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Emmes Announces its Contribution to NIH ACTT Clinical Trial for Remdesivir

Two Employees Co-Author New England Journal of Medicine Preliminary Report

Rockville, MD – May 26, 2020 – Emmes today announced that its data and statistical analysis work for the Adaptive COVID-19 Treatment Trial (ACTT) played an important role in the accelerated timetable to evaluate remdesivir's effectiveness in treating hospitalized COVID-19 patients.

The National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health, sponsored the clinical trial, which included 1,063 participants at 60 sites in 10 countries. Emmes has a long history in supporting NIAID's Division of Microbiology and Infectious Diseases and has served as a Statistical and Data Coordinating Center for more than 350 of its clinical trials since 1998.

Two Emmes employees, Michelle Green and Dr. Mat Makowski, were co-authors on the Preliminary Report about the clinical trial, "Remdesivir for the Treatment of COVID-19," published in the May 22, 2020, *New England Journal of Medicine*. Green, a vice president, is Emmes' lead project manager, and Makowski is the lead Emmes biostatistician on the trial. Jennifer Ferreira, senior biostatistician, and Dr. Michael Wierzbicki, biostatistician manager, were also recognized for their work.

Dr. Anne Lindblad, president and chief executive officer, said, "Our Emmes team was able to support the launch of this pivotal therapeutic trial during a pandemic in less than four days from receipt of the study protocol to the first patient enrolled. Our experience in supporting clinical trials for H1N1 influenza, SARS, Ebola and Zika, among others, has proven extremely valuable."

The ACTT clinical trial began in late February to evaluate the use of remdesivir, an investigational anti-viral treatment developed by Gilead Sciences, Inc. Preliminary results showed remdesivir to be superior to standard care in improving time to recovery in adults hospitalized with lung involvement and moderate-severe COVID-19. The median recovery time was 11 days for subjects who received remdesivir compared to 15 days in subjects receiving placebo. On May 1, the U.S. Food and Drug Administration announced an Emergency Use Authorization that allowed hospitals to use the drug to treat patients with severe cases.

Emmes' Michelle Green, one of the authors of the *New England Journal of Medicine* preliminary report, said, "Our Emmes team has been working nearly around the clock to support this research. The response to the pandemic called for both unprecedented speed and stringent attention to detail, and we are all proud to play a part in this important study."

Emmes continues to support the adaptive-design ACTT trial in its second stage, in which subjects will be treated with remdesivir and randomized to receive the anti-inflammatory drug baricitinib, developed by Eli Lilly and Company, or placebo. ACTT2 is expected to enroll more than 1,000 hospitalized adults at up to 100 U.S. and international sites.

The company is providing scientific and operational support for a number of other organizations conducting research associated with COVID-19 therapies and vaccines. One, for SaNOtize, is a clinical trial for Nitric Oxide releasing solutions to prevent and treat mild/moderate infection. Another is for the NIH Phase 1 clinical trial for Moderna, Inc.'s mRNA-1273, an investigational vaccine.

About the Research

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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.