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Emmes Announces New Role for the Blood and Marrow Transplant Clinical Trials Network

Rockville, MD – August 2, 2021 – Emmes today announced that it launched a new study assessing the durability of response to COVID-19 vaccinations in patients with hematological malignancies who are undergoing cellular therapies, such as blood or marrow transplantation or CAR-T infusions. The study is part of an expanded portfolio of projects conducted under the Blood and Marrow Transplant Clinical Trials Network (BMT CTN). The study is supported by National Marrow Donor Program (NMDP)/Be The Match®, The Leukemia & Lymphoma Society (LLS), the National Heart, Lung, and Blood Institute (NHLBI), the National Cancer Institute (NCI), the Fred Hutchinson Cancer Research Center, the Multiple Myeloma Research Foundation (MMRF), American Society for Transplantation and Cellular Therapy (ASTCT), LabCorp, and Adaptive Biotechnologies.

Emmes has partnered with the Center for International Blood and Marrow Transplant Research (CIBMTR) and NMDP/Be The Match to develop and implement a study enrolling patients and collecting samples to determine how these immunocompromised patients respond to the COVID-19 vaccines. Emmes, the CIBMTR and NMDP/Be The Match collaborated to design a streamlined data collection strategy that uses the company's proprietary Advantage eClinical system with standard data collected as part of the CIBMTR registry. The result: an efficient data collection strategy that was deployed in record time.

Adam Mendizabal, Ph.D., Emmes vice president and co-director of the Emmes Transplant Research Unit, said, "Because patients who have received cellular therapies have diminished responses to other vaccines, the study will help determine if this also applies to COVID-19 vaccines."

Mendizabal noted, "I am proud of the Emmes team, along with our collaborators at the CIBMTR and NMDP/Be The Match, for organizing a study plan, raising funds, and enrolling patients in record time. The support of our clinical colleagues across the United States has been critical to our success."

Krisy Peyton, Emmes project leader, added, "We were ready to launch the study in only one month, and we have already made key changes to the system under tight timelines to accommodate new requirements and expanding needs."

She continued, "Our history of successful collaborations with the BMT CTN, combined with deep subject matter expertise on the part of our Emmes project team, were critical components of a rapid, successful launch."

The study aims to follow 732 patients who have received hematopoietic cell transplantation (HCT) and chimeric antigen receptor (CAR) T-cell therapy in the last 12 months and who are scheduled to receive a COVID-19 vaccination as part of their standard of care.

The 732 patients enrolled in the study will be in six cohorts defined by type of cellular therapy and timing of vaccination. The primary objective is to compare the immunogenicity of COVID-19 vaccines in patients starting their vaccination course less than six months after HCT/CAR T-cell therapy versus those starting the vaccination course six to 12 months after the therapy.

Findings from the study will provide physicians with evidence-based guidance and recommendations about COVID-19 vaccinations for their transplant patients.

Dr. Christine Dingivan, Chief Executive Officer of Emmes, said, "Over the last year, Emmes team members have been dedicated to supporting or conducting clinical trials associated with the accelerated development of safe and effective COVID-19 vaccines and therapies. This work has required tight deadlines, intensive effort and creativity, particularly in conducting remote patient trials.

"This new work is no exception," she added. "It demonstrates that there will be a continued need for research that addresses very specific sets of the population and their responses to COVID-19 vaccines. Emmes is proud to collaborate with the Blood and Marrow Transplant Clinical Trials Network, the CIBMTR and the strong coalition of partners involved in this project."

About Emmes

Founded in 1977, Emmes is a global, full-service Clinical Research Organization dedicated to excellence in supporting the advancement of public health and biopharmaceutical innovation. The company's clients include numerous agencies and institutes of the U.S. federal government and a wide range of biotechnology, pharmaceutical and medical device companies throughout the world. To learn more about how our research is making a positive impact on human health, go to the Emmes website at www.emmes.com.

About the BMT CTN

The Blood and Marrow Transplant Clinical Trials Network (BMT CTN) conducts rigorous multiinstitutional clinical trials of high scientific merit, focused on improving survival for patients undergoing hematopoietic cell transplantation and/or receiving cellular therapies. The BMT CTN has completed accrual to 46 Phase II and III trials at more than 100 transplant centers and enrolled over 14,600 study participants.

BMT CTN is funded by the National Heart, Lung, and Blood Institute and the National Cancer Institute, both parts of the National Institutes of Health (NIH), and is a collaborative effort of 20 Core Transplant Centers/Consortia, The Center for International Blood and Marrow Transplant Research (CIBMTR), the National Marrow Donor Program (NMDP)/Be The Match and the Emmes Company, LLC, a clinical research organization. CIBMTR is a research collaboration between the NMDP/Be The Match and the Medical College of Wisconsin. Together with MCW/ CIBMTR and NMDP, Emmes has been providing research support to the BMT CTN since 2001, as a key member of the data coordinating center.

More information about the BMT CTN can be found at www.bmtctn.net.

About CIBMTR

The CIBMTR® (Center for International Blood and Marrow Transplant Research®) is a research collaboration between the National Marrow Donor Program® (NMDP)/Be The Match® and the Medical College of Wisconsin (MCW). The CIBMTR collaborates with the global scientific community to advance hematopoietic cell transplantation (HCT) and cellular therapy worldwide to increase survival and enrich quality of life for patients. The CIBMTR facilitates critical observational and interventional research through scientific and statistical expertise, a large network of transplant centers, and a unique and extensive clinical outcomes database. For more information on the CIBMTR, please visit www.cibmtr.org or follow the CIBMTR on Facebook, LinkedIn, or Twitter at @CIBMTR.