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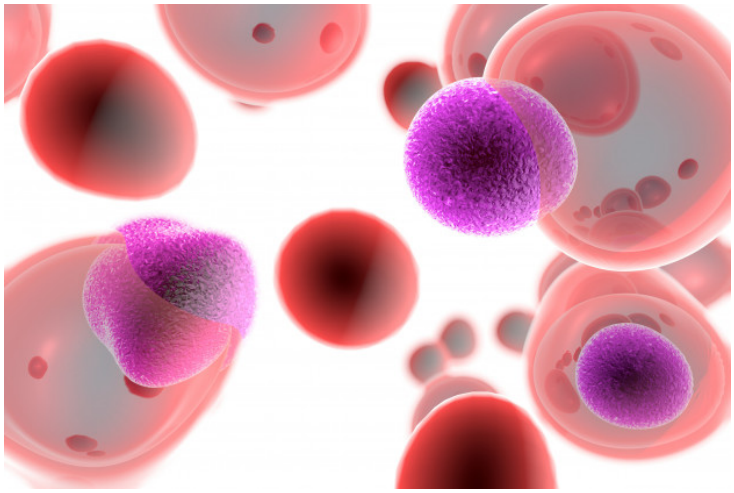
ASIA EDITION

HSA approves first commercial CAR-T therapy by Novartis

10 March 2021 | News

Novartis receives approval for Kymriah® (tisagenlecleucel) in Southeast Asia to treat two life-threatening cancers that have limited treatment options and historically poor outcomes



Novartis has announced that Singapore Health Sciences Authority (HSA) has approved Kymriah (tisagenlecleucel) as the first commercial chimeric antigen receptor T-cell (CAR-T) therapy in Singapore under the new cell, tissue and gene therapy products (CTGTP) regulatory framework. Kymriah, a CD19-directed genetically modified autologous T-cell immunocellular therapy, is approved to treat two life-threatening cancers that have limited treatment options and historically poor outcomes, addressing the critical need for new therapies for these patients.

HSA approved Kymriah for the treatment of pediatric and young adult patients from 2 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.

CAR-T therapy represents a significant step forward in treating these cancers and is the embodiment of personalized medicine. Kymriah is manufactured individually for each patient using their own cells. It is not a pill or chemotherapy, but instead, it is an individualized treatment produced via pioneering technology and a sophisticated manufacturing and supply chain process.

The approval was based on the review of two global registration CAR-T clinical trials, JULIET and ELIANA. In these trials, Kymriah demonstrated strong and durable response rates and a consistent safety profile in two difficult-to-treat patient populations.

Kymriah is an individualised treatment that modifies a patient's own T-cells to fight and kill cancer cells. Bringing this new innovative therapy to Singapore requires collaboration among many health system stakeholders. This includes obtaining regulatory approval, the validation and training of qualified treatment centres for the appropriate indications, and integrating a delivery system that did not previously exist for individualised treatments to ensure safe and seamless delivery of Kymriah to

patients.

Singapore General Hospital (SGH) is the first Kymriah treatment centre to become operational in Southeast Asia to treat adult r/r DLBCL and young adult r/r B-cell ALL patients. Novartis is currently in discussions with the National University Hospital (NUH) to expand the availability of Kymriah for both adult r/r DLBCL and pediatric and young adult r/r B-cell ALL patients.

The approval of Kymriah in Singapore and the presence of these regional centers of excellence will enable the city-state to help an underserved patient population in the Southeast Asia region where treatment unmet needs are present.