

Supplementary Material

Title

Safety and Effectiveness of Dolutegravir/Rilpivirine in Japanese People Living with HIV: Final Report of 6-Year Post-marketing Surveillance Study

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Supplementary Table S1 Treatment status

Item	Survey forms collected (n = 44)	Safety analysis set (n = 43)	Effectiveness analysis set (n = 41)
Duration of treatment, days			
≤180	2 (4.55)	1 (2.33)	0 (0.00)
>180, ≤365	2 (4.55)	2 (4.65)	2 (4.88)
>365, ≤730	7 (15.91)	7 (16.28)	7 (17.07)
>730	33 (75.00)	33 (76.74)	32 (78.05)
Concomitant medication			
Yes	33 (75.00)	32 (74.42)	30 (73.17)
No	11 (25.00)	11 (25.58)	11 (26.83)
Type of concomitant medication ^a			
ART	9 (27.27)	8 (25.00)	8 (26.67)
Other antiviral therapy	4 (12.12)	4 (12.50)	3 (10.00)
Other	30 (90.91)	30 (93.75)	28 (93.33)
Type of concomitant ART ^b			
NRTI	6 (13.64)	5 (11.63)	5 (12.20)

NNRTI	1 (2.27)	1 (2.33)	1 (2.44)
PI	4 (9.09)	4 (9.30)	4 (9.76)
INSTI	0 (0.00)	0 (0.00)	0 (0.00)
CCR5 antagonist	1 (2.27)	1 (2.33)	1 (2.44)
Outpatient or inpatient			
Outpatient	41 (93.18)	40 (93.02)	38 (92.68)
Inpatient	0 (0.00)	0 (0.00)	0 (0.00)
Outpatient and inpatient	3 (6.82)	3 (6.98)	3 (7.32)

Values shown as n (%)

^aMultiple answers were allowed. The proportions shown are those among participants who had concomitant medication.

^bMultiple answers were allowed. NRTI (n = 4), PI (n = 2), NNRTI + PI (n = 1), and NRTI + PI + CCR5 antagonist (n = 1)

ART, antiretroviral therapy; CCR5, C-C chemokine receptor type 5; INSTI, integrase strand transfer inhibitor; NNRTI, non-nucleoside reverse transcriptase inhibitor; NRTI, nucleoside/nucleotide reverse transcriptase inhibitor; PI, protease inhibitor

Supplementary Table S2 Incidence of ADRs by participant characteristics (safety analysis set, n = 43)

Item	Participants with ADRs, n/N (%)	<i>p</i> value
Sex		1.000 ^a
Male	3/39 (7.69)	
Female	0/4 (0.00)	
Race		1.000 ^a
Japanese	3/42 (7.14)	
Non-Japanese	0/1 (0.00)	
Age, years		0.084 ^a
<15	0/0	
≥15, <65	1/35 (2.86)	
≥65	2/8 (25.00)	
CDC Classification System		0.864 ^b
A	1/27 (3.70)	
B	0/1 (0.00)	
C	1/14 (7.14)	
Unknown	1/1 (100.00)	

Comorbidity		0.538 ^a
Yes	3/27 (11.11)	
No	0/13 (0.00)	
Unknown	0/3 (0.00)	
Hepatic disorder		0.002 ^a
Yes	3/6 (50.00)	
No	0/34 (0.00)	
Unknown	0/3 (0.00)	
Renal disorder		0.029 ^a
Yes	3/14 (21.43)	
No	0/29 (0.00)	
Duration of treatment ^c , days		0.003 ^b
≤180	1/1 (100.00)	
>180, ≤365	0/2 (0.00)	
>365, ≤730	0/7 (0.00)	
>730	2/33 (6.06)	
Concomitant medication		0.558 ^a
Yes	3/32 (9.38)	

No	0/11 (0.00)	
Type of concomitant medication ^d		-
ART	0/8 (0.00)	
Other antiviral therapy	1/4 (25.00)	
Other	3/30 (10.00)	
Outpatient or inpatient		0.199 ^a
Outpatient	2/40 (5.00)	
Inpatient	0/0	
Outpatient and inpatient	1/3 (33.33)	

^aFisher's exact test

^b χ^2 test

^cOverall treatment duration, not duration before ADRs

^dMultiple answers were allowed

ADR, adverse drug reaction; ART, antiretroviral therapy; CDC, Centers for Disease

Control and Prevention; N, number of participants in each category