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CIBMTR completes enrollment in Yescarta® long-term post-marketing safety study, 2 years ahead of schedule

-Genetically engineered therapy treats relapsed or refractory large B-cell lymphoma, a blood cancer-

Milwaukee, WI, September 8, 2020 – The CIBMTR® (Center for International Blood and Marrow Transplant Research®) today announced that it has reached a study enrollment goal 2 years early, and 1,500 patients have now enrolled in the post-marketing safety study for Yescarta® (axicabtagene ciloleucel). The study is part of a collaboration with Kite, a Gilead Company.

This collaboration between the CIBMTR and Kite tracks long-term outcomes of patients treated with Yescarta, a chimeric antigen receptor T-cell (CAR T) therapy. This study will generate real-world evidence to assess long-term safety and effectiveness. Enrollment is the first step in the study; next, researchers will follow the participants for at least 15 years. The U.S. Food and Drug Administration (FDA) has required this long-term study for Yescarta.

Yescarta is the first CAR T therapy approved by the FDA for the treatment of adult patients with relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy, including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, primary mediastinal large B-cell lymphoma, high grade B-cell lymphoma, and DLBCL arising from follicular lymphoma. Yescarta is not indicated for the treatment of patients with primary central nervous system lymphoma.

“This prospective study was created to meet a post-marketing requirement for this therapy, and the accrual completion is an important milestone,” said Marcelo Pasquini, MD, MS, co-lead investigator and Senior Scientific Director of the CIBMTR; Cellular Therapy Registry Director; and Professor of Medicine, Division of Hematology / Oncology at the Medical College of Wisconsin. “Together, the CIBMTR and Kite are the first to have reached our target enrollment, and we are pleased to have done so ahead of our initial projections.”

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"Even though we've met our initial goal for this study, we continue to enroll people in the CIBMTR's Cellular Immunotherapy Data Resource (CIDR). The CIBMTR will continue to reimburse medical centers for reporting cell therapy data," said Dr. Pasquini. The CIDR is part of a federal initiative to accelerate cancer research; medical centers and pharmaceutical companies can participate.

Interim and final study results will be shared with the FDA, and eventually, the public. For more information about the CIBMTR's Cellular Immunotherapy Data Resource, visit cibmtr.org/About/WhatWeDo/CIDR.

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About the 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 network of more than 300 transplant centers, and one of the largest databases worldwide for clinical outcomes of cellular therapy, and a biorepository with tissue samples.

For more information on the CIBMTR, please visit www.cibmtr.org or follow the CIBMTR on Facebook, LinkedIn, or Twitter at @CIBMTR.

About the National Marrow Donor Program/Be The Match

The National Marrow Donor Program® (NMDP)/Be The Match® is the global leader in providing a cure to patients with life-threatening blood and marrow cancers like leukemia and lymphoma, as well as other diseases. The NMDP/Be The Match manages the world's largest registry of potential blood stem cell donors and cord blood units, connects patients to their donor match for a life-saving marrow or umbilical cord blood transplant and educates health care professionals and patients. In 2016, the NMDP/Be The Match established Be The Match BioTherapies® to accelerate patient access to life-saving therapies, by providing proven services and support to companies developing and delivering cell and gene therapies.

Learn more at BeTheMatchClinical.org.

About the Medical College of Wisconsin

With a history dating back to 1893, The Medical College of Wisconsin (MCW) is dedicated to leadership and excellence in education, patient care, research and community engagement. More than 1,200 students are enrolled in MCW's medical school and graduate school programs in Milwaukee, Green Bay, and Central Wisconsin in 2016. MCW's School of Pharmacy opened in 2017. A major national research center, MCW is the largest research institution in the Milwaukee metro area and second largest in Wisconsin. In FY2016, faculty received more than

$184 million in external support for research, teaching, training and related purposes. This total includes highly competitive research and training awards from the National Institutes of Health (NIH). Annually, MCW faculty direct or collaborate on more than 3,100 research studies, including clinical trials. Additionally, more than 1,500 physicians provide care in virtually every specialty of medicine for more than 525,000 patients annually.

Yescarta is a trademark of Kite Pharma, Inc.

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