



CIBMTR to Track Long-Term Outcomes Data for Kymriah®

Milwaukee, Wis., September 14, 2018 – A new collaboration focused on tracking long-term outcomes of patients treated with chimeric antigen receptor T-cell (CAR-T) therapies has been established between the CIBMTR® (Center for International Blood and Marrow Transplant Research), and Novartis. Under the terms of the collaboration, CIBMTR will collect long-term safety and efficacy data from patients (pediatrics and adults) treated with Kymriah® (tisagenlecleucel) who agree to participate in the CIBMTR registry for cellular therapy.

Novartis received the first ever FDA approval for a CAR-T cell therapy in the US with Kymriah. Kymriah is a novel immunocellular therapy and a one-time treatment that uses a patient's own T cells to fight cancer. In the United States, Kymriah is intended for the treatment of relapsed or refractory (r/r) acute lymphoblastic leukemia (ALL) in children and young adults, and for adults with relapsed / refractory large B-cell lymphoma after two or more lines of systemic therapy.

This alliance will collect and examine real-world data about the use of Kymriah. CIBMTR's central database allows medical centers to fulfil multiple data commitments with a single entry and provide physicians the opportunity to retrieve their own center's data. All centers treating patients with Kymriah in the US are encouraged to offer patient participation in this registry and begin reporting patient data into the CIBMTR registry database.

"We are excited to announce this collaboration with Novartis, a pioneer in the field of immunocellular therapy," said Marcelo Pasquini, MD, MS, Senior Scientific Director. "Novartis is the first pharmaceutical company to conduct global CAR-T clinical trials and receive a regulatory approval for a CAR-T product."

"This alliance will leverage CIBMTR's deep experience collecting and analyzing data on both short and long-term outcomes of complex cellular therapies. For decades, we collected research data about hematopoietic cell transplantation (HCT). Previously, HCT was the only successful cellular therapy for cancer. We look forward to expanding into the field of targeted cellular therapies to help people with cancer," Pasquini continued.

CIBMTR has implemented a Cellular Therapy Registry that accurately captures the nature, sequence and effects of modern cellular therapies, including CAR-T cells. CIBMTR is leading a unique effort to standardize registration of cellular therapies such as CAR-T cells in the US and across the globe. CIBMTR provides guidance on the minimal data requirements needed for long-term follow-up of patients receiving CAR-T cells.

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). Together, CIBMTR and Be The Match BioTherapies, a subsidiary of NMDP/Be The Match, offer end-to-end solutions for developers of cell therapies, including cell sourcing and collection, clinical trial services, supply chain logistics, manufacturing and commercialization support, and outcomes management. Through this partnership, CIBMTR and Be The Match BioTherapies are identifying and providing opportunities for standardization in cellular therapy from the collection of starting material, through transportation and logistics management, to reporting and analysis of long-term follow-up data. 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.

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