



Moderna Announces Funding Award from BARDA for \$8 Million with Potential of up to \$125 Million to Accelerate Development of Zika Messenger RNA (mRNA) Vaccine

September 7, 2016

Company plans to file IND by end of 2016

CAMBRIDGE, Mass., September 7, 2016 — Moderna Therapeutics, a clinical stage biotechnology company pioneering messenger RNA (mRNA) Therapeutics™ to create a new generation of transformative medicines for patients, today announced a funding award of \$8 million with the potential of up to \$125 million from 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), to accelerate development of a novel Zika mRNA vaccine.

Under the terms of the agreement, the initial \$8 million award will support a Phase 1 clinical study, toxicology studies, vaccine formulation and manufacturing. The agreement includes options for additional funding up to \$117 million to support Phase 2 and Phase 3 clinical studies, as well as large-scale manufacturing.

Moderna plans to file an investigational new drug (IND) application with the U.S. Food & Drug Administration (FDA) by the end of 2016. The company's preclinical work for its Zika vaccine has been funded through a grant from the Defense Advanced Research Projects Agency (DARPA). Development efforts are being led by Valera, Moderna's infectious disease-focused venture.

"We believe our mRNA vaccine technology offers potential advantages in efficacy, speed of development, and production scalability and reliability, which may position Moderna as a leader in preparing for and responding to infectious disease threats, such as Zika, that place millions of people at risk around the world," said Stéphane Bancel, CEO of Moderna. "We feel a tremendous sense of responsibility to advance our Zika mRNA vaccine as quickly as possible, and we are thankful to BARDA for its commitment to support and help expedite our development efforts. We plan to initiate a Phase 1 study within the next several months."

Moderna has two additional Phase 1 mRNA infectious disease vaccine studies currently underway in the US and Europe and has dosed approximately 250 healthy human volunteers to date. The company expects to publish clinical data on its first Phase 1 study in 2017. Additional areas of therapeutic focus for Moderna currently include rare diseases, immuno-oncology and cardiovascular disease, among others.

"With two mRNA infectious disease vaccines already advancing through clinical studies and a growing pipeline of vaccines, all based on the same underlying mRNA vaccine technology, we're in the fortunate position of being able to rapidly apply learnings to inform our Zika vaccine development program," said Michael Watson, President of Valera. "It's clear the world needs novel, innovative approaches to address both known and future infectious disease threats. We hope to be at the forefront of advancing this innovation."

About Moderna's mRNA Vaccine Technology

Vaccines work by mimicking an infection from a known pathogen, such as a virus, without causing disease. They teach the immune system to recognize antigens, which are parts of pathogens. Current vaccines introduce antigens to the body as weakened or inactivated pathogens or as selected antigens produced outside the body. Moderna's approach more closely mimics nature by delivering mRNA to the body's cells, which, in turn, produce antigenic proteins as if the body was infected by a virus. These antigenic proteins are identified and remembered by the immune system. When a person is exposed to the pathogen in the future, the body is able to recognize it as foreign and mounts an immune response, including production of antibodies that can help to destroy the pathogen.

About Moderna Therapeutics

Moderna is a clinical stage pioneer of [messenger RNA Therapeutics™](#), an entirely new *in vivo* drug technology that produces human proteins, antibodies and entirely novel protein constructs inside patient cells, which are in turn secreted or active intracellularly. This breakthrough platform addresses currently undruggable targets and offers a superior alternative to existing drug modalities for a wide range of diseases and conditions. Moderna is developing and plans to commercialize its innovative mRNA drugs through its own ventures and its strategic relationships with established pharmaceutical and biotech companies. Its current ventures are: [Onkaido](#), focused on oncology, [Valera](#), focused on infectious diseases, [Elpidera](#), focused on rare diseases, and [Caperna](#), focused on personalized cancer vaccines. Founded by [Flagship Venture Labs™](#), Cambridge-based Moderna is privately held and currently has strategic agreements with [AstraZeneca](#), [Alexion Pharmaceuticals](#), [Merck](#) and [Vertex Pharmaceuticals](#). To learn more, visit www.modernatx.com.

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