

Contact: Karen Warmkessel, <u>kwarmkessel@umm.edu</u> (410) 328-8919

UNIVERSITY OF MARYLAND GREENEBAUM COMPREHENSIVE CANCER CENTER NOW AMONG SELECT INSTITUTIONS CERTIFIED TO ADMINISTER CAR T-CELL THERAPY FOR LYMPHOMA

UMGCCC Treating Blood Cancer Patients with New Genetically Engineered Immunotherapy

Baltimore, Md. March 19, 2018 – The University of Maryland Marlene and Stewart Greenebaum Comprehensive Cancer Center (UMGCCC) is now certified to offer a groundbreaking treatment for non-Hodgkin lymphoma, in which a patient's own immune cells are genetically engineered to recognize and attack the cancer.

Last October, the U.S. Food and Drug Administration (FDA) approved Yescarta, a chimeric antigen receptor (CAR) T-cell therapy, to treat adults with certain types of large B-cell lymphoma, a cancer of white blood cells. It was the FDA's second approval of a gene therapy to treat cancer since August 2017.

"We are very excited to offer this customized gene therapy to non-Hodgkin lymphoma patients who have not been helped by other treatments, such as chemotherapy or bone marrow transplants," says Aaron P. Rapoport, MD, the Gary Jobson Professor in Medical Oncology at the University of Maryland School of Medicine (UMSOM). "Having the ability to reprogram a patient's immune cells to attack their cancer is a powerful new tool, which will help many patients who have few treatment options."

Fifty-four percent of large B-cell lymphoma patients who participated in a multi-center clinical study showed no evidence of cancer after treatment, even though they had received two or more previous therapies that had failed.

Dr. Rapoport, a hematologist/oncologist who directs the Blood and Marrow Transplant Program at UMGCCC at the University of Maryland Medical Center (UMMC), notes that the treatment can cause serious side effects, including neurological problems and a life-threatening condition known as cytokine release syndrome (CRS), a systemic inflammatory response that causes high fever and flu-like symptoms.

"The FDA has mandated that cancer centers be specially certified to administer this treatment and their staff trained to recognize and manage side effects, particularly CRS and serious nervous system symptoms," Dr. Rapoport says. "Our staff has completed the training, and it has been an extraordinary

team effort to be able to offer this treatment to lymphoma patients who might benefit from CAR T-cell therapy. We recently treated our first patient."

To date, Kite Pharma, Inc., which makes Yescarta (axicabtagene ciloleucel), has certified 34 cancer centers nationwide to offer its new treatment. UMGCCC is the only authorized center in the Baltimore-Washington-Virginia region.

The customized therapy involves removing immune cells, or T cells, from the patient and shipping them to a laboratory, where they are genetically modified to produce receptors on their surface called chimeric antigen receptors, or CARS. The receptors enable the T cells to recognize a protein on the surface of the patient's cancer cells. The modified cells are infused back into the patient, where they increase rapidly, and seek out and destroy lymphoma cells.

The FDA approved Yescarta for use in adults with large B-cell lymphomas who haven't responded to, or have relapsed after, at least two other kinds of treatment. The types of lymphoma are: diffuse large B-cell lymphoma (DLBCL), primary mediastinal large B-cell lymphoma, high grade B-cell lymphoma and DLBCL arising from follicular lymphoma.

DLBCL is the most common aggressive non-Hodgkin lymphoma, accounting for three of every five cases. Approximately 30,000 people in the United States are diagnosed with this type of lymphoma each year. Officials estimate that up to 4,000 patients annually may benefit from this treatment.

"We are happy to be able to offer this personalized therapy to our patients," says Kevin J. Cullen, MD, the Marlene and Stewart Greenebaum Distinguished Professor of Oncology and the cancer center's director. "These treatments are complex and require very sophisticated care. We are delighted that the skill of our patient care team has been recognized in this way. This is an exciting new day in oncology."

"As an academic medical center, with a National Cancer Institute-designated comprehensive cancer center, we are uniquely qualified to provide our patients with the most scientifically advanced treatments available," says Mohan Suntha, MD, MBA, the Marlene and Stewart Greenebaum professor of radiation oncology at UMSOM and president and chief executive officer of UMMC.

"Immunotherapy is changing the face of cancer care, and this groundbreaking gene therapy reflects the type of precision medicine, tailored to the individual, that we want to offer our patients," Dr. Suntha says. "Launching a new and innovative treatment like this is no small lift. We would like to thank the Governor, Maryland legislators and the Maryland Health Services Cost Review Commission for their support in making sure this therapy could be offered to Marylanders."

"CAR T-cell therapy is a rapidly emerging technology that is revolutionizing the field of oncology, particularly the treatment of blood cancers," says UM SOM Dean E. Albert Reece, MD, PhD, MBA, University Executive Vice President for Medical Affairs and the John Z. and Akiko K. Bowers Distinguished Professor. "We are very pleased to be able to add this exciting new therapy to our arsenal of therapies for patients with difficult-to-treat lymphomas."

The Greenebaum Comprehensive Cancer Center has a robust hematologic malignancies research and treatment program, caring for patients with various types of blood cancers, such as leukemia, lymphoma and multiple myeloma. Dr. Rapoport, who co-leads the cancer center's immunology and immunotherapy research program, is nationally recognized for his research on using engineered T-cells to treat blood cancers.

In August 2017, the FDA approved the first gene therapy to treat cancer – Kymriah (tisagenlecleucel) for certain pediatric and young adult patients with a form of acute lymphoblastic leukemia. The therapy is manufactured by Novartis.

About the University of Maryland School of Medicine

Commemorating its 210th Anniversary, the University of Maryland School of Medicine was chartered in 1807 as the first public medical school in the United States. It continues today as one of the fastest growing, top-tier biomedical research enterprises in the world -- with 43 academic departments, centers, institutes, and programs; and a faculty of more than 3,000 physicians, scientists, and allied health professionals, including members of the National Academy of Sciences, and a distinguished recipient of the Albert E. Lasker Award in Medical Research. With an operating budget of more than \$1 billion, the School of Medicine works closely in partnership with the University of Maryland Medical Center and Medical System to provide research-intensive, academic and clinically-based care for more than 1.2 million patients each year. The School has over 2,500 students, residents, and fellows, and nearly \$450 million in extramural funding, with more than half of its academic departments ranked in the top 20 among all public medical schools in the nation in research funding. As one of the seven professional schools that make up the University of Maryland, Baltimore campus, the School of Medicine has a total workforce of nearly 7,000 individuals. The combined School and Medical System ("University of Maryland Medicine") has a total budget of \$5 billion and an economic impact of nearly \$15 billion on the state and local community. The School of Medicine faculty, which ranks as the 8th-highest public medical school in research productivity, is an innovator in translational medicine with 600 active patents and 24 start-up companies. The School works locally, nationally, and globally, with research and treatment facilities in 36 countries around the world. Visit medschool.umaryland.edu/

About the University of Maryland Marlene and Stewart Greenebaum Comprehensive Cancer Center

The University of Maryland Marlene and Stewart Greenebaum Comprehensive Cancer Center is a National Cancer Institute-designated Comprehensive Cancer Center in Baltimore. The center is a joint entity of the University of Maryland Medical Center and University of Maryland School of Medicine. It offers a multidisciplinary approach to treating all types of cancer and has an active cancer research program. It is ranked among the top cancer programs in the nation by *U.S. News & World Report*. www.umgccc.org.