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Novartis announces landmark steps for Kymriah® (tisagenlecleucel): reimbursement for adult DLBCL eligible patients and agreement to manufacture in Australia

- *Kymriah®*, an innovative chimeric antigen receptor T cell (CAR-T) treatment, will be publically funded for eligible adult patients with relapsed or refractory diffuse large B cell lymphoma (DLBCL) in Australia
- *Kymriah* is currently the only CAR-T therapy approved by the Therapeutic Goods Administration (TGA) for use in Australia.^[1] It is an immunocellular therapy, a one-time treatment manufactured individually for each patient using their own T cells, genetically reengineered and programmed to recognise and destroy cancer cells
- *Novartis and Cell Therapies* have agreed to manufacture *Kymriah* at the Cell Therapies' production facility within the Peter MacCallum Cancer Centre in Melbourne

Sydney, January 28th, 2020 - Novartis today announces that *Kymriah*® (tisagenlecleucel) will be publicly funded following a recommendation from the Medical Services Advisory Committee (MSAC) for the treatment of eligible adult patients with relapsed or refractory diffuse large B cell lymphoma (DLBCL) in Australia. There are limited treatment options within this patient group whose median life expectancy is approximately six months.^[2, 3]

Today's announcement follows the reimbursement of *Kymriah* in eligible paediatric and young adult patients up to 25 years of age with acute lymphoblastic leukaemia (ALL), which was announced in 2019.

Novartis also announces today an agreement with Cell Therapies to manufacture *Kymriah* at their production facility within the Peter MacCallum Cancer Centre in Melbourne. Cell Therapies is an Australia-based, globally-active commercial contract development and manufacturing company, specialising in cell therapy, gene therapy, regenerative medicine, and cellular immunotherapy products.

"Novartis is delighted about today's announcements and the meaningful difference this therapy can make to eligible patients in Australia," said Didier Dargent, Head of International Markets Cell & Gene, Novartis Oncology. "I am also delighted that Novartis has signed an agreement with Cell Therapies to manufacture *Kymriah* in Australia. Novartis has been a pioneer in individualised medicine, making a bold early commitment to reimagine cancer care in the emerging field of CAR-T therapies," he added.

“CAR-T therapy is not like a traditional drug, it is a highly individualised cellular treatment,” said Associate Professor Dominic Wall, who is Executive Director of Business Ventures at Peter MacCallum Cancer Centre and Chief Scientific Officer at Cell Therapies.

“Unlike traditional therapies, CAR-T uses a patient’s own immune cells to fight some types of blood cancers. To have this innovative cancer therapy approved in Australia, and now manufactured locally for the first time, represents a major step forward for Australian patients and clinicians,” he added.

“The decision to fund Kymriah for eligible patients with relapsed and refractory diffuse large B-cell lymphoma will dramatically change our treatment approach for this disease in Australia. Its availability is a milestone in cancer treatment, and we welcome this announcement,” said Dr Michael Dickinson, Peter MacCallum Cancer Centre.

DLBCL is the most common form of non-Hodgkin lymphoma (NHL), a cancer of the lymphatic system, accounting for up to 40% of all NHL cases.^[4] Roughly one-third of patients with DLBCL relapse after receiving first-line treatment.^[5] Out of those patients diagnosed with DLBCL, about 10% have refractory disease and about 75% of patients who relapse or are refractory to treatment are ineligible for autologous stem cell transplant.^[2,4]

The Cell Therapies manufacturing facility within the Peter MacCallum Cancer Centre will be used to supply patients with Kymriah in Australia and across the world. Novartis is in the process of transferring the innovative manufacturing technology for Kymriah to Cell Therapies, with the goal of manufacturing capabilities being ready in the second half of 2020.

Kymriah® (tisagenlecleucel) Important Safety information

Warning: Cytokine Release Syndrome (CRS), including fatal or life threatening reactions, occurred in patients receiving KYMRIAH. Do not administer KYMRIAH to patients with active infection or inflammatory disorders. Treat severe or life threatening CRS with tocilizumab as per the CRS management algorithm.

SPECIAL WARNINGS AND PRECAUTIONS FOR USE: Cytokine release syndrome; Neurological events; Infections and febrile neutropenia; Prolonged cytopenias; Secondary malignancies; Hypogammaglobulinemia; Live vaccines; Tumour lysis syndrome; Blood, organ, tissue and cell donation; Active central nervous system (CNS) leukaemia or lymphoma; Concomitant disease such as patients with a history of active CNS disorder or inadequate renal, pulmonary or cardiac function; Prior bone marrow transplant; HIV, Hepatitis B, Hepatitis C and viral reactivation; Prior treatment with an anti-CD19 therapy; Effects on laboratory tests; Use in the elderly and paediatric use; Reasons to delay treatment such as Unresolved serious adverse reactions, Active uncontrolled infection; active chronic GVHD, Significant clinical worsening of leukaemia burden or rapid progression of lymphoma with unstable clinical presentation following lymphodepleting chemotherapy; Patient information regarding adverse event symptoms.

Approved Product Information

See approved Product Information before prescribing. Approved Product Information available on request. For the most up to date Product Information go to <https://www.novartis.com.au/products/healthcare-professionals>

About Novartis

Novartis is reimagining medicine to improve and extend people’s lives. As a leading global medicines company, we use innovative science and digital technologies to create transformative treatments in areas of great medical need. In our quest to find new medicines,

we consistently rank among the world's top companies investing in research and development. Novartis products reach more than 750 million people globally and we are finding innovative ways to expand access to our latest treatments. About 109,000 people of more than 140 nationalities work at Novartis around the world. Find out more at www.novartis.com.

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