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FDA APPROVES FIRST CAR T-CELL TREATMENT FOR ACUTE LYMPHOBLASTIC LEUKEMIA

Aug. 30, 2017—Following today's historic approval of tisagenlecleucel (Kymriah®, Novartis Pharmaceuticals Corp.), an innovative gene therapy for certain pediatric and young adult patients with some forms of acute lymphoblastic leukemia (ALL), from the Food and Drug Administration, the American Society of Gene & Cell Therapy (ASGCT) offers unwavering support to the advancement of gene and cell therapy and sincere congratulations to all who worked to bring this new therapy to patients.

Kymriah, a cell-based gene therapy, is now approved in the United States for the treatment of patients up to 25 years of age with B-cell precursor ALL that is refractory or in relapse. Kymriah is a genetically-modified chimeric antigen receptor (CAR) T-cell therapy and is the first gene therapy of its kind to gain FDA approval. Kymriah provides realistic, actionable hope to certain patients with ALL. The continued advancement and approval of these gene and cell therapy treatments presents the opportunity to revolutionize medicine and change the way disease is treated.

"We are incredibly excited to see a CAR T-cell treatment come to patients in the United States," Dr. Helen E. Heslop, ASGCT President and Director of the Center for Cell and Gene Therapy at Baylor College of Medicine, Texas Children's Hospital and Houston Methodist Hospital says. "This remarkable approval is the beginning of what we see as a chance to transform the way in which we treat cancer."

The FDA also approved today tocilizumab (Actemra®, Genentech Inc.) for the treatment of patients two years of age or older with cytokine release syndrome (CRS) that often occurs with CAR T-cell therapy.

You can read the FDA's full release regarding the approval of Kymriah here:
https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm574058.htm

The American Society of Gene & Cell Therapy is the primary professional membership organization for gene and cell therapy. The Society's members are scientists, physicians, patient advocates, and other professionals. ASGCT's mission is to advance knowledge, awareness, and education leading to the discovery and clinical application of gene and cell therapies to alleviate human disease. For more information, please visit *www.asgct.org*.

For media members interested in speaking with experts in gene therapy or CAR T-cell therapies, please contact ASGCT's **Alex Wendland** by phone (**414-278-1341**) or by email (**awendland@asgct.org**).

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