Supplemental Approvals

Generic Name (Trade Nameâ€"Company)

May 7, 2018

Tisagenlecleucel

(Kymriah—Novartis)

Agent receives second FDA approval for treatment of 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 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

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