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Emmes Announces its Contribution to Second Remdesivir Clinical Trial for COVID-19

Three Employees Co-Author New England Journal of Medicine Report

Rockville, MD – December 14, 2020 – Emmes today announced that it has conducted the data and statistical analysis for the second iteration of the Adaptive COVID-19 Treatment Trial (ACTT-2). The ACTT-2 trial assessed the efficacy and safety of a 4-mg dose of baricitinib with remdesivir, versus remdesivir alone, in hospitalized COVID-19 patients.

Baricitinib, produced by Eli Lilly and Company, has been used to treat adults with moderate to severe rheumatoid arthritis. Baricitinib, in combination with remdesivir for COVID-19 patients, received Emergency Use Authorization on November 19.

The ACTT-2 study, which was conducted from May to July 2020, was a randomized, double-blind, placebo-controlled trial that enrolled more than 1,000 participants at more than 60 U.S. and international sites. The National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health, sponsored the trial.

The trial found that baricitinib plus remdesivir was superior to remdesivir alone in reducing recovery time and accelerating clinical status improvement. This was especially notable among patients requiring high-flow oxygen or non-invasive mechanical ventilation. The combination therapy reduced recovery time in these patients from 18 days to 10 days and was associated with fewer adverse events compared to remdesivir alone.

Three Emmes employees were among the co-authors on the report about the ACTT-2 trial,

"Baricitinib plus Remdesivir for the Treatment of Hospitalized Adults with COVID-19)," published in *New England Journal of Medicine* on December 11, 2020. They are Michelle Green, a vice president and Emmes' lead project manager for the trial; Dr. Mat Makowski, lead Emmes biostatistician; and Jennifer Ferreira, senior biostatistician.

Additional Emmes team members who contributed to the report included Dr. Thomas Conrad, Jill El-Khorazaty, Dr. Michael Wierzbicki, and Heather Hill.

"This is the fourth time this year that Emmes employees have co-authored articles in the *New England Journal of Medicine* on COVID-19," said Dr. Christine Dingivan, president and chief executive officer of Emmes. "We are honored to have many members of our team as active contributors in finding ways to treat and prevent COVID-19."

Michelle Green, one of the Emmes authors of the *New England Journal of Medicine* report, added, "Once again, the Emmes ACTT team has executed high-quality activities at an accelerated pace to meet trial timelines."

The first iteration of the study, ACTT-1, evaluated remdesivir's effectiveness alone in treating patients hospitalized with COVID-19. Developed by Gilead Sciences, Inc., remdesivir is an antiviral medication that was approved by the Food and Drug Administration (FDA) for emergency use on May 1. The ACTT-1 preliminary report was published in the *New England Journal of Medicine* on May 22, with the Final Report issued on October 8. The ACTT-1 trial was one of the studies used in support of the FDA approval of remdesivir on October 22.

Emmes has served as a Statistical and Data Coordinating Center for more than 350 trials supporting NIAID's Division of Microbiology and Infectious Diseases since 1998. This includes recent support of the Phase 1 clinical trial for mRNA-1273, the investigational COVID-19 vaccine developed by Moderna, Inc. and NIAID. The company is also providing scientific and operational support for other organizations conducting research associated with COVID-19 therapies and vaccines.

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.