

Supplemental Approvals

Generic Name (Trade Name—Company)

May 7, 2018

Tisagenlecleucel

(Kymriah—Novartis)

Agent receives second FDA approval to refractory or relapsed large B-cell lymphoma

Uses/Notes

FDA has approved [tisagenlecleucel suspension](#) for I.V. infusion for its second indication—treatment of adult patients with relapsed or refractory (r/r) large B-cell lymphoma after two or more lines of systemic therapy, including diffuse large B-cell lymphoma (DLBCL), high grade B-cell lymphoma, and DLBCL arising from follicular lymphoma. It is not indicated for treatment of patients with primary central nervous system lymphoma.

The agent was the first chimeric antigen receptor T cell (CAR-T) therapy to receive regulatory approval in August 2017 to treat patients up to 25 years of age with B-cell precursor acute lymphoblastic leukemia (ALL) that is refractory or in second or later relapse.

Tisagenlecleucel is now the only CAR-T cell therapy to receive FDA approval for two distinct indications in non-Hodgkin lymphoma (NHL) and B-cell ALL

Source URL:

<http://blog.pharmacist.com/supplemental-approvals/agent-receives-second-fda-approval-refractory-or-relapsed-large-b-cell>

APhA DrugInfoLine is an official publication of, and is owned and copyrighted by the American Pharmacists Association, the national professional society of pharmacists. Materials in APhA DrugInfoLine do not necessarily represent the policy, recommendations, or endorsement of APhA. The publisher, authors, editors, reviewers, and contributors have taken care to ensure that information contained in APhA DrugInfoLine is accurate and current; however, they shall have no liability to any person or entity with regard to claims, losses, or damages caused or alleged to be caused, directly or indirectly, by use of any information contained in the publication. All decisions about drug therapy must be based on the independent judgment of the clinician. Copyright © 2000–2011, American Pharmacists Association. All rights reserved.