

Moderna Receives FDA Fast Track Designation for Zika Vaccine

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Investigational Zika vaccine (mRNA-1893) is currently being evaluated in a Phase 1 study for the prevention of Zika virus infection in healthy adults



Moderna, Inc., a clinical stage biotechnology company pioneering messenger RNA (mRNA) therapeutics and vaccines to create a new generation of transformative medicines for patients, has 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.

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