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Emmes Announces Its Work on a Phase 3 Clinical Trial for Breakthrough Therapy Designation Product

Company's Clinical Research Support Demonstrates Continued Cell Therapy Expertise

Rockville, MD – June 15, 2020 – Emmes today announced that it provided the Phase 3 clinical trial support for a new investigational cell therapy that offers a promising treatment opportunity for patients who need an allogeneic bone marrow transplant. Emmes' work for Gamida Cell Ltd. , an advanced cell therapy company committed to finding cures for blood cancers and serious blood diseases, involved full scope clinical trial support for this study that was conducted at more than 50 centers in the United States, Latin America, Europe and Asia. Emmes also supported the early development Phase 1 and 2 trials that began in 2010.

The therapy in development, omidubicel, is the first bone marrow transplant product to receive Breakthrough Therapy Designation from the U.S. Food and Drug Administration. The intent-to-treat results of this study in 125 patients showed that omidubicel was generally well tolerated and that the median time to neutrophil engraftment was 12 days for patients randomized to omidubicel compared to 22 days for the comparator group of patients who received standard umbilical cord blood ($p<0.001$).

The chief medical officer for Gamida Cell, Dr. Ronit Simantov, stated, "We are very proud of this rigorous, well executed trial and we truly appreciate the support of everyone who partnered with us to help move the field forward. We truly value the work and expertise that Emmes provided, and the agility and commitment of the Emmes staff played a critical role in achieving this clinical development milestone."

Dr. Anne Lindblad, president and chief executive officer at Emmes, added, “Gamida Cell’s positive topline data from the trial is very encouraging, and we are hopeful that it represents a life-saving treatment option for bone marrow transplant candidates. Our employees are proud to work on therapies like this that bring hope to people who are suffering, and I’m proud that we’ve partnered with Gamida on this effort for 10 years.”

The international, multi-center, randomized Phase 3 study was designed to evaluate the safety and efficacy of omidubicel in patients with high-risk hematologic malignancies undergoing a bone marrow transplant. The study included patients aged 12-65 years with acute lymphoblastic leukemia, acute myelogenous leukemia, chronic myelogenous leukemia, myelodysplastic syndrome, or lymphoma.

Omidubicel is an investigational therapy, and its safety and efficacy have not been evaluated by the U.S. Food and Drug Administration or any other health authority.

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.