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Novartis's Kymriah gets EC approval to treat blood cancer

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Drugmaker Novartis announced that the European Commission (EC) has approved Kymriah®(tisagenlecleucel, formerly CTL019).

The approved indications are for the treatment of pediatric and young adult patients up to 25 years of age with B-cell acute lymphoblastic leukemia (ALL) that is refractory, in relapse post-transplant or in second or later relapse; and for the treatment of adult patients with relapsed or refractory (r/r) diffuse large B-cell lymphoma (DLBCL) after two or more lines of systemic therapy.

Kymriah developed in collaboration with the University of Pennsylvania (Penn) is a ground-breaking one-time treatment that uses a patient's own T cells to fight cancer, and the only chimeric antigen receptor T cell (CAR-T) therapy to receive regulatory approval in the EU for these two distinct B-cell malignancies.

Kymriah was also the first CAR-T cell therapy ever approved by the US Food and Drug Administration (FDA).

Novartis will continue to build out facilities to manufacture Kymriah, which costs up to $475,000 for children and young adults with B-cell acute lymphoblastic leukemia and $373,000 for adults with B-cell lymphoma in the United States.