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Emmes Employees Co-Author COVID-19 Vaccine Report for the New England Journal of Medicine

Rockville, MD – November 2, 2020 – Emmes today announced that it provided the data and statistical analysis support for a Phase 1 clinical trial of an investigational COVID-19 vaccine, mRNA-1273, that enrolled adult volunteers. The results of this clinical trial were published in the *New England Journal of Medicine* (NEJM) on September 29.

Three Emmes employees were among the co-authors of the recent report, "Safety and Immunogenicity of SARS-CoV-2 mRNA-1273 Vaccine in Older Adults." The employees are Jim Albert, lead project manager; Dr. Mat Makowski, senior biostatistician; and Kaitlyn Cross, senior biostatistician.

In its role as the statistical and data collection and coordination center, Emmes managed development of the statistical analysis plan and performed all data analysis.

The recent NEJM publication focused on the immune response to the vaccine and whether the vaccine produced any adverse effects in two groups of older adults (56 to 70 years or ≥ 71 years). An earlier report in NEJM described findings from a Phase 1 trial of the mRNA-1273 candidate vaccine in adults ages 18 to 55 years old.

According to Albert, "It's an honor to contribute to a study targeted on finding a vaccine for COVID-19 and to participate in writing two articles published in the prestigious *New England Journal of Medicine* during the same year."

He added, "The whole world is watching the results of this and other vaccine trials, as we move

closer to finding safe, effective ways to address this devastating disease."

The first part of the Phase 1 trial, which began in March, tested 45 adults, while the subsequent portion enrolled 40 older adults during April and May. As described in the Preliminary Report published in NEJM in July, this was a dose-escalation, open-label trial to assess the safety of the mRNA-1273 vaccine and its ability to induce an immune response. Both papers concluded that adverse effects were predominantly mild or moderate in severity. The side effects, such as fatigue, chills and headache, were found to be dose-dependent and were more common after the second immunization. According to this Sept. 29 report, volunteers receiving the 100 mcg dose produced a stronger antibody response than the 25 mcg dose. This observation supported the use of the 100 mcg dose vaccine in a Phase 3 trial of the candidate.

The trial was conducted at Kaiser Permanente Washington Health Research Institute in Seattle, the Emory University School of Medicine in Atlanta and the National Institute of Allergy and Infectious Diseases (NIAID) Vaccine Research Center in Bethesda, Maryland. The vaccine was co-developed by researchers at the Vaccine Research Center, NIAID and at Moderna, Inc. Moderna, Inc. manufactured and provided the vaccine candidate.

"COVID-19 is the latest in a long history of infectious disease research that Emmes has supported," noted Dr. Christine Dingivan, Emmes president and chief executive officer. "This includes H1N1 influenza, SARS, Ebola and Zika. Our team has spent many long hours – nights and weekends – collecting and evaluating the statistical data, and we'll continue to do everything we can to combat this global public health emergency."

About the Research

This project has been funded in whole or in part with federal funds from the National Institute of Allergy and Infectious Diseases, National Institutes of Health, Department of Health and Human Services, under Contract No. HHSN272201500002C.

About Emmes

Emmes is a leading Contract Research Organization working with both public and private sector organizations. We collaborate with our clients to produce valued, trusted scientific research, and our team members are passionate about making a difference in the quality of human health. Emmes has supported more than a thousand studies across a diverse range of diseases since our formation in 1977. Our research is contributing to a healthier world. For more information, visit the Emmes website at www.emmes.com.