Title: Safety and effectiveness of Molnupiravir (LAGEVRIO®) capsules in Japanese patients with COVID-19: Interim Report of Post-marketing Surveillance in Japan

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Table S1. Severity level defined by the Clinical Management of Patients with COVID-19[13]

Severity	Oxygen saturation level	Clinical state
Mild	$SpO_2 \geq 96\%$	Absence of respiratory symptoms Only coughing; no dyspnea
Moderate I (Patient does not experience respiratory failure)	$93\% < SpO_2 < 96\%$	Dyspnea and confirmation of pneumonia
Moderate II (Patient experiences respiratory failure)	$SpO_2 \leq 93\%$	Oxygen therapy necessary
Severe	—	ICU admission or mechanical ventilator treatment necessary

Table S2. List of ADRs

ADR	Patients reported the event		Number of events
	n	(%)	
Total	68	(6.60)	78
Infections and infestations	2	(0.19)	2
Pneumonia	1	(0.10)	1
COVID-19	1	(0.10)	1
Blood and lymphatic system disorders	1	(0.10)	1
Anaemia	1	(0.10)	1
Metabolism and nutrition disorders	3	(0.29)	3
Hypokalaemia	1	(0.10)	1
Decreased appetite	2	(0.19)	2
Nervous system disorders	12	(1.16)	12
Dizziness	5	(0.48)	5
Dizziness postural	1	(0.10)	1
Headache	3	(0.29)	3
Hypoaesthesia	1	(0.10)	1
Somnolence	1	(0.10)	1
Taste disorder	1	(0.10)	1
Respiratory, thoracic and mediastinal disorders	1	(0.10)	1
Interstitial lung disease	1	(0.10)	1
Gastrointestinal disorders	33	(3.20)	36
Abdominal pain upper	1	(0.10)	1
Diarrhoea	26	(2.52)	26
Nausea	2	(0.19)	2
Vomiting	3	(0.29)	3
Faeces soft	4	(0.39)	4
Hepatobiliary disorders	1	(0.10)	1
Hepatic function abnormal	1	(0.10)	1
Skin and subcutaneous tissue disorders	12	(1.16)	13
Dermatitis allergic	1	(0.10)	1
Drug eruption	2	(0.19)	2
Eczema	1	(0.10)	1
Rash	6	(0.58)	6
Skin exfoliation	1	(0.10)	1
Urticaria	2	(0.19)	2
General disorders and administration site conditions	1	(0.10)	1
Hypothermia	1	(0.10)	1
Investigations	6	(0.58)	8
Blood uric acid increased	1	(0.10)	1
Full blood count abnormal	1	(0.10)	1
Platelet count decreased	1	(0.10)	1
White blood cell count decreased	2	(0.19)	2
White blood cell count increased	1	(0.10)	1
Hepatic enzyme increased	2	(0.19)	2

MedDRA/J version(25.0)

ADR: adverse drug reaction

Table S3. Use of oxygen administration and mechanical ventilation in the effectiveness analysis set (n=884)

Variables	n	(%)
Oxygen administration		
No	849	(96.04)
Yes	35	(3.96)
Started after the start of molnupiravir administration	12	(1.36)
Volume of oxygen administration[a] (L/min), med (min, max)	2	(1, 15)
Oxygen administration started after the start of molnupiravir administration[b]		
Nasal cannula	9	(1.02)
Oxygen mask	4	(0.45)
Nasal high flow	0	(0.00)
Mask with reservoir	1	(0.11)
Other	0	(0.00)
Mechanical ventilation started after the start of molnupiravir administration		
No	883	(99.89)
Yes	1	(0.11)
Started after the start of molnupiravir administration	0	(0.00)

[a] Based on 10 patients with the data available

[b] Including duplicate count