

Supplementary Material

Title :

Real-world safety and effectiveness of cabotegravir in people living with HIV: Interim report of a post-marketing surveillance in Japan

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Supplementary Table S1. Incidence of ADRs by preferred term in participants in the safety analysis set

No. of participants in the safety analysis set	121
No. of participants with ADRs	45
Incidence rate of ADRs	37.19%
Preferred term	Participants with ADR n (%)
Injection site pain	15 (12.40%)
Musculoskeletal pain	15 (12.40%)
Dyslipidemia	3 (2.48%)
Injection site induration	3 (2.48%)
Oral herpes	3 (2.48%)
Pyrexia	3 (2.48%)
White blood cell count decreased	3 (2.48%)
Acne	2 (1.65%)
Injection site reaction	2 (1.65%)
Abdominal pain upper	1 (0.83%)
Androgenetic alopecia	1 (0.83%)
Asthma	1 (0.83%)
Back pain	1 (0.83%)
Bronchitis	1 (0.83%)
COVID-19	1 (0.83%)
Diarrhea	1 (0.83%)
Gastritis	1 (0.83%)
Gastroesophageal reflux disease	1 (0.83%)
Hemorrhage subcutaneous	1 (0.83%)
Hepatitis B DNA increased	1 (0.83%)
Hepatitis B reactivation	1 (0.83%)
Hyperventilation	1 (0.83%)
Malaise	1 (0.83%)

Monkeypox	1 (0.83%)
Myalgia	1 (0.83%)
Mycoplasma urethritis	1 (0.83%)
Nausea	1 (0.83%)
Pharyngitis	1 (0.83%)
Seasonal allergy	1 (0.83%)
Seborrheic dermatitis	1 (0.83%)
Somnolence	1 (0.83%)
Syphilis	1 (0.83%)
Treatment noncompliance	1 (0.83%)
Type 2 diabetes mellitus	1 (0.83%)
Urticaria	1 (0.83%)
Vomiting	1 (0.83%)

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ADR, adverse drug reactions; HIV human immunodeficiency virus

Supplementary Table S2. Incidence of ADRs by age group in the safety analysis set

Preferred term	All participants (n=121)		<10 years (n=0)		10≤<20 years (n=1)		20≤<30 years (n=12)		30≤<40 years (n=44)		40≤<50 years (n=34)		50≤<60 years (n=21)		60≤<70 years (n=7)		70≤ years (n=2)	
	No. of events	No. of participants (%)	No. of events	No. of participants (%)	No. of events	No. of participants (%)	No. of events	No. of participants (%)	No. of events	No. of participants (%)	No. of events	No. of participants (%)	No. of events	No. of participants (%)	No. of events	No. of participants (%)	No. of events	No. of participants (%)
All ADRs	76	45 (37.19)	—	— (—)	0	0 (0.00)	7	4 (33.33)	39	24 (54.55)	25	12 (35.29)	5	5 (23.81)	0	0 (0.00)	0	0 (0.00)
Injection site pain	15	15 (12.40%)	—	— (—)	0	0 (0.00)	1	1 (8.33)	6	6 (13.64)	6	6 (17.65)	2	2 (9.52)	0	0 (0.00)	0	0 (0.00)
Musculoskeletal pain	15	15 (12.40%)	—	— (—)	0	0 (0.00)	0	0 (0.00)	11	11 (25.00)	3	3 (8.82)	1	1 (4.76)	0	0 (0.00)	0	0 (0.00)
Dyslipidemia	3	3 (2.48%)	—	— (—)	0	0 (0.00)	0	0 (0.00)	1	1 (2.27)	1	1 (2.94)	1	1 (4.76)	0	0 (0.00)	0	0 (0.00)
Injection site induration	3	3 (2.48%)	—	— (—)	0	0 (0.00)	0	0 (0.00)	1	1 (2.27)	2	2 (5.88)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)
Oral herpes	3	3 (2.48%)	—	— (—)	0	0 (0.00)	1	1 (8.33)	0	0 (0.00)	2	2 (5.88)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)
Pyrexia	3	3 (2.48%)	—	— (—)	0	0 (0.00)	0	0 (0.00)	2	2 (4.55)	1	1 (2.94)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)
White blood cell count decreased	3	3 (2.48%)	—	— (—)	0	0 (0.00)	0	0 (0.00)	2	2 (4.55)	1	1 (2.94)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)
Acne	2	2 (1.65%)	—	— (—)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	2	2 (5.88)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)
Injection site reaction	2	2 (1.65%)	—	— (—)	0	0 (0.00)	0	0 (0.00)	2	2 (4.55)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)
Abdominal pain upper	1	1 (0.83%)	—	— (—)	0	0 (0.00)	1	1 (8.33)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)
Androgenetic alopecia	1	1 (0.83%)	—	— (—)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	1	1 (2.94)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)
Asthma	1	1 (0.83%)	—	— (—)	0	0 (0.00)	0	0 (0.00)	1	1 (2.27)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)
Back pain	1	1 (0.83%)	—	— (—)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	1	1 (2.94)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)
Bronchitis	1	1 (0.83%)	—	— (—)	0	0 (0.00)	0	0 (0.00)	1	1 (2.27)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)
COVID-19	1	1 (0.83%)	—	— (—)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	1	1 (2.94)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)
Diarrhea	1	1 (0.83%)	—	— (—)	0	0 (0.00)	1	1 (8.33)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)
Gastritis	1	1 (0.83%)	—	— (—)	0	0 (0.00)	1	1 (8.33)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)

Gastroesophageal reflux disease	1	1 (0.83%)	—	— (—)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	1	1 (2.94)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)
Hemorrhage subcutaneous	1	1 (0.83%)	—	— (—)	0	0 (0.00)	0	0 (0.00)	1	1 (2.27)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)
Hepatitis B DNA increased	1	1 (0.83%)	—	— (—)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	1	1 (2.94)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)
Hepatitis B reactivation	1	1 (0.83%)	—	— (—)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	1	1 (4.76)	0	0 (0.00)	0	0 (0.00)
Hyperventilation	1	1 (0.83%)	—	— (—)	0	0 (0.00)	0	0 (0.00)	1	1 (2.27)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)
Malaise	1	1 (0.83%)	—	— (—)	0	0 (0.00)	0	0 (0.00)	1	1 (2.27)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)
Monkeypox	1	1 (0.83%)	—	— (—)	0	0 (0.00)	0	0 (0.00)	1	1 (2.27)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)
Myalgia	1	1 (0.83%)	—	— (—)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	1	1 (2.94)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)
Mycoplasma urethritis	1	1 (0.83%)	—	— (—)	0	0 (0.00)	0	0 (0.00)	1	1 (2.27)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)
Nausea	1	1 (0.83%)	—	— (—)	0	0 (0.00)	0	0 (0.00)	1	1 (2.27)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)
Pharyngitis	1	1 (0.83%)	—	— (—)	0	0 (0.00)	1	1 (8.33)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)
Seasonal allergy	1	1 (0.83%)	—	— (—)	0	0 (0.00)	0	0 (0.00)	1	1 (2.27)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)
Seborrheic dermatitis	1	1 (0.83%)	—	— (—)	0	0 (0.00)	0	0 (0.00)	1	1 (2.27)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)
Somnolence	1	1 (0.83%)	—	— (—)	0	0 (0.00)	0	0 (0.00)	1	1 (2.27)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)
Syphilis	1	1 (0.83%)	—	— (—)	0	0 (0.00)	0	0 (0.00)	1	1 (2.27)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)
Treatment noncompliance	1	1 (0.83%)	—	— (—)	0	0 (0.00)	1	1 (8.33)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)
Type 2 diabetes mellitus	1	1 (0.83%)	—	— (—)	0	0 (0.00)	0	0 (0.00)	1	1 (2.27)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)
Urticaria	1	1 (0.83%)	—	— (—)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	1	1 (2.94)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)
Vomiting	1	1 (0.83%)	—	— (—)	0	0 (0.00)	0	0 (0.00)	1	1 (2.27)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)

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ADR, adverse drug reactions

Supplementary Table S3. Incidence of ADRs by presence or absence of allergy in the safety analysis set

Preferred term	Without allergy (n=103)		With allergy (n=18)	
	No. of events	No. of participants (%)	No. of events	No. of participants (%)
All ADRs	72	43 (41.75)	4	2 (11.11)
Injection site pain	15	15 (14.56)	0	0 (0.00)
Musculoskeletal pain	15	15 (14.56)	0	0 (0.00)
Dyslipidemia	3	3 (2.91)	0	0 (0.00)
Injection site induration	3	3 (2.91)	0	0 (0.00)
Oral herpes	3	3 (2.91)	0	0 (0.00)
Pyrexia	3	3 (2.91)	0	0 (0.00)
White blood cell count decreased	3	3 (2.91)	0	0 (0.00)
Acne	2	2 (1.94)	0	0 (0.00)
Injection site reaction	2	2 (1.94)	0	0 (0.00)
Androgenetic alopecia	1	1 (0.97)	0	0 (0.00)
Asthma	1	1 (0.97)	0	0 (0.00)
Back pain	1	1 (0.97)	0	0 (0.00)
Bronchitis	1	1 (0.97)	0	0 (0.00)
COVID-19	1	1 (0.97)	0	0 (0.00)
Diarrhea	1	1 (0.97)	0	0 (0.00)
Gastroesophageal reflux disease	1	1 (0.97)	0	0 (0.00)
Hemorrhage subcutaneous	1	1 (0.97)	0	0 (0.00)
Hepatitis B DNA increased	1	1 (0.97)	0	0 (0.00)
Hyperventilation	1	1 (0.97)	0	0 (0.00)
Malaise	1	1 (0.97)	0	0 (0.00)
Monkeypox	1	1 (0.97)	0	0 (0.00)
Myalgia	1	1 (0.97)	0	0 (0.00)
Mycoplasma urethritis	1	1 (0.97)	0	0 (0.00)
Nausea	1	1 (0.97)	0	0 (0.00)
Seasonal allergy	1	1 (0.97)	0	0 (0.00)
Seborrheic dermatitis	1	1 (0.97)	0	0 (0.00)
Somnolence	1	1 (0.97)	0	0 (0.00)
Syphilis	1	1 (0.97)	0	0 (0.00)
Treatment noncompliance	1	1 (0.97)	0	0 (0.00)
Type 2 diabetes mellitus	1	1 (0.97)	0	0 (0.00)
Urticaria	1	1 (0.97)	0	0 (0.00)
Vomiting	1	1 (0.97)	0	0 (0.00)
Abdominal pain upper	0	0 (0.00)	1	1 (5.56)
Gastritis	0	0 (0.00)	1	1 (5.56)
Hepatitis B reactivation	0	0 (0.00)	1	1 (5.56)
Pharyngitis	0	0 (0.00)	1	1 (5.56)

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ADR, adverse drug reactions; HIV human immunodeficiency virus