EBMT
European Society
for Blood and Marrow Transplantation

PRESS RELEASE

EBMT to track long-term outcome data for Kymriah®

Barcelona, Monday February 10, 2020 - The European Society for Blood and Marrow Transplantation (EBMT) announces a new collaboration with Novartis Pharmaceuticals to study the long-term outcomes of patients treated with chimeric antigen receptor T cell (CAR T) therapies. Under the terms of the collaboration, EBMT will collect treatment and long-term safety and efficacy data from patients treated with Kymriah® (tisagenlecleucel) in both approved indications in the EBMT registry for cellular therapy in the European regions.

This important collaboration will provide real-world data on the use of Kymriah. A central database will allow centers to fulfill multiple data commitments with a single entry. All centers treating patients with Kymriah in Europe are encouraged to enter patient data into the current EBMT registry database ProMISe. The centers will be compensated for patient registration and data reporting.

In 2018, Novartis received the European Commission approval of its CAR-T cell therapy, Kymriah® (tisagenlecleucel). The approved indications are for the treatment of pediatric and young adult patients up to 25 years of age with B-cell acute lymphoblastic leukemia (ALL) that is refractory, in relapse post-transplant or in second or later relapse; and for the treatment of adult patients with relapsed or refractory (r/r) diffuse large B-cell lymphoma (DLBCL) after two or more lines of systemic therapy.

EBMT received in February 2019 a qualification opinion from the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) to use its expanded patient registry to support chimeric antigen receptor (CAR) T cell therapy benefit-risk evaluations and post-authorisation follow-up.

EBMT has recently implemented a new Cellular Therapy Form based on the required EMA item list which is currently captured in the EBMT registry database ProMISe and that will be implemented in the EBMT's new registry, allowing a more user-friendly capture of the nature, sequence and effects of modern cellular therapies, including CAR-T cells. The forms that are used to capture data – including the Cellular Therapy Form – are living documents that will be revised on a regular basis to respond to regulatory needs.

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About the EBMT

The European Society for Blood and Marrow Transplantation (EBMT) is a not-for-profit medical and scientific organisation established in 1974. It is dedicated to fighting life-threatening blood cancers and diseases and improving patients' lives.

The EBMT members - more than 4,000 physicians, nurses, scientists and other healthcare professionals - participate in a unique collaborative network of peers involved in haematopoietic stem cell transplantation (HSCT) and cellular therapy research.

The EBMT patient Registry was established in the early 1970s. It is the only data source of its kind in Europe. The data are submitted continuously by more than 600 centres, including from outside Europe. The Registry holds data on more than 600,000 HSCT procedures including details on disease, transplant type, donor type and stem cell source. It contains data on patients that have undergone HSCT and also on patients receiving immunosuppressive therapies or other cell therapies. The Registry also offers the possibility to enter donors' follow-up data, which is crucial to ensure maximum donor safety. The Registry underpins extensive European research that translates into changes in clinical practice and improvements in patient outcome and care.
For further information about the EBMT, please visit the website: https://www.ebmt.org and follow us on Twitter: @TheEBMT

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