate the safety, tolerability and immunogenicity of mRNA-1893 in healthy flavivirus seropositive and seronegative adults ages 18 to 49 years. Primary outcome measures include frequency and grade of adverse events. Secondary outcome measures include geometric mean titers of neutralizing antibodies against Zika virus.

About Zika

Zika virus has rapidly emerged in recent years as a pandemic with potential long-term public health implications. Zika is primarily transmitted by mosquitos, but can also be transmitted sexually. Children born to mothers infected with Zika can develop microcephaly, a severe disease characterized by small, not fully developed heads and severe disabilities. In adults, outbreaks in Latin American and Caribbean countries have been associated with Guillain-Barre syndrome, a rare but serious autoimmune disorder in which the immune system attacks part of the nervous system.² There is no approved vaccine for Zika.

About Moderna

Moderna is advancing messenger RNA (mRNA) science to create a new class of transformative medicines for patients. mRNA medicines are designed to direct the body's cells to produce intracellular, membrane or secreted proteins that can have a therapeutic or preventive benefit and have the potential to address a broad spectrum of diseases. Moderna's platform builds on continuous advances in basic and applied mRNA science, delivery technology and manufacturing, providing the Company the capability to pursue in parallel a robust pipeline of new development candidates. Moderna is developing therapeutics and vaccines for infectious diseases, immuno-oncology, rare diseases and cardiovascular diseases, independently and with strategic collaborators.

Headquartered in Cambridge, Mass., Moderna currently has strategic alliances for development programs with AstraZeneca, Plc. and Merck, Inc., as well as the Defense Advanced Research Projects Agency (DARPA), an agency of the U.S. Department of Defense; the Biomedical Advanced Research and Development Authority (BARDA), a division of the Office of the Assistant Secretary for Preparedness and Response (ASPR) within the U.S. Department of Health and Human Services (HHS). Moderna has been ranked in the top ten of *Science's* list of top biopharma industry employers for the past four years. To learn more, visit www.modernatx.com.

Special Note Regarding Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended including, but not limited to, statements concerning: the potential of mRNA therapeutics and vaccines as a new generation of transformative medicines for patients, the potential of Fast Track Designation to accelerate development and approval of mRNA-1893, Moderna's belief in the clinical potential of mRNA-1893 and its potential to be rapidly developed and deployed, Moderna's ability to improve global public health through developing mRNA vaccines to prevent the spread of infectious diseases. In some cases, forward-looking statements can be identified by terminology such as "will," "may," "should," "expects," "intends," "plans," "design," "aims," "anticipates," "believes," "estimates," "predicts," "potential," "continue," or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words. The forward-looking statements in this press release are neither promises nor guarantees, and you should not place undue reliance on these forward-looking statements because they involve known and unknown risks, uncertainties, and other factors, many of which are beyond Moderna's control and which could cause actual results to differ materially from those expressed or implied by these forward-looking statements. These risks, uncertainties, and other factors include, among others: Fast Track Designation by the FDA for mRNA-1893 may not lead to a faster development process, review, or approval compared to

conventional FDA procedures, and it does not increase the likelihood that mRNA-1893 will receive marketing approval; the FDA may withdraw Fast Track Designation if it believes that the designation is no longer supported by data from mRNA-1893's clinical development program; Fast Track Designation alone does not guarantee qualification for the FDA's priority review procedures; preclinical and clinical development is lengthy and uncertain, especially for a new class of medicines such as mRNA, and therefore our preclinical programs or development candidates may be delayed, terminated, or may never advance to or in the clinic; no mRNA drug has been approved in this new potential class of medicines, and may never be approved; mRNA drug development has substantial clinical development and regulatory risks due to the novel and unprecedented nature of this new class of medicines; and those risks and uncertainties described under the heading "Risk Factors" in Moderna's most recent Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission (SEC) and in subsequent filings made by Moderna with the SEC, which are available on the SEC's website at www.sec.gov. Except as required by law, Moderna disclaims any intention or responsibility for updating or revising any forward-looking statements contained in this press release in the event of new information, future developments or otherwise. These forward-looking statements are based on Moderna's current expectations and speak only as of the date hereof.

¹ Jagger et al. Protective efficacy of nucleic acid vaccines against transmission of Zika virus during pregnancy in mice. *The Journal of Infectious Diseases*. 2019; jiz338, <https://doi.org/10.1093/infdis/jiz338>.

² Krauer et al. Zika virus infection as a cause of congenital brain abnormalities and Guillain-Barré syndrome: Systematic review. *PLoS Med*. 2017; 14(1):e1002203.

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