

Expanding CAR-T manufacturing in Australia

Cell Therapies Pty Ltd has become the first approved CAR-T commercial manufacturing site in Australia, providing potentially faster access to CAR-T therapies to eligible patients in the region with life-threatening blood cancers.

Novartis global commercial CAR-T manufacturing footprint now spans four continents, bringing these transformative therapies closer to patients and healthcare professionals around the world.

Feb 12, 2021

Basel, February 12, 2021 - Novartis today announced it has received approval from the Therapeutic Goods Administration (TGA) for Cell Therapies to manufacture and supply its CAR-T therapies commercially for eligible patients in Australia. The Cell Therapies manufacturing facility in the Peter MacCallum Cancer Center in Melbourne is the first and only approved commercial manufacturing site for CAR-T cell therapies in Australia.

As a pioneer in individualized medicine, Novartis is committed to reimagining cancer care in the emerging field of CAR-T therapies. We are determined to bring these transformative therapies to the maximum number of patients with difficult-to-treat cancers and limited treatment options. We are proud to have the largest geographical CAR-T manufacturing network in the world, which makes our therapies accessible to healthcare practitioners and patients across the globe. Cell Therapies, a world-leading manufacturing facility, adds their experience to our leadership in pioneering research, development and supply of cell and gene therapies. International collaborations such as these are critical in accelerating advancements in areas of great medical need.

Steffen Lang, Global Head of Novartis Technical Operations

The CAR-T manufacturing network of Novartis comprises of seven facilities across four continents. This includes commercial and clinical trial manufacturing now ongoing at Novartis-owned facilities in Stein, Switzerland, Les Ulis, France and Morris Plains, New Jersey, USA, as well as at the contract manufacturing sites at Fraunhofer-Institut for Cell Therapy and Immunology (Fraunhofer-Institut für Zelltherapie und Immunologie) facility in Leipzig, Germany, FBRI in Kobe, Japan, and now Cell Therapies in Australia. Manufacturing at Cellular Biomedicine Group in China is forthcoming. This comprehensive, integrated footprint strengthens the flexibility, resilience and sustainability of the Novartis manufacturing and supply chain.

To date, more than 100 patients in Australia have now been treated with Novartis CAR-T treatment across clinical trials and commercially available therapy. Local manufacturing means patients' cells can stay in Australia without the need to ship them overseas, generating greater efficiencies and an expectation of quicker timelines for eligible patients.

About Novartis Commitment to Oncology Cell & Gene

Novartis has a mission to reimagine medicine by bringing curative cell & gene therapies to patients worldwide, and was the first pharmaceutical company to significantly invest in pioneering CAR-T research and initiate global CAR-T trials. Novartis has a deep CAR-T pipeline and ongoing investment in manufacturing and supply chain process improvements. With active research underway to broaden the impact of cell and gene therapy in

oncology, Novartis is going deeper in hematological malignancies, reaching patients with other cancer types and evaluating next-generation CAR-T cell therapies that focus on new targets and utilize new technologies.

Learn more about CAR-T Cell Therapy and beyond

Novartis is pioneering the way in the class of cell and gene treatment. This includes setting the standard in patient and caregiver support, safety and efficacy, access, and partnerships with healthcare institutions, local health authorities, and academic institutions around the world.

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