Public Summary

Summary for ARTG Entry:	410143	Cellular Therapies - T cells-Ciltacabtagene autoleucel, cryopreserved-T-CARVYKTI - Janssen-Cilag Pty Ltd - Injection, intravenous infusion - Bag

ARTG entry for	Biological Included Class 4
Sponsor	Janssen-Cilag Pty Ltd
Postal Address	Locked Bag 2070, NORTH RYDE, NSW, 1670 Australia
ARTG Start Date	6/06/2023
Product Category	Included Class 4
Status	Active
Approval Area	Biologicals

Products

1 . T cells-Ciltacabtagene autoleucel, cryopreserved-T-CARVYKTI

Product Type	Cellular Therapies	**Effective Date**	15/04/2024
Therapeutic Indication	CARVYKTI is indicated for the treatment of adult patients with relapsed or refractory multiple myeloma, who have received at least three prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent and an anti-CD38 antibody.		

Specific Conditions

The actual date of commencement of supply of the biological after inclusion under Part 3-2A of the Act must be notified to the Director, Biological Sciences Section of the TGA. Please note the definition of 'supply' in subsection 3(1) of the Act for this purpose

The Carvykti EU-Risk Management Plan (RMP) (version 1.6, dated 26 May 2022, data lock point 15 April 2021), with Australian Specific Annex (version 0.3, dated 1 September 2022), included with submission BIO-2021-BA-00119-1, and any subsequent revisions, as agreed with the TGA will be implemented in Australia.

An obligatory component of risk management plans is routine pharmacovigilance. Routine pharmacovigilance includes the submission of periodic safety update reports (PSURs). Unless agreed separately between the supplier who is the recipient of the approval and the TGA, the first report must be submitted to TGA no later than 15 calendar months after the date of this approval letter. The subsequent reports must be submitted no less frequently than annually from the date of the first submitted report until the period covered by such reports is not less than three years from the date of this approval letter. The annual submission may be made up of two PSURs each covering six months. If the sponsor wishes, the six monthly reports may be submitted separately as they become available. If the product is approved in the EU during the three years period, reports can be provided in line with the published list of EU reference dates no less frequently than annually from the date of the first submitted report until the period covered by such reports is not less than three years from the date of this approval letter. The reports are to at least meet the requirements for PSURs as described in the European Medicines Agency's Guideline on good pharmacovigilance practices (GVP) Module VII-periodic safety update report (Rev 1), Part VII.B Structures and processes. Note that submission of a PSUR does not constitute an application to vary the registration. Each report must have been prepared within ninety calendar days of the data lock point for that report.

Data should be collected from Australian patients, either through a registry or by other agreed mechanism, and provided to TGA annually. This may be timed to align with reporting requirements for the EU. Data to be collected should capture timing of crucial decision points, such as the date of Carvykti product request, diagnosis for which Carvykti is prescribed, age of patient at treatment (infusion), duration from decision (product request) to treat with Carvykti to apheresis for starting product and duration from first apheresis procedure to infusion of Carvykti. Additional information to be collected and reported to TGA where possible should include dose of Carvykti received, best overall response, duration of remission (if relevant), duration of survival, and adverse events (including, but not exclusively, expected adverse events of cytokine release syndrome, neurological toxicities, prolonged cytopaenias beyond 28 days after infusion and any serious unexpected severe adverse events).

Data should be collected for all patients for whom treatment with Carvykti is planned and apheresis carried out, even if a CAR T-cell product is not ultimately infused, including the reason for patients not being treated with Carvykti once apheresed. A report detailing these instances will be provided to TGA annually.

Components

1 . Component Description

Dosage Form	Injection, intravenous infusion
Route of Administration	Intravenous Infusion
Visual Identification	

Active Ingredients

ciltacabtagene autoleucel	**500000 cells/kg**

Other Ingredients (Excipients)

dimethyl sulfoxide

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