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TGA approves first Australian commercial CAR-T manufacturing site – bringing faster access to eligible Australians with life-threatening blood cancers

- *Kymriah[®] (tisagenlecleucel), a chimeric antigen receptor T cell (CAR-T) one-time treatment, will be the first commercially approved CAR-T therapy to be manufactured in Australia*
- *Providing manufacturing capabilities in Australia will help reduce transportation time previously from overseas sites, facilitating faster access to Kymriah for patients*
- *Cell Therapies located within the Peter MacCallum Cancer Centre, Melbourne, has become the first approved local CAR-T commercial manufacturing site for Kymriah*
- *Australia is one of seven manufacturing sites worldwide as part of the extensive Novartis CAR-T manufacturing network*

Sydney, February 12th, 2020 — Novartis today announced that its CAR-T therapy, Kymriah[®] (tisagenlecleucel), will now be manufactured right here in Australia. This will bring faster access to treatment for eligible Australians with life-threatening blood cancers.

The Therapeutic Goods Administration (TGA) has now granted approval for Cell Therapies Pty Ltd to commence commercial manufacturing of Kymriah, a chimeric antigen receptor T cell (CAR-T) one-time treatment, in its manufacturing facility in the Peter MacCallum Cancer Centre in Melbourne.

The approval makes Cell Therapies the first and only approved commercial manufacturing site for CAR-T in Australia for both clinical trial and non-clinical trial patients.

Kymriah was the first CAR-T to be approved by the TGA and publicly funded in Australia, for the treatment of eligible adult patients with relapsed or refractory DLBCL (diffuse large B cell lymphoma) and eligible paediatric and young adult patients up to 25 years of age with relapsed or refractory ALL (acute lymphoblastic leukaemia)^[1].

“Novartis is extremely proud to have secured the approval for local manufacturing of Kymriah, which represents a substantial achievement for the clinical and patient community,” said Cheryl Maley, General Manager Oncology, Novartis ANZ. “Australia now becomes one of the select countries in the world to locally manufacture CAR-T, demonstrating the advanced medical manufacturing capabilities we have here.”

“This important milestone is good news for patients, the clinical community and the economy,” said Associate Professor Dominic Wall, Executive Director of Business Ventures at Peter MacCallum Cancer Centre and Interim Chief Executive Officer at Cell Therapies “We anticipate this announcement will provide a significant economic boost through the creation of new highly-skilled jobs, now and into the future.”

The Kymriah manufacturing process is highly complex and requires a number of carefully performed steps. The patient’s cells are first extracted then reprogrammed in the manufacturing facility and returned as a personalised, one-time treatment for infusion back into the patient.

Until now this advanced manufacturing process was conducted either in the Novartis Morris Plains facility in New Jersey, USA, or other approved overseas facilities.

“The manufacturing process for Kymriah requires an extraordinary amount of testing and quality control to ensure the reprogrammed cells created are compliant with the Good Manufacturing Practice (GMP) standards. Our manufacturing set-up has been highly collaborative and successfully executed despite the challenges of COVID-19,” added Associate Professor Wall.

“Local manufacturing means patients’ cells can stay here in Australia without the need to ship them overseas, generating greater efficiencies and an expectation of quicker timelines for eligible patients to access Kymriah,” said Professor Simon Harrison, Director of the Centre of Excellence in Cellular Immunotherapy at the Peter MacCallum Cancer Centre.

Dr Katie Allen MP, Federal member for Higgins, stated “I am delighted that the Federal Government funding of \$80million provided to Cell Therapies in 2019, has had such a profound impact on the scientific and patient community. Seeing this important step today in building local manufacturing capabilities that not only will provide life changing therapies for Australians with cancer but also create numerous highly skilled jobs, reinforces the significance of this important Government investment.”

Novartis has the largest geographical CAR-T manufacturing network in the world, including seven CAR-T manufacturing facilities, across four continents^[2]. This comprehensive, integrated footprint strengthens the flexibility, resilience and sustainability of the Novartis manufacturing and supply chain.

Cell Therapies is an Australian-based, globally-active commercial manufacturing organisation, specialising in cell therapy, gene therapy, regenerative medicine, and cellular immunotherapy products.

To date, over 100 Australians have now been treated with Novartis CAR-T across clinical trials and commercially available therapy in seven treatment sites spanning Victoria, New South Wales, and Queensland and Western Australia.

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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 (CRS); Neurological toxicities; Infections and febrile neutropenia; Prolonged cytopenias; Hypogammaglobulinemia or agammaglobulinemia; Tumour lysis syndrome (TLS); Prior stem cell transplantation; HIV, Hepatitis B, Hepatitis C and viral reactivation; Prior treatment with an anti-CD19 therapy; Blood, organ, tissue and cell donation; Active central nervous system (CNS) leukaemia or lymphoma; Secondary malignancies; Use in Elderly; Paediatric use; Effects on laboratory tests; Effects on ability to drive and use machines; Pregnancy, lactation, females and males of reproductive potential; Monitoring after infusion and Patient information. **Reasons to delay treatment:** Unresolved serious adverse reactions (especially pulmonary and cardiac reactions or hypotension) from preceding chemotherapies; Active uncontrolled infection; Active chronic graft versus host disease (GvHD); significant clinical worsening of leukaemia burden or rapid progression of lymphoma with unstable clinical presentation following lymphodepleting chemotherapy

Approved Consumer Medical Information

See approved Consumer Medical Information. Approved Consumer Information available on request. For the most up to date Consumer Information go to <https://www.novartis.com.au/products/consumer-information/products>

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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References

- [1] Kymriah approved product information: <https://www.novartis.com.au/products/healthcare-professionals>
[2] Novartis Media Release. Novartis expands Kymriah® manufacturing footprint with first-ever approved site for commercial CAR-T cell therapy manufacturing in Asia. Available at: <https://www.novartis.com/news/media-releases/novartis-expands-kymriah-manufacturing-footprint-first-ever-approved-site-commercial-car-t-cell-therapy-manufacturing-asia>. Accessed Jan 2021.

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