Table 251.11. Summary of adverse events[a] leading to withdrawal or permanent discontinuation of investigational product in at least two subjects in any treatment group—phase III trials with antiretroviral therapy-naive adults.

	SPRING-2[b]		SINGLE[c]		FLAMINGO[d]	
System Organ Class	Dolutegravir (*N* = 411) *n* (%)	RAL (*N* = 411) *n* (%)	Dolutegravir (*N* = 414) *n* (%)	EFV–TDF–FTC (*N* = 419) *n* (%)	Dolutegravir (*N* = 242) *n* (%)	DRV–RTV (*N* = 242) *n* (%)
Any event leading to withdrawal or permanent discontinuation	**10 (2)**	**10 (2)**	**16 (4)**	**58 (14)**	**7 (3)**	**15 (6)**
Abnormal dreams	0	0	1 (< 1)	6 (1)	0	0
Alopecia	0	0	0	2 (< 1)	0	0
ALT increased	2 (< 1)	1 (< 1)	0	0	0	2 (< 1)
Anxiety	0	0	0	4 (< 1)	0	0
AST increased	1 (< 1)	1 (< 1)	0	0	0	2 (< 1)
Decreased appetite	0	0	0	2 (< 1)	0	0
Depression	0	0	1 (< 1)	5 (1)	0	0
Diarrhea	0	0	0	0	0	2 (< 1)
Dizziness	1 (< 1)	0	0	8 (2)	0	0
Drug eruption	0	1 (< 1)	0	3 (< 1)	0	0
Fatigue	0	0	0	7 (2)	0	0
Headache	1 (< 1)	0	0	5 (1)	0	1 (< 1)
Hepatitis C	2 (< 1)	1 (< 1)	2 (< 1)	1 (< 1)	0	1 (< 1)
Hypersensitivity	0	1 (< 1)	1 (< 1)	3 (< 1)	0	0
Insomnia	0	0	1 (< 1)	4 (< 1)	0	0
Irritability	0	0	0	2 (< 1)		0
Nausea	1 (< 1)	1 (< 1)	0	4 (< 1)	0	2 (< 1)
Nightmare	0	0	1 (< 1)	2 (< 1)	0	0
Rash	1 (< 1)	0	2 (< 1)	1 (< 1)	0	1 (< 1)
Sleep disorder	0	0	0	3 (< 1)	0	0
Somnolence	0	0	0	3 (< 1)	0	0
Vertigo	0	0	0	3 (< 1)	0	0

[a]Listed adverse events are not necessarily related to study drug.
[b]Treatment arms: dolutegravir = dolutegravir 50 mg once daily plus two NRTIs; RAL = RAL 400 mg twice daily plus two NRTIs.
[c]Treatment arms: dolutegravir = dolutegravir 50 mg once daily plus ABC–3TC; EFV–TDF–FTC once daily.
[d]Treatment arms: dolutegravir = dolutegravir 50 mg once daily plus two NRTIs; DRV–RTV = DRV 800 mg plus RTV 100 mg once daily plus two NRTIs.
Abbreviations: *N*: number of subjects; *n*: number of events; RAL: raltegravir; EFV: efavirenz; TDF: tenofovir; FTC: emtricitabine; DRV: darunavir; RTV: ritonavir; ALT: alanine aminotransferase; AST: aspartate aminotransferase; NRTI: nucleoside reverse transcriptase inhibitor; ABC: abacavir; 3TC: lamivudine.
Source: ViiV (data on file).

Table 251.12. Summary of adverse events[a] leading to withdrawal or permanent discontinuation of investigational product in at least two subjects in any treatment group—phase III trials with antiretroviral therapy-naive adults.

	INSTI naive		INSTI resistant			
	SAILING[b]		VIKING-3[c]	VIKING-4[d]		
System Organ Class	Dolutegravir (*N* = 357) *n* (%)	RAL (*N* = 362) *n* (%)	Dolutegravir (*N* = 183) *n* (%)	Dolutegravir (*N* = 14) *n* (%)	Dolutegravir (*N* = 16) *n* (%)	Study total (*N* = 30) *n* (%)
Any event leading to withdrawal or permanent discontinuation	**7 (2)**	**13 (4)**	**8 (4)**	**2 (14)**	**0**	**2 (7)**
ALT increased	0	0	2 (1)	0	0	0
Renal failure acute	2 (< 1)	1 (< 1)	0	0	0	0

[a]Listed adverse events are not necessarily related to study drug.
[b]Treatment arms: dolutegravir = dolutegravir 50 mg once daily plus background regimen; RAL = RAL 400 mg twice daily plus background regimen.
[c]Treatment arm: dolutegravir = dolutegravir 50 mg twice daily plus background regimen.
[d]Treatment arms: dolutegravir = dolutegravir 50 mg twice daily for 7 days, then dolutegravir 50 mg twice daily plus background regimen; PCB–dolutegravir = placebo for 7 days, then dolutegravir 50 mg twice daily plus background regimen. There were no adverse events leading to withdrawal or permanent discontinuation in ≥ 2 subjects reported from VIKING-4.
Abbreviations: *N*: number of subjects; *n*: number of events; RAL: raltegravir; ALT: alanine aminotransferase; PCB: placebo.
Source: ViiV (data on file).