Provisional Consent to the Distribution of a New Medicine

Pursuant to section 23(1) of the Medicines Act 1981, the Minister of Health hereby provisionally consents to the sale, supply or use in New Zealand of the new medicine set out in the Schedule hereto:

Schedule

Product:	**Evusheld**
Component 1:	
Active Ingredient:	Tixagevimab 100mg/mL
Dosage Form:	Solution for injection
Component 2:	
Active Ingredient:	Cilgavimab 100mg/mL
Dosage Form:	Solution for injection
New Zealand Sponsor:	AstraZeneca Limited
Manufacturer:	Samsung Biologics Co Limited, Incheon, South Korea

Provisional consent is granted for a period of two years.

This consent is given subject to the following conditions.

The New Zealand Sponsor must fulfil the following obligations within the timelines specified, which may be altered by mutual agreement with Medsafe:

1. Provide biochemical hold time stability data for cilgavimab and tixagevimab drug substance intermediates. Due date: 30 September 2022.
2. Provide the results of the chromatography resin lifetime studies for both drug substances. Due date: 30 September 2022.
3. Provide the results of the virus filtration and 0.2µm filtration reprocessing studies for both drug substances. Due date: 30 September 2022.
4. Provide the results of a recalculation of the tolerance intervals used to assess process variability for the stability limits approach and non-stability limits approach for the drug substance potency assay once 30 batches of each drug substance are available. Due date: 30 September 2022.
5. Provide the results of a recalculation of the drug substance specification acceptance criteria once 30 batches of each drug substance are available. Due date: 30 September 2022.
6. Provide the results of a recalculation of the criteria for cIEF once 12 months of drug substance stability data are available from the process validation lots of both drug substances. Due date: 30 September 2022.
7. Revise the drug substance host cell protein acceptance limits on the basis of batch results for both drug substances. Due date: 30 September 2022.
8. Provide the updated analysis for the multivariate drug product formulation characterisation studies for both finished products. Due date: 30 September 2022.
9. Incorporate drug substance method robustness data into the appropriate validation sections of the dossier. Due date: 30 September 2022.
10. List the references for the in-house method documents in dossier sections 3.2.S.4.1 and 3.2.P.5.1. Due date: 30 September 2022.
11. Provide the simulated drug substance container leachables study data for both drug substances. Due date for results generated at 12 months under the 2–8°C and 23–27°C conditions: 30 September 2022. Due date for 24 months data: 30 September 2023.
12. Include information about the area of the sterilising filter in dossier section 3.2.P.3.3 for both finished products, in accordance with EMA/CHMP/CVMP/QWP/850374/2015. Due date: 30 September 2022.
13. Provide the final results of the elemental impurities risk assessment of both drug substances. Due date: 30 June 2024.
14. Provide the final study reports for the PROVENT, STORM CHASER, and TACKLE clinical studies within five working days of the reports being produced. PROVENT and STORM CHASER due date: 31 December 2022. TACKLE due date: 30 April 2023.

15. Provide the results of outstanding anti-drug antibody (ADA) assessments for subjects from the PROVENT clinical trial for Days 1, 29, 58, and 183 within five working days of any reports being produced. Due date: 30 September 2022.
16. Provide the interim analysis results through Day 28 for the first 50 subjects to receive a second dose from the PROVENT repeat-dose sub-study within five working days of any results being produced. Due date: 30 September 2022.
17. Provide baseline and all subsequent study visit data for the d dimer, P selectin, thrombin, and Factor VIII biomarkers from the PROVENT repeat-dose sub-study within five working days of any reports being produced.
18. Provide top line data, to include safety, pharmacokinetic, ADA, and biomarker results for thrombotic events from the first nine months of the PROVENT repeat-dose sub-study should within five working days of any reports being produced. 31 March 2023.
19. Provide monthly aggregate reports for serious adverse events in the cardiac disorder System Organ Class (SOC) and other non-cardiac thrombotic serious adverse events.
20. Collect systematic data from spontaneous reporting of cardiac events and report the results regularly to Medsafe.
21. Provide additional safety and efficacy data supporting an increased dose of EVUSHELD (600mg) for the prophylaxis indication in SARS-CoV-2 variants and sub-variants against which it is shown to have reduced in-vitro potency within five working days of any reports being produced.

Dated this 29th day of July 2022.

CHRIS JAMES, Group Manager, Medsafe, Ministry of Health (pursuant to delegation given by the Minister of Health on 11 September 2013).

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