

EBMT to track long-term outcome data for Yescarta®, a CAR T therapy for adults living with two types of aggressive non-Hodgkin lymphoma

Barcelona, Tuesday 2nd of June, 2020 - The European Society for Blood and Marrow Transplantation (EBMT) announces a new collaboration with Kite, a Gilead Company, to study the long-term outcomes of patients treated with Yescarta® (axicabtagene ciloleucel), a chimeric antigen receptor T cell (CAR T) therapy. Under the terms of the collaboration, EBMT will collect treatment and long-term safety and efficacy data for 20 years from patients treated with Yescarta® in the EBMT registry for cellular therapy.

Yescarta® was granted European marketing authorisation by the European Medicines Agency's (EMA) in August 2018. The approved indication is for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) and primary mediastinal large B-cell lymphoma (PMBCL) after two or more lines of systemic therapy.

This important collaboration will provide real-world data on the use of Yescarta® in Europe over the next 20 years. A central database will allow centers to fulfill multiple data commitments with a single entry. Since the marketing authorisation in August 2018, all centers treating patients with Yescarta® in Europe have been encouraged to enter patient data into the current EBMT registry database ProMISe. The centers will be compensated for patient registration and data reporting.

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

Full European Summary of Product Characteristics for Yescarta® is available from the EMA website at www.ema.europa.eu.

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 with more than 5,000 physicians, nurses, scientists and other healthcare professionals - participating in a unique collaborative network of peers involved in haematopoietic stem cell transplantation (HSCT) and cellular therapy research.

The EBMT patient Registry is the only data source of its kind in Europe. The data are submitted continuously by more than 500 centres and holds data on more than 700,000 HSCT procedures. It contains data on patients that have undergone HSCT, immunosuppressive therapies or cell or gene therapies. 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: <u>https://www.ebmt.org</u> and follow us on Twitter: @TheEBMT

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