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 which was referred to the Minister of Health under the provisions of section 24(5) of the Act and set out in the Schedule hereto:

Schedule

Product:	**Jemperli**
Active Ingredient:	Dostarlimab 50mg/mL
Dosage Form:	Solution for infusion
New Zealand Sponsor:	GlaxoSmithKline NZ Limited
Manufacturer:	Ajinomoto Althea Inc, California, United States of America

Provisional consent is granted until 6 July 2025.

This consent is given subject to the following conditions:

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

1. Provide confirmatory efficacy and safety data from the Ruby study 4010-03-001. Due date: 31 December 2023.
2. Submit PBRERs as they become available.

Dated this 20th day of May 2024.

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

2024-go2387 23-05-2024 10:00