Moderna Announces First Participant Dosed in Phase 1 Study of its mRNA Epstein-Barr Virus (EBV) Vaccine

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Moderna expects to enroll approximately 270 participants in the U.S.

EBV is a major cause of infectious mononucleosis, which can debilitate patients for weeks to months; there is no approved vaccine to prevent EBV.

EBV can also lead to lifelong medical conditions and is associated with an increased risk of developing multiple sclerosis, certain lymphoproliferative disorders, cancers, and autoimmune diseases.

Moderna now has a portfolio of two vaccines against latent viruses in the clinic: CMV and EBV.

CAMBRIDGE, MA / ACCESSWIRE / January 5, 2022 / Moderna, Inc. (NASDAQ:MRNA), a biotechnology company pioneering messenger RNA (mRNA) therapeutics and vaccines, today announced the first participant has been dosed in the Phase 1 study of mRNA-1189, the Company’s Epstein-Barr Virus (EBV) vaccine candidate. The study is known as Eclipse.

"EBV is one of the most common viral infections in the world, and despite the fact that it causes infectious mononucleosis, which impacts millions of adolescents globally, no vaccine is currently available. Adolescents who develop infectious mononucleosis are frequently absent from school for weeks and even months at a time, impacting the quality of their education and their families," said Stéphane Bancel, Chief Executive Officer of Moderna. "The start of this Phase 1 study is a significant milestone as we continue to advance mRNA vaccines against latent viruses, which remain in the body for life after infection and can lead to chronic medical conditions."
Moderna is committed to developing a portfolio of first-in-class vaccines against latent viruses for which there are no approved vaccines today, including vaccines against CMV, EBV and HIV. Our research team is working to bring even more vaccines against latent viruses to the clinic. We believe these vaccines could have a profound impact on quality of health for hundreds of millions of people around the world.

EBV is a common viral infection with 83% of Americans seropositive by 19 years of age. It is spread through bodily fluids (e.g., saliva) and is typically contracted in early childhood or adolescence. While EBV infection in early childhood is predominantly asymptomatic, primary infection in adolescence can lead to infectious mononucleosis (IM), a clinical syndrome including fever, fatigue, sore throat, and lymphadenopathy. IM can debilitate patients for weeks to months, sometimes requiring hospitalization for serious complications such as splenic rupture and significant airway compromise. EBV is responsible for approximately 90% of the one million cases of IM each year in the U.S. As a latent virus, EBV remains in the body for life after infection and can lead to lifelong medical conditions, which causes significant direct and indirect costs to the healthcare system. EBV is associated with a 4- to 10-fold risk of developing multiple sclerosis, and development of certain lymphoproliferative disorders, cancers and autoimmune diseases.

Moderna's vaccine candidate against EBV (mRNA-1189) is being developed to prevent EBV-induced IM and potentially EBV infection. Similar to Moderna's cytomegalovirus (CMV) vaccine candidate (mRNA-1647), mRNA-1189 contains four mRNAs that encode EBV envelope glycoproteins (gH, gL, gp42, gp220), which mediate viral entry into B-cells (a type of immune system cells) and epithelial surface cells, the major targets of EBV infection. Currently, there is no approved vaccine for EBV or IM. Potential future indications may be the prevention of EBV reactivation in other types of conditions such as post-transplant lymphoproliferative disease.

The Phase 1 randomized, observer-blind, placebo-controlled study of mRNA-1189 will be conducted at approximately 15 sites in the U.S. The primary purpose of the Phase 1 study is to assess safety and tolerability of mRNA-1189 in healthy adults ages 18 to 30. Moderna expects to enroll approximately 270 participants. The ClinicalTrials.gov identifier is NCT05164094. To learn more about eligibility, please click here.

Moderna's mRNA vaccine portfolio includes candidates against respiratory viruses, tropical viruses, and latent viruses. Moderna is committed to developing first-in-class vaccines against latent viruses for which there are no approved vaccines today, including vaccines against EBV, CMV and human immunodeficiency virus (HIV).

For individuals with weakened immune systems or infants born with CMV infection, it can have serious consequences. A pregnant mother with an active CMV infection may pass the virus to her unborn child, resulting in congenital CMV infection, which is the leading infectious cause of birth defects in the U.S. The Company's vaccine candidate against CMV (mRNA-1647) is currently being evaluated for safety and efficacy in a Phase 3 study, CMVictory.
HIV is the virus responsible for acquired immunodeficiency syndrome (AIDS), a lifelong, progressive illness with no effective cure. Worldwide, approximately 38 million are currently living with HIV, including approximately 1.2 million in the U.S.6 Moderna is advancing two vaccine candidates against HIV including mRNA-1644, a collaboration with the International AIDS Vaccine Initiative (IAVI) and the Bill and Melinda Gates Foundation, and mRNA-1574, which is being evaluated in collaboration with the U.S. National Institutes of Health (NIH).

About Moderna

In 10 years since its inception, Moderna has transformed from a research-stage company advancing programs in the field of messenger RNA (mRNA), to an enterprise with a diverse clinical portfolio of vaccines and therapeutics across seven modalities, a broad intellectual property portfolio in areas including mRNA and lipid nanoparticle formulation, and an integrated manufacturing plant that allows for both clinical and commercial production at scale and at unprecedented speed. Moderna maintains alliances with a broad range of domestic and overseas government and commercial collaborators, which has allowed for the pursuit of both groundbreaking science and rapid scaling of manufacturing. Most recently, Moderna's capabilities have come together to allow the authorized use of one of the earliest and most-effective vaccines against the COVID-19 pandemic.

Moderna's mRNA platform builds on continuous advances in basic and applied mRNA science, delivery technology and manufacturing, and has allowed the development of therapeutics and vaccines for infectious diseases, immuno-oncology, rare diseases, cardiovascular diseases, and auto-immune diseases. Moderna has been named a top biopharmaceutical employer by Science for the past seven years. To learn more, visit www.modernatx.com.

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 regarding: the Company's development of a vaccine candidate against EBV (mRNA-1189); the Company's conduct of its Phase 1 study of mRNA-1189 and the expected enrollment in such study; potential future indications addressable by mRNA-1189; the Company's development of vaccine candidates against other viruses, including CMV and HIV, and the Company's conduct of clinical trials for such candidates; and the disease burdens associated with EBV, CMV and HIV infection. 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 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.

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