Table 2.6.2.6.2
Maraviroc Summary of Clinical Safety
Laboratory Data RFTs - Incidences of Increase in Creatinine Relative to ULN (Abnormal Baseline) - Multiple Dose - Phase 2

n=Number of Subjects	Maximum Creatinine (MG/DL) on Treatment					
	<= ULN	> ULN to <= 1.5 ULN	> 1.5 ULN to <= 3 ULN	> 3 ULN to <= 6 ULN	> 6 ULN	Total
	n	n	n	n	n	n
Treatment Group						
Placebo	0	0	0	0	0	0
<100mg unit dose	0	0	0	0	0	0
100mg QD	1	0	0	0	0	1
100mg BID	0	0	0	0	0	0
150mg BID	0	0	0	0	0	0
300mg QD	0	0	0	0	0	0
300mg BID	0	0	0	0	0	0

Includes Protocols: A4001007 and A4001015.
Date of Table Generation: 15AUG2006 (11:31)

Table 3.1.1
Maraviroc Summary of Clinical Safety
Subject Evaluation Groups by Gender
Phase 2b/3 Studies All Maraviroc Therapy

Gender: MALE

	maraviroc	
Number (%) of Subjects		
Screened 3121		
Assigned to Study Treatment 1073		
Treated	1052	
Completed	0	
Discontinued	510	(48.5)
Discontinued from blinded therapy	441	(41.9)
Discontinued from open label	100	(9.5)
Ongoing at date of cut-off	542	(51.5)
Analyzed for Safety:		
Adverse events	1052	(100.0)
Laboratory data	1037	(98.6)
ECG	690	(65.6)
Vital Signs	838	(79.7)

1027 and 1028 data is based on an 11SEP2006 (Week 24) cut-off. 1029 data is based on a cut-off of 08Dec2005.
Subjects are evaluable for Laboratory data if they have at least one on-treatment assessment for the applicable data type.
For protocol 1026 only the QD arm is included. For 1027 and 1028 both blinded and open label treatment are included.

Table 3.1.1
Maraviroc Summary of Clinical Safety
Subject Evaluation Groups by Gender
Phase 2b/3 Studies All Maraviroc Therapy

Gender: FEMALE

	maraviroc	
Number (%) of Subjects		
Screened	532	
Assigned to Study Treatment	166	
Treated	160	
Completed	0	
Discontinued	89	(55.6)
Discontinued from blinded therapy	84	(52.5)
Discontinued from open label	9	(5.6)
Ongoing at date of cut-off	71	(44.4)
Analyzed for Safety:		
Adverse events	160	(100.0)
Laboratory data	158	(98.8)
ECG	85	(53.1)
Vital Signs	110	(68.8)

1027 and 1028 data is based on an 11SEP2006 (Week 24) cut-off. 1029 data is based on a cut-off of 08Dec2005.
Subjects are evaluable for Laboratory data if they have at least one on-treatment assessment for the applicable data type.
For protocol 1026 only the QD arm is included. For 1027 and 1028 both blinded and open label treatment are included.

Table 3.1.2
Maraviroc Summary of Clinical Safety
Subject Evaluation Groups by Gender
Phase 3 Treatment Experienced CCR5 Tropic Studies

Gender: MALE

	maraviroc QD	maraviroc BID	Placebo
Number (%) of Subjects			
Screened 2785			
Assigned to Study Treatment 951			
Treated	363	382	185
Completed	0	0	0
Discontinued	126 (34.7)	125 (32.7)	118 (63.8)
Ongoing at date of cut-off	237 (65.3)	257 (67.3)	67 (36.2)
Analyzed for Efficacy:			
Full Analysis Set - As Randomized	363 (100.0)	382 (100.0)	185 (100.0)
Full Analysis Set - As Treated	363 (100.0)	382 (100.0)	185 (100.0)
Per Protocol - As Randomized	289 (79.6)	308 (80.6)	151 (81.6)
Per Protocol - As Treated	289 (79.6)	308 (80.6)	151 (81.6)
Analyzed for Safety:			
Adverse events	363 (100.0)	382 (100.0)	185 (100.0)
Laboratory data	357 (98.3)	377 (98.7)	184 (99.5)
ECG	292 (80.4)	321 (84.0)	138 (74.6)
Vital Signs	355 (97.8)	375 (98.2)	184 (99.5)

Table based on data as at 11SEP2006 (Week 24) cut-off date.
Subjects are evaluable for Laboratory data, ECG and Vital Signs if they have at least one on-treatment assessment for the applicable data type.

Table 3.1.2
Maraviroc Summary of Clinical Safety
Subject Evaluation Groups by Gender
Phase 3 Treatment Experienced CCR5 Tropic Studies

Gender: FEMALE

	maraviroc QD	maraviroc BID	Placebo
Number (%) of Subjects			
Screened 459			
Assigned to Study Treatment 125			
Treated	51	44	24
Completed	0	0	0
Discontinued	17 (33.3)	13 (29.5)	15 (62.5)
Ongoing at date of cut-off	34 (66.7)	31 (70.5)	9 (37.5)
Analyzed for Efficacy:			
Full Analysis Set - As Randomized	51 (100.0)	44 (100.0)	24 (100.0)
Full Analysis Set - As Treated	51 (100.0)	44 (100.0)	24 (100.0)
Per Protocol - As Randomized	38 (74.5)	37 (84.1)	15 (62.5)
Per Protocol - As Treated	38 (74.5)	37 (84.1)	15 (62.5)
Analyzed for Safety:			
Adverse events	51 (100.0)	44 (100.0)	24 (100.0)
Laboratory data	51 (100.0)	44 (100.0)	23 (95.8)
ECG	40 (78.4)	35 (79.5)	18 (75.0)
Vital Signs	51 (100.0)	43 (97.7)	23 (95.8)

Table based on data as at 11SEP2006 (Week 24) cut-off date.
Subjects are evaluable for Laboratory data, ECG and Vital Signs if they have at least one on-treatment assessment for the applicable data type.

Table 3.1.3.1
Maraviroc Summary of Clinical Safety
Discontinuation from Study
Phase 2b/3 Treatment Experienced Studies

Number (%) of Subjects	maraviroc QD 477		maraviroc BID 487		Placebo 271	
Discontinuations						
Subject Died	5	(1.0)	6	(1.2)	3	(1.1)
Related to Study Drug	128	(26.8)	126	(25.9)	137	(50.6)
Adverse event	12	(2.5)	11	(2.3)	7	(2.6)
Lack of efficacy	116	(24.3)	115	(23.6)	130	(48.0)
Not Related to Study Drug	48	(10.1)	38	(7.8)	31	(11.4)
Adverse event	4	(0.8)	7	(1.4)	5	(1.8)
Other	13	(2.7)	5	(1.0)	10	(3.7)
Subject defaulted	31	(6.5)	26	(5.3)	16	(5.9)
Total	181	(37.9)	170	(34.9)	171	(63.1)

The 'Subject defaulted' row comprises subjects with discontinuation reasons 'Refusal to participate further' and 'Lost to follow-up'.

Table 3.1.3.2
Maraviroc Summary of Clinical Safety
Discontinuations from Study due to Adverse Events
Phase 2b/3 Treatment Experienced Studies

Treatment Group: maraviroc QD

System Organ Class	MedDRA (v9.0) Preferred Term/ INVESTIGATOR ENTRY	Trt Phase	Treatment At Onset	Adverse Event ------- Start Day++/ Stop Day++	SEVERITY/ Outcome	ACTION/ Causality	SAE
A4001027 1[redacted]0001 (F/ [redacted](YEARS)/ [redacted]							
GASTROINTESTINAL DISORDERS	Abdominal distension*/ ABDOMINAL BLOATING	Active	maraviroc QD	1/ 111	Grade 2/ Resolved (01AUG2[redacted])	STUDY DRUG ACTION: (PERMANENTLY DISCONTINUED) SUBJECT ACTION: (D/C STUDY)/ Study drug	NO
A4001027 1[redacted]0008 (M/ [redacted](YEARS)/ [redacted]							
HEPATOBILIARY DISORDERS	Hepatic failure*/ HEPATIC FAILURE	Active	maraviroc QD	35/ 42	Grade 4/ Resolved (13JAN2[redacted])	STUDY DRUG ACTION: (PERMANENTLY DISCONTINUED) SUBJECT ACTION: (D/C STUDY)/ Other event-possibly r/t to recreational drug use interaction with arv's	YES

Age is at screening.
++ Day relative to first day of each treatment period. First day of each treatment period = day 1
* Treatment-emergent
[] Values in brackets are imputed from incomplete dates and times.
SAE = Serious Adverse Event (according to Investigators assessment).
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Table 3.1.3.2
Maraviroc Summary of Clinical Safety
Discontinuations from Study due to Adverse Events
Phase 2b/3 Treatment Experienced Studies

Treatment Group: maraviroc QD

System Organ Class	MedDRA (v9.0) Preferred Term/ INVESTIGATOR ENTRY	Trt Phase	Treatment At Onset	Adverse Event ------- Start Day++/ Stop Day++	SEVERITY/ Outcome	ACTION/ Causality	SAE
A4001027 1[redacted]0014 (M/ [redacted](YEARS)/ [redacted]							
INVESTIGATIONS	Alanine aminotransferase increased*/ ELEVATED ALT	Active	maraviroc QD	58/ 66	Grade 3/ Resolved (05JUN2[redacted]	STUDY DRUG ACTION: (PERMANENTLY DISCONTINUED) SUBJECT ACTION: (D/C STUDY)/ Concomitant treatment-obt: possibly tipranavir.	NO
A4001027 1[redacted]0008 (M/ [redacted](YEARS)/ [redacted]							
INVESTIGATIONS	Aspartate aminotransferase increased*/ ELEVATED AST	Active	maraviroc QD	28/ [>28]	Grade 3/ Still Present	STUDY DRUG ACTION: (PERMANENTLY DISCONTINUED) SUBJECT ACTION: (D/C STUDY)/ Study drug	NO

Age is at screening.
++ Day relative to first day of each treatment period. First day of each treatment period = day 1
* Treatment-emergent
[] Values in brackets are imputed from incomplete dates and times.
SAE = Serious Adverse Event (according to Investigators assessment).
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Maraviroc Summary of Clinical Safety
Discontinuations from Study due to Adverse Events
Phase 2b/3 Treatment Experienced Studies

Treatment Group: maraviroc QD

System Organ Class	MedDRA (v9.0) Preferred Term/ INVESTIGATOR ENTRY	Trt Phase	Treatment At Onset	Adverse Event ------- Start Day++/ Stop Day++	SEVERITY/ Outcome	ACTION/ Causality	SAE
A4001027 1C[redacted]0001 (M/ 7[redacted](YEARS)/ [redacted])							
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	Intervertebral disc degeneration*/ DEGENERATIVE DISC DISEASE	Active	maraviroc QD	291/ [>291]	Grade 3/ Still Present	STUDY DRUG ACTION: (PERMANENTLY DISCONTINUED) SUBJECT ACTION: (D/C STUDY)/ Other event-degenerative disease	YES
	Spinal disorder*/ CERVICAL SPINE DISEASE	Active	maraviroc QD	291/ [>291]	Grade 3/ Still Present	STUDY DRUG ACTION: (PERMANENTLY DISCONTINUED) SUBJECT ACTION: (D/C STUDY)/ Other event-degenerative disease	YES
A4001027 1C[redacted]0003 (M/ 5[redacted](YEARS)/ [redacted])							

Age is at screening.
++ Day relative to first day of each treatment period. First day of each treatment period = day 1
* Treatment-emergent
[] Values in brackets are imputed from incomplete dates and times.
SAE = Serious Adverse Event (according to Investigators assessment).
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Table 3.1.3.2
Maraviroc Summary of Clinical Safety
Discontinuations from Study due to Adverse Events
Phase 2b/3 Treatment Experienced Studies

Treatment Group: maraviroc QD

System Organ Class	MedDRA (v9.0) Preferred Term/ INVESTIGATOR ENTRY	Trt Phase	Treatment At Onset	Adverse Event ------- Start Day++/ Stop Day++	SEVERITY/ Outcome	ACTION/ Causality	SAE
RENAL AND URINARY DISORDERS	Renal failure*/ RENAL FAILURE	Active	maraviroc QD	12/ [>12]	Grade 3/ Still Present	STUDY DRUG ACTION: (PERMANENTLY DISCONTINUED) SUBJECT ACTION: (D/C STUDY)/ Study drug	YES
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	Rash*/ RASH	Active	maraviroc QD	10/ 17	Grade 3/ Resolved (20APR2[redacted]	STUDY DRUG ACTION: (PERMANENTLY DISCONTINUED) SUBJECT ACTION: (D/C STUDY)/ Study drug	YES
A4001027 1[redacted]0002 (M/ [redacted](YEARS)/ [redacted]							
GASTROINTESTINAL DISORDERS	Abdominal pain upper*/ EPIGASTRIC PAIN	Active	maraviroc QD	51/ 53	Grade 3/ Resolved (21AUG2[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Concomitant treatment-emtricitabine/tenofovir disoproxil fumarate# and epivir	YES

Age is at screening.
++ Day relative to first day of each treatment period. First day of each treatment period = day 1
* Treatment-emergent
[] Values in brackets are imputed from incomplete dates and times.
SAE = Serious Adverse Event (according to Investigators assessment).
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.
#: 新薬承認情報提供時に置換えた。

Table 3.1.3.2
Maraviroc Summary of Clinical Safety
Discontinuations from Study due to Adverse Events
Phase 2b/3 Treatment Experienced Studies

Treatment Group: maraviroc QD

System Organ Class	MedDRA (v9.0) Preferred Term/ INVESTIGATOR ENTRY	Trt Phase	Treatment At Onset	Adverse Event ------- Start Day++/ Stop Day++	SEVERITY/ Outcome	ACTION/ Causality	SAE
GASTROINTESTINAL DISORDERS	Abdominal pain upper*/ EPIGASTRIC PAIN	Active	maraviroc QD	187/ 194	Grade 3/ Resolved (20JAN2[redacted])	STUDY DRUG ACTION: (PERMANENTLY DISCONTINUED) SUBJECT ACTION: (D/C STUDY)/ Study drug	YES
A4001027 1[redacted]0006 (M/ [redacted](YEARS)/ [redacted])							
BLOOD AND LYMPHATIC SYSTEM DISORDERS	Anaemia*/ WORSENING ANEMIA	Active	maraviroc QD	16/ 47	Grade 2/ Resolved (24AUG2[redacted])	STUDY DRUG ACTION: (PERMANENTLY DISCONTINUED) SUBJECT ACTION: (D/C STUDY)/ Study drug	YES
A4001027 1[redacted]0018 (M/ [redacted](YEARS)/ [redacted])							

Age is at screening.
++ Day relative to first day of each treatment period. First day of each treatment period = day 1
* Treatment-emergent
[] Values in brackets are imputed from incomplete dates and times.
SAE = Serious Adverse Event (according to Investigators assessment).
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Table 3.1.3.2
Maraviroc Summary of Clinical Safety
Discontinuations from Study due to Adverse Events
Phase 2b/3 Treatment Experienced Studies

Treatment Group: maraviroc QD

System Organ Class	MedDRA (v9.0) Preferred Term/ INVESTIGATOR ENTRY	Trt Phase	Treatment At Onset	Adverse Event ------- Start Day++/ Stop Day++	SEVERITY/ Outcome	ACTION/ Causality	SAE
INVESTIGATIONS	Lipase increased*/ LIPASE INCREASED	Active	maraviroc QD	15/ 61	Grade 3/ Resolved (22AUG2[redacted])	STUDY DRUG ACTION: (PERMANENTLY DISCONTINUED) SUBJECT ACTION: (D/C STUDY)/ Disease under study	NO
	Lipase increased*/ LIPASE INCREASED	Active	maraviroc QD	62/ 64	Grade 4/ Resolved (11OCT2[redacted])	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Disease under study	NO
A4001028 1[redacted]0007 (F/ [redacted](YEARS)/ [redacted])							
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	Muscular weakness*/ WEAKNESS IN BOTH LEGS	Active	maraviroc QD	79/ [>79]	Grade 3/ Still Present	STUDY DRUG ACTION: (PERMANENTLY DISCONTINUED) SUBJECT ACTION: (D/C STUDY)/ Study drug	NO
A4001028 1[redacted]0035 (M/ [redacted](YEARS)/ [redacted])							

Age is at screening.
++ Day relative to first day of each treatment period. First day of each treatment period = day 1
* Treatment-emergent
[] Values in brackets are imputed from incomplete dates and times.
SAE = Serious Adverse Event (according to Investigators assessment).
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Table 3.1.3.2
Maraviroc Summary of Clinical Safety
Discontinuations from Study due to Adverse Events
Phase 2b/3 Treatment Experienced Studies

Treatment Group: maraviroc QD

System Organ Class	MedDRA (v9.0) Preferred Term/ INVESTIGATOR ENTRY	Trt Phase	Treatment At Onset	Adverse Event ------- Start Day++/ Stop Day++	SEVERITY/ Outcome	ACTION/ Causality	SAE
INVESTIGATIONS	Alanine aminotransferase increased*/ INCREASE OF ALT	Active	maraviroc QD	139/ [>139]	Grade 2/ Still Present	STUDY DRUG ACTION: (PERMANENTLY DISCONTINUED) SUBJECT ACTION: (D/C STUDY)/ Study drug	NO
	Aspartate aminotransferase increased*/ INCREASE OF AST	Active	maraviroc QD	139/ [>139]	Grade 2/ Still Present	STUDY DRUG ACTION: (PERMANENTLY DISCONTINUED) SUBJECT ACTION: (D/C STUDY)/ Study drug	NO
A4001028 11[redacted]0001 (M/ 4[redacted](YEARS)/ [redacted]							
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	Oedema peripheral*/ SWOLLEN HANDS	Active	maraviroc QD	113/ [>113]	Grade 1/ Still Present	STUDY DRUG ACTION: (PERMANENTLY DISCONTINUED) SUBJECT ACTION: (D/C STUDY)/ Study drug	NO

Age is at screening.
++ Day relative to first day of each treatment period. First day of each treatment period = day 1
* Treatment-emergent
[] Values in brackets are imputed from incomplete dates and times.
SAE = Serious Adverse Event (according to Investigators assessment).
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Table 3.1.3.2
Maraviroc Summary of Clinical Safety
Discontinuations from Study due to Adverse Events
Phase 2b/3 Treatment Experienced Studies

Treatment Group: maraviroc QD

System Organ Class	MedDRA (v9.0) Preferred Term/ INVESTIGATOR ENTRY	Trt Phase	Treatment At Onset	Adverse Event ------- Start Day++/ Stop Day++	SEVERITY/ Outcome	ACTION/ Causality	SAE
A4001028 11[redacted]50001 (M/ 5[redacted](YEARS)/ [redacted]							
BLOOD AND LYMPHATIC SYSTEM DISORDERS	Anaemia*/ ANEMIA	Active	maraviroc QD	31/ [>31]	Grade 1/ Still Present	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Concomitant treatment-voriconazol	NO
	Anaemia*/ WORSENING OF ANEMIA	Active	maraviroc QD	56/ 70	Grade 3/ Resolved (27DEC2[redacted]	STUDY DRUG ACTION: (PERMANENTLY DISCONTINUED) SUBJECT ACTION: (D/C STUDY)/ Study drug	YES
A4001028 11[redacted]70011 (M/ 4[redacted](YEARS)/ [redacted]							

Age is at screening.
++ Day relative to first day of each treatment period. First day of each treatment period = day 1
* Treatment-emergent
[] Values in brackets are imputed from incomplete dates and times.
SAE = Serious Adverse Event (according to Investigators assessment).
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Table 3.1.3.2
Maraviroc Summary of Clinical Safety
Discontinuations from Study due to Adverse Events
Phase 2b/3 Treatment Experienced Studies

Treatment Group: maraviroc QD

System Organ Class	MedDRA (v9.0) Preferred Term/ INVESTIGATOR ENTRY	Trt Phase	Treatment At Onset	Adverse Event Start Day++/ Stop Day++	SEVERITY/ Outcome	ACTION/ Causality	SAE
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	Myalgia*/ MUSCLE ACHES	Active	maraviroc QD	37/ 63	Grade 3/ Resolved (11APR2[redacted])	STUDY DRUG ACTION: (PERMANENTLY DISCONTINUED) SUBJECT ACTION: (D/C STUDY)/ Study drug	NO
A4001028 11[redacted]0001 (M/ 4[redacted](YEARS)/ [redacted])							
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	Myalgia*/ MYALGIA	Active	maraviroc QD	77/ 89	Grade 1/ Resolved (28MAY2[redacted])	STUDY DRUG ACTION: (PERMANENTLY DISCONTINUED) SUBJECT ACTION: (D/C STUDY)/ Study drug	NO
A4001028 11[redacted]0003 (M/ 4[redacted](YEARS)/ [redacted])							

Age is at screening.
++ Day relative to first day of each treatment period. First day of each treatment period = day 1
* Treatment-emergent
[] Values in brackets are imputed from incomplete dates and times.
SAE = Serious Adverse Event (according to Investigators assessment).
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Table 3.1.3.2
Maraviroc Summary of Clinical Safety
Discontinuations from Study due to Adverse Events
Phase 2b/3 Treatment Experienced Studies

Treatment Group: maraviroc QD

System Organ Class	MedDRA (v9.0) Preferred Term/ INVESTIGATOR ENTRY	Trt Phase	Treatment At Onset	Adverse Event ------- Start Day++/ Stop Day++	SEVERITY/ Outcome	ACTION/ Causality	SAE
GASTROINTESTINAL DISORDERS	Diarrhoea*/ DIARRHEA	Active	maraviroc QD	6/ 23	Grade 2/ Resolved (18APR2[redacted])	STUDY DRUG ACTION: (PERMANENTLY DISCONTINUED) SUBJECT ACTION: (D/C STUDY)/ Study drug	NO

Age is at screening.
++ Day relative to first day of each treatment period. First day of each treatment period = day 1
* Treatment-emergent
[] Values in brackets are imputed from incomplete dates and times.
SAE = Serious Adverse Event (according to Investigators assessment).
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Table 3.1.3.2
Maraviroc Summary of Clinical Safety
Discontinuations from Study due to Adverse Events
Phase 2b/3 Treatment Experienced Studies

Treatment Group: maraviroc BID

System Organ Class	MedDRA (v9.0) Preferred Term/ INVESTIGATOR ENTRY	Trt Phase	Treatment At Onset	Adverse Event ------- Start Day++/ Stop Day++	SEVERITY/ Outcome	ACTION/ Causality	SAE
A4001027 10[redacted]40016 (M/ 6[redacted](YEARS)/ [redacted])							
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	Heat exhaustion*/ HEAT EXHAUSTION	Active	maraviroc BID	184/ 193	Grade 3/ Resolved (03AUG2C[redacted])	STUDY DRUG ACTION: (PERMANENTLY DISCONTINUED) SUBJECT ACTION: (D/C STUDY)/ Other event-heat, dehydration	YES
INVESTIGATIONS	Transaminases increased*/ ELEVATED TRANSAMINASES	Active	maraviroc BID	187/ 193	Grade 4/ Resolved (03AUG2C[redacted])	STUDY DRUG ACTION: (PERMANENTLY DISCONTINUED) SUBJECT ACTION: (D/C STUDY)/ Study drug	YES
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	Rhabdomyolysis*/ RHABDOMYOLYSIS	Active	maraviroc BID	184/ 193	Grade 3/ Resolved (03AUG2C[redacted])	STUDY DRUG ACTION: (PERMANENTLY DISCONTINUED) SUBJECT ACTION: (D/C STUDY)/ Other event-heat, dehydration	YES

Age is at screening.
++ Day relative to first day of each treatment period. First day of each treatment period = day 1
* Treatment-emergent
[] Values in brackets are imputed from incomplete dates and times.
SAE = Serious Adverse Event (according to Investigators assessment).
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Table 3.1.3.2
Maraviroc Summary of Clinical Safety
Discontinuations from Study due to Adverse Events
Phase 2b/3 Treatment Experienced Studies

Treatment Group: maraviroc BID

System Organ Class	MedDRA (v9.0) Preferred Term/ INVESTIGATOR ENTRY	Trt Phase	Treatment At Onset	Adverse Event ------- Start Day++/ Stop Day++	SEVERITY/ Outcome	ACTION/ Causality	SAE
A4001027 1C[redacted]0005 (M/ 4[redacted](YEARS)/ [redacted]							
INVESTIGATIONS	Aspartate aminotransferase increased*/ ELEVATED AST	Active	maraviroc BID	15/ 29	Grade 4/ Resolved (10MAR2C[redacted])	STUDY DRUG ACTION: (PERMANENTLY DISCONTINUED) SUBJECT ACTION: (D/C STUDY)/ Concomitant treatment-anaesthesia	NO
A4001027 1C[redacted]0021 (M/ 3[redacted](YEARS)/ [redacted]							
GASTROINTESTINAL DISORDERS	Abdominal pain upper*/ RUQ PAIN	Active	maraviroc BID	32/ 34	Grade 2/ Resolved (17JAN2C[redacted])	STUDY DRUG ACTION: (PERMANENTLY DISCONTINUED) SUBJECT ACTION: (D/C STUDY)/ Study drug	NO

Age is at screening.
++ Day relative to first day of each treatment period. First day of each treatment period = day 1
* Treatment-emergent
[] Values in brackets are imputed from incomplete dates and times.
SAE = Serious Adverse Event (according to Investigators assessment).
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Table 3.1.3.2
Maraviroc Summary of Clinical Safety
Discontinuations from Study due to Adverse Events
Phase 2b/3 Treatment Experienced Studies

Treatment Group: maraviroc BID

System Organ Class	MedDRA (v9.0) Preferred Term/ INVESTIGATOR ENTRY	Trt Phase	Treatment At Onset	Adverse Event ------- Start Day++/ Stop Day++	SEVERITY/ Outcome	ACTION/ Causality	SAE
INVESTIGATIONS	Liver function test abnormal*/ ELEVATED LFT'S	Active	maraviroc BID	32/ [>32]	Grade 4/ Still Present	STUDY DRUG ACTION: (PERMANENTLY DISCONTINUED) SUBJECT ACTION: (D/C STUDY)/ Study drug	NO
A4001027 1[redacted]0010 (M/ 4[redacted](YEARS)/ [redacted]							
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	Anal cancer*/ CARCINOMA OF ANUS	Active	maraviroc BID	161/ [>161]	Grade 2/ Still Present	STUDY DRUG ACTION: (PERMANENTLY DISCONTINUED) SUBJECT ACTION: (D/C STUDY)/ Other event-cancer	YES
A4001027 1[redacted]0009 (M/ 5[redacted](YEARS)/ [redacted]							

Age is at screening.
++ Day relative to first day of each treatment period. First day of each treatment period = day 1
* Treatment-emergent
[] Values in brackets are imputed from incomplete dates and times.
SAE = Serious Adverse Event (according to Investigators assessment).
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Table 3.1.3.2
Maraviroc Summary of Clinical Safety
Discontinuations from Study due to Adverse Events
Phase 2b/3 Treatment Experienced Studies

Treatment Group: maraviroc BID

System Organ Class	MedDRA (v9.0) Preferred Term/ INVESTIGATOR ENTRY	Trt Phase	Treatment At Onset	Adverse Event ------- Start Day++/ Stop Day++	SEVERITY/ Outcome	ACTION/ Causality	SAE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	Pyrexia*/ FEVER	Active	maraviroc BID	11/ 23	Grade 2/ Resolved (04JUL2[redacted])	STUDY DRUG ACTION: (PERMANENTLY DISCONTINUED) SUBJECT ACTION: (D/C STUDY)/ Study drug	YES
A4001027 1[redacted]0003 (M/ 4[redacted](YEARS)/ [redacted])							
NERVOUS SYSTEM DISORDERS	Convulsion*/ LOSS OF CONSCIOUSNESS, POSSIBLE SEIZURE	Active	maraviroc BID	93/ 94	Grade 4/ Resolved (21SEP2[redacted])	STUDY DRUG ACTION: (PERMANENTLY DISCONTINUED) SUBJECT ACTION: (D/C STUDY)/ Study drug	YES
A4001027 1[redacted]0002 (M/ 4[redacted](YEARS)/ [redacted])							

Age is at screening.
++ Day relative to first day of each treatment period. First day of each treatment period = day 1
* Treatment-emergent
[] Values in brackets are imputed from incomplete dates and times.
SAE = Serious Adverse Event (according to Investigators assessment).
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Treatment Group: maraviroc BID

System Organ Class	MedDRA (v9.0) Preferred Term/ INVESTIGATOR ENTRY	Trt Phase	Treatment At Onset	Adverse Event ------- Start Day++/ Stop Day++	SEVERITY/ Outcome	ACTION/ Causality	SAE
GASTROINTESTINAL DISORDERS	Abdominal pain upper*/ EPIGASTRIC PAIN	Active	maraviroc BID	9/ [>9]	Grade 4/ Still Present	STUDY DRUG ACTION: (PERMANENTLY DISCONTINUED) SUBJECT ACTION: (D/C STUDY)/ Other event-unknown	YES
	Diarrhoea*/ DIARRHEA	Active	maraviroc BID	9/ 16	Grade 2/ Resolved (06FEB2[redacted]	STUDY DRUG ACTION: (PERMANENTLY DISCONTINUED) SUBJECT ACTION: (D/C STUDY)/ Other event-unknown etiology	YES
	Odynophagia*/ ODYNOPHAGIA	Active	maraviroc BID	9/ [>9]	Grade 4/ Still Present	STUDY DRUG ACTION: (PERMANENTLY DISCONTINUED) SUBJECT ACTION: (D/C STUDY)/ Other event-unknown	YES
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	Arthralgia*/ INCREASED LEFT HIP PAIN	Active	maraviroc BID	9/ [>9]	Grade 4/ Still Present	STUDY DRUG ACTION: (PERMANENTLY DISCONTINUED) SUBJECT ACTION: (D/C STUDY)/ Other event-arthritis	YES

Age is at screening.
++ Day relative to first day of each treatment period. First day of each treatment period = day 1
* Treatment-emergent
[] Values in brackets are imputed from incomplete dates and times.
SAE = Serious Adverse Event (according to Investigators assessment).
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Table 3.1.3.2
Maraviroc Summary of Clinical Safety
Discontinuations from Study due to Adverse Events
Phase 2b/3 Treatment Experienced Studies

Treatment Group: maraviroc BID

System Organ Class	MedDRA (v9.0) Preferred Term/ INVESTIGATOR ENTRY	Trt Phase	Treatment At Onset	Adverse Event ------- Start Day++/ Stop Day++	SEVERITY/ Outcome	ACTION/ Causality	SAE
A4001027 11[redacted]0007 (M/ 4[redacted](YEARS)/ [redacted]							
HEPATOBILIARY DISORDERS	Hyperbilirubinaemia*/ HYPERBILIRUBINEMIA	Active	maraviroc BID	42/ [>42]	Grade 3/ Still Present	STUDY DRUG ACTION: (PERMANENTLY DISCONTINUED) SUBJECT ACTION: (D/C STUDY)/ Other event-other illness-hcv/etoh	YES
A4001027 13[redacted]0003 (F/ 2[redacted](YEARS)/ [redacted]							
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	Rash generalised*/ GENERALIZED RASH	Active	maraviroc BID	8/ 13	Grade 3/ Resolved (26MAR20[redacted]	STUDY DRUG ACTION: (PERMANENTLY DISCONTINUED) SUBJECT ACTION: (D/C STUDY)/ Study drug	YES
A4001028 10[redacted]0003 (M/ 5[redacted](YEARS)/ [redacted]							

Age is at screening.
++ Day relative to first day of each treatment period. First day of each treatment period = day 1
* Treatment-emergent
[] Values in brackets are imputed from incomplete dates and times.
SAE = Serious Adverse Event (according to Investigators assessment).
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Table 3.1.3.2
Maraviroc Summary of Clinical Safety
Discontinuations from Study due to Adverse Events
Phase 2b/3 Treatment Experienced Studies

Treatment Group: maraviroc BID

System Organ Class	MedDRA (v9.0) Preferred Term/ INVESTIGATOR ENTRY	Trt Phase	Treatment At Onset	Adverse Event ------- Start Day++/ Stop Day++	SEVERITY/ Outcome	ACTION/ Causality	SAE
INVESTIGATIONS	Viral load increased*/ VIRAL LOAD INCREASED	Active	maraviroc BID	72/ 80	Grade 1/ Resolved (21JUL2[redacted])	STUDY DRUG ACTION: (PERMANENTLY DISCONTINUED) SUBJECT ACTION: (D/C STUDY)/ Study drug	NO
A4001028 1[redacted]30006 (M/ 4[redacted](YEARS)/ [redacted]							
INVESTIGATIONS	Alanine aminotransferase increased*/ ELEVATED ALT	Active	maraviroc BID	127/ 135	Grade 4/ Resolved (22MAR2[redacted])	STUDY DRUG ACTION: (PERMANENTLY DISCONTINUED) SUBJECT ACTION: (D/C STUDY)/ Study drug	YES
	Aspartate aminotransferase increased*/ INCREASED AST G4	Active	maraviroc BID	127/ 134	Grade 4/ Resolved (15MAR2[redacted])	STUDY DRUG ACTION: (PERMANENTLY DISCONTINUED) SUBJECT ACTION: (D/C STUDY)/ Study drug	YES

Age is at screening.
++ Day relative to first day of each treatment period. First day of each treatment period = day 1
* Treatment-emergent
[] Values in brackets are imputed from incomplete dates and times.
SAE = Serious Adverse Event (according to Investigators assessment).
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Table 3.1.3.2
Maraviroc Summary of Clinical Safety
Discontinuations from Study due to Adverse Events
Phase 2b/3 Treatment Experienced Studies

Treatment Group: maraviroc BID

System Organ Class	MedDRA (v9.0) Preferred Term/ INVESTIGATOR ENTRY	Trt Phase	Treatment At Onset	Adverse Event ------- Start Day++/ Stop Day++	SEVERITY/ Outcome	ACTION/ Causality	SAE
A4001028 11[redacted]20002 (M/ 4[redacted](YEARS)/ [redacted]							
NERVOUS SYSTEM DISORDERS	Syncope*/ SYNCOPAL EPISODE	Active	maraviroc BID	65/ 65	Grade 4/ Resolved (28FEB2[redacted]	STUDY DRUG ACTION: (PERMANENTLY DISCONTINUED) SUBJECT ACTION: (D/C STUDY)/ Study drug	YES
A4001028 11[redacted]10004 (M/ 5[redacted](YEARS)/ [redacted]							
VASCULAR DISORDERS	Orthostatic hypotension*/ ORTHOSTATIC HYPOTENSION	Active	maraviroc BID	98/ 100	Grade 3/ Resolved (05JUL2[redacted]	STUDY DRUG ACTION: (PERMANENTLY DISCONTINUED) SUBJECT ACTION: (D/C STUDY)/ Study drug	YES
A4001028 11[redacted]50002 (M/ 6[redacted](YEARS)/ [redacted]							

Age is at screening.
++ Day relative to first day of each treatment period. First day of each treatment period = day 1
* Treatment-emergent
[] Values in brackets are imputed from incomplete dates and times.
SAE = Serious Adverse Event (according to Investigators assessment).
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Treatment Group: maraviroc BID

System Organ Class	MedDRA (v9.0) Preferred Term/ INVESTIGATOR ENTRY	Trt Phase	Treatment At Onset	Adverse Event ------- Start Day++/ Stop Day++	SEVERITY/ Outcome	ACTION/ Causality	SAE
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	Tongue neoplasm malignant stage unspecified*/ SQUAMOUS CELL CARCINOMA OF THE L TONGUE BASE.	Active	maraviroc BID	49/ [>49]	Grade 3/ Still Present	STUDY DRUG ACTION: (PERMANENTLY DISCONTINUED) SUBJECT ACTION: (D/C STUDY)/ Other event-diagnosis of squamous cell carcinoma of the left tongue base.	YES
A4001028 12[redacted]50011 (M/ 4[redacted](YEARS)/ [redacted]							
INFECTIONS AND INFESTATIONS	Gastrointestinal infectio n*/ GASTROINTESTINAL INFECTION	Active	maraviroc BID	33/ 57	Grade 2/ Resolved (18APR2[redacted])	STUDY DRUG ACTION: (PERMANENTLY DISCONTINUED) SUBJECT ACTION: (D/C STUDY)/ Other event-norovirus infection	NO
A4001029 10[redacted]70009 (M/ 4[redacted](YEARS)/ [redacted]							

Age is at screening.
++ Day relative to first day of each treatment period. First day of each treatment period = day 1
* Treatment-emergent
[] Values in brackets are imputed from incomplete dates and times.
SAE = Serious Adverse Event (according to Investigators assessment).
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Maraviroc Summary of Clinical Safety
Discontinuations from Study due to Adverse Events
Phase 2b/3 Treatment Experienced Studies

Treatment Group: maraviroc BID

System Organ Class	MedDRA (v9.0) Preferred Term/ INVESTIGATOR ENTRY	Trt Phase	Treatment At Onset	Adverse Event ------- Start Day++/ Stop Day++	SEVERITY/ Outcome	ACTION/ Causality	SAE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	Neutropenia*/ NEUTROPENIA	Active	maraviroc BID	29/ [>29]	Grade 3/ Still Present	STUDY DRUG ACTION: (PERMANENTLY DISCONTINUED) SUBJECT ACTION: (D/C STUDY)/ Study drug	NO
A4001029 1[redacted]50001 (M/ 4[redacted](YEARS)/ [redacted]							
IMMUNE SYSTEM DISORDERS	Hypersensitivity*/ HYPERSENSITIVITY	Active	maraviroc BID	4/ 22	Grade 4/ Resolved (25MAY20[redacted]	STUDY DRUG ACTION: (PERMANENTLY DISCONTINUED) SUBJECT ACTION: (D/C STUDY)/ Concomitant treatment-TM2#	YES
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	Rash*/ SYSTEMIC RASH	Active	maraviroc BID	4/ 22	Grade 4/ Resolved (25MAY20[redacted]	STUDY DRUG ACTION: (PERMANENTLY DISCONTINUED) SUBJECT ACTION: (D/C STUDY)/ Concomitant treatment-TM2#	YES

Age is at screening.
++ Day relative to first day of each treatment period. First day of each treatment period = day 1
* Treatment-emergent
[] Values in brackets are imputed from incomplete dates and times.
SAE = Serious Adverse Event (according to Investigators assessment).
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

#:新薬承認情報提供時に置換えた。
TM2#はlopinavir/ritonavirを示す。

Table 3.1.3.2
Maraviroc Summary of Clinical Safety
Discontinuations from Study due to Adverse Events
Phase 2b/3 Treatment Experienced Studies

Treatment Group: Placebo

System Organ Class	MedDRA (v9.0) Preferred Term/ INVESTIGATOR ENTRY	Trt Phase	Treatment At Onset	Adverse Event ------- Start Day++/ Stop Day++	SEVERITY/ Outcome	ACTION/ Causality	SAE
A4001027 1[redacted]30004 (M/ 4[redacted](YEARS)/ [redacted])							
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	Pyrexia*/ MILD FEVER	Active	Placebo	10/ 15	Grade 1/ Resolved (31AUG2[redacted])	STUDY DRUG ACTION: (PERMANENTLY DISCONTINUED) SUBJECT ACTION: (D/C STUDY)/ Study drug	NO
A4001027 1[redacted]10001 (M/ 5[redacted](YEARS)/ [redacted])							
INVESTIGATIONS	Liver function test abnormal*/ ELEVATED LFT TEST	Active	Placebo	232/ [>232]	Grade 4/ Still Present	STUDY DRUG ACTION: (PERMANENTLY DISCONTINUED) SUBJECT ACTION: (D/C STUDY)/ Study drug	NO

Age is at screening.
++ Day relative to first day of each treatment period. First day of each treatment period = day 1
* Treatment-emergent
[] Values in brackets are imputed from incomplete dates and times.
SAE = Serious Adverse Event (according to Investigators assessment).
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Maraviroc Summary of Clinical Safety
Discontinuations from Study due to Adverse Events
Phase 2b/3 Treatment Experienced Studies

Treatment Group: Placebo

System Organ Class	MedDRA (v9.0) Preferred Term/ INVESTIGATOR ENTRY	Trt Phase	Treatment At Onset	Adverse Event ------- Start Day++/ Stop Day++	SEVERITY/ Outcome	ACTION/ Causality	SAE
INVESTIGATIONS	White blood cell count decreased*/ LOW WHITE BLOOD CELL COUNT	Active	Placebo	294/ [>294]	Grade 1/ Still Present	STUDY DRUG ACTION: (PERMANENTLY DISCONTINUED) SUBJECT ACTION: (D/C STUDY)/ Concomitant treatment-neupogen 480mcg sq for 5 days	NO
A4001027 1C[redacted]0015 (M/ 5[redacted](YEARS)/ [redacted]							
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	Chest pain*/ CHEST PAIN	Active	Placebo	69/ 75	Grade 3/ Resolved (17JUN2C[redacted])	STUDY DRUG ACTION: (PERMANENTLY DISCONTINUED) SUBJECT ACTION: (D/C STUDY)/ Other event-unknown	YES
A4001027 1C[redacted]0019 (M/ 4[redacted](YEARS)/ [redacted]							

Age is at screening.
++ Day relative to first day of each treatment period. First day of each treatment period = day 1
* Treatment-emergent
[] Values in brackets are imputed from incomplete dates and times.
SAE = Serious Adverse Event (according to Investigators assessment).
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Maraviroc Summary of Clinical Safety
Discontinuations from Study due to Adverse Events
Phase 2b/3 Treatment Experienced Studies

Treatment Group: Placebo

System Organ Class	MedDRA (v9.0) Preferred Term/ INVESTIGATOR ENTRY	Trt Phase	Treatment At Onset	Adverse Event ------- Start Day++/ Stop Day++	SEVERITY/ Outcome	ACTION/ Causality	SAE
GASTROINTESTINAL DISORDERS	Gingivitis*/ GINGIVITIS	Active	Placebo	7/ 72	Grade 2/ Resolved (31OCT2[redacted])	STUDY DRUG ACTION: (PERMANENTLY DISCONTINUED) SUBJECT ACTION: (D/C STUDY)/ Study drug	NO
A4001027 1[redacted]10012 (F/ 5[redacted](YEARS)/ [redacted])							
INFECTIONS AND INFESTATIONS	Pneumonia*/ PNEUMONIA	Active	Placebo	5/ 14	Grade 4/ Resolved (13JAN2[redacted])	STUDY DRUG ACTION: (PERMANENTLY DISCONTINUED) SUBJECT ACTION: (D/C STUDY)/ Disease under study	YES
A4001027 11[redacted]70012 (F/ 3[redacted](YEARS)/ [redacted])							

Age is at screening.
++ Day relative to first day of each treatment period. First day of each treatment period = day 1
* Treatment-emergent
[] Values in brackets are imputed from incomplete dates and times.
SAE = Serious Adverse Event (according to Investigators assessment).
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Treatment Group: Placebo

System Organ Class	MedDRA (v9.0) Preferred Term/ INVESTIGATOR ENTRY	Trt Phase	Treatment At Onset	Adverse Event ------- Start Day++/ Stop Day++	SEVERITY/ Outcome	ACTION/ Causality	SAE
INFECTIONS AND INFESTATIONS	Mycobacterium avium compl ex infection/ MYCOBACTERIUM AVIUM COMPLEX INFECTION	Post	Placebo	63/ [>63]	Grade 3/ Still Present	STUDY DRUG ACTION: (PERMANENTLY DISCONTINUED) SUBJECT ACTION: (D/C STUDY)/ Disease under study	YES
METABOLISM AND NUTRITION DISORDERS	Lactic acidosis*/ LACTIC ACIDOSIS	Active	Placebo	96/ 101	Grade 3/ Resolved (01APR2[redacted]	STUDY DRUG ACTION: (PERMANENTLY DISCONTINUED) SUBJECT ACTION: (D/C STUDY)/ Other event-sepsis on drug induced ddi	YES
A4001028 1[redacted]0003 (M/ 4[redacted](YEARS)/ [redacted]							
HEPATOBILIARY DISORDERS	Cytolytic hepatitis*/ HEPATIC CYTOLYSIS	Active	Placebo	14/ 37	Grade 2/ Resolved (02DEC2[redacted]	STUDY DRUG ACTION: (PERMANENTLY DISCONTINUED) SUBJECT ACTION: (D/C STUDY)/ Study drug	NO

Age is at screening.
++ Day relative to first day of each treatment period. First day of each treatment period = day 1
* Treatment-emergent
[] Values in brackets are imputed from incomplete dates and times.
SAE = Serious Adverse Event (according to Investigators assessment).
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Maraviroc Summary of Clinical Safety
Discontinuations from Study due to Adverse Events
Phase 2b/3 Treatment Experienced Studies

Treatment Group: Placebo

System Organ Class	MedDRA (v9.0) Preferred Term/ INVESTIGATOR ENTRY	Trt Phase	Treatment At Onset	Adverse Event ------- Start Day++/ Stop Day++	SEVERITY/ Outcome	ACTION/ Causality	SAE
A4001028 1C[redacted]10034 (M/ 4[redacted](YEARS)/ [redacted])							
NERVOUS SYSTEM DISORDERS	Dizziness*/ DIZZINESS	Active	Placebo	2/ 22	Grade 2/ Resolved (30DEC2C[redacted])	STUDY DRUG ACTION: (PERMANENTLY DISCONTINUED) SUBJECT ACTION: (D/C STUDY)/ Study drug	NO
A4001029 1C[redacted]90004 (M/ 5[redacted](YEARS)/ [redacted])							
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	Asthenia*/ WORSENING OF WEAKNESS	Active	Placebo	8/ 15	Grade 4/ Resolved (10MAY2C[redacted])	STUDY DRUG ACTION: (PERMANENTLY DISCONTINUED) SUBJECT ACTION: (D/C STUDY)/ Other event-sickle cell, dehydration, pneumonia	YES

Age is at screening.
++ Day relative to first day of each treatment period. First day of each treatment period = day 1
* Treatment-emergent
[] Values in brackets are imputed from incomplete dates and times.
SAE = Serious Adverse Event (according to Investigators assessment).
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Table 3.1.3.2
Maraviroc Summary of Clinical Safety
Discontinuations from Study due to Adverse Events
Phase 2b/3 Treatment Experienced Studies

Treatment Group: Placebo

System Organ Class	MedDRA (v9.0) Preferred Term/ INVESTIGATOR ENTRY	Trt Phase	Treatment At Onset	Adverse Event ------- Start Day++/ Stop Day++	SEVERITY/ Outcome	ACTION/ Causality	SAE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	Fatigue*/ FATIGUE	Active	Placebo	8/ 15	Grade 4/ Resolved (10MAY2[redacted])	STUDY DRUG ACTION: (PERMANENTLY DISCONTINUED) SUBJECT ACTION: (D/C STUDY)/ Other event-sickle cell, dehydration, pneumonia	YES
INFECTIONS AND INFESTATIONS	Candidiasis*/ CANDIDIASIS	Active	Placebo	8/ 15	Grade 4/ Resolved (10MAY2[redacted])	STUDY DRUG ACTION: (PERMANENTLY DISCONTINUED) SUBJECT ACTION: (D/C STUDY)/ Disease under study	YES
	Pneumonia*/ PNEUMONIA	Active	Placebo	8/ 15	Grade 4/ Resolved (10MAY2[redacted])	STUDY DRUG ACTION: (PERMANENTLY DISCONTINUED) SUBJECT ACTION: (D/C STUDY)/ Disease under study	YES

Age is at screening.
++ Day relative to first day of each treatment period. First day of each treatment period = day 1
* Treatment-emergent
[] Values in brackets are imputed from incomplete dates and times.
SAE = Serious Adverse Event (according to Investigators assessment).
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Maraviroc Summary of Clinical Safety
Discontinuations from Study due to Adverse Events
Phase 2b/3 Treatment Experienced Studies

Treatment Group: Placebo

System Organ Class	MedDRA (v9.0) Preferred Term/ INVESTIGATOR ENTRY	Trt Phase	Treatment At Onset	Adverse Event ------- Start Day++/ Stop Day++	SEVERITY/ Outcome	ACTION/ Causality	SAE
METABOLISM AND NUTRITION DISORDERS	Dehydration*/ DEHYDRATION	Active	Placebo	8/ 15	Grade 4/ Resolved (10MAY2[redacted])	STUDY DRUG ACTION: (PERMANENTLY DISCONTINUED) SUBJECT ACTION: (D/C STUDY)/ Other event-sickle cell, pneumonia	YES
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	Pleural effusion*/ PLEURAL EFFUSION	Active	Placebo	8/ 15	Grade 4/ Resolved (10MAY2[redacted])	STUDY DRUG ACTION: (PERMANENTLY DISCONTINUED) SUBJECT ACTION: (D/C STUDY)/ Other event-pneumonia	YES
A4001029 1[redacted]10001 (M/ 4[redacted](YEARS)/ [redacted])							
GASTROINTESTINAL DISORDERS	Nausea*/ NAUSEA	Active	Placebo	22/ 27	Grade 1/ Resolved (26JUL2[redacted])	STUDY DRUG ACTION: (PERMANENTLY DISCONTINUED) SUBJECT ACTION: (D/C STUDY)/ Study drug	NO

Age is at screening.
++ Day relative to first day of each treatment period. First day of each treatment period = day 1
* Treatment-emergent
[] Values in brackets are imputed from incomplete dates and times.
SAE = Serious Adverse Event (according to Investigators assessment).
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Maraviroc Summary of Clinical Safety
Discontinuations from Study due to Adverse Events
Phase 2b/3 Treatment Experienced Studies

Treatment Group: Placebo

System Organ Class	MedDRA (v9.0) Preferred Term/ INVESTIGATOR ENTRY	Trt Phase	Treatment At Onset	Adverse Event ------- Start Day++/ Stop Day++	SEVERITY/ Outcome	ACTION/ Causality	SAE
GASTROINTESTINAL DISORDERS	Vomiting*/ VOMIT	Active	Placebo	22/ 27	Grade 1/ Resolved (26JUL2[redacted])	STUDY DRUG ACTION: (PERMANENTLY DISCONTINUED) SUBJECT ACTION: (D/C STUDY)/ Study drug	NO
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	Malaise*/ MALAISE	Active	Placebo	12/ 15	Grade 1/ Resolved (14JUL2[redacted])	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Study drug	NO
	Malaise*/ MALAISE	Active	Placebo	22/ 27	Grade 1/ Resolved (26JUL2[redacted])	STUDY DRUG ACTION: (PERMANENTLY DISCONTINUED) SUBJECT ACTION: (D/C STUDY)/ Study drug	NO
	Pyrexia*/ FEVER	Active	Placebo	12/ 15	Grade 1/ Resolved (14JUL2[redacted])	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Study drug	NO
	Pyrexia*/ FEVER	Active	Placebo	22/ 27	Grade 1/ Resolved (26JUL2[redacted])	STUDY DRUG ACTION: (PERMANENTLY DISCONTINUED) SUBJECT ACTION: (D/C STUDY)/ Study drug	NO

Age is at screening.
++ Day relative to first day of each treatment period. First day of each treatment period = day 1
* Treatment-emergent
[] Values in brackets are imputed from incomplete dates and times.
SAE = Serious Adverse Event (according to Investigators assessment).
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Table 3.1.3.2
Maraviroc Summary of Clinical Safety
Discontinuations from Study due to Adverse Events
Phase 2b/3 Treatment Experienced Studies

Treatment Group: Placebo

System Organ Class	MedDRA (v9.0) Preferred Term/ INVESTIGATOR ENTRY	Trt Phase	Treatment At Onset	Adverse Event ------- Start Day++/ Stop Day++	SEVERITY/ Outcome	ACTION/ Causality	SAE
NERVOUS SYSTEM DISORDERS	Paraesthesia oral*/ PERIORAL PARESTHESIA	Active	Placebo	12/ 20	Grade 1/ Resolved (19JUL2[redacted])	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Study drug	NO
	Paraesthesia oral*/ PERIORAL PARESTHESIA	Active	Placebo	22/ 27	Grade 1/ Resolved (26JUL2[redacted])	STUDY DRUG ACTION: (PERMANENTLY DISCONTINUED) SUBJECT ACTION: (D/C STUDY)/ Study drug	NO
A4001029 12[redacted]40001 (M/ 9[redacted](YEARS)/ [redacted])							
INVESTIGATIONS	Lipase increased*/ ELEVATED LIPASE	Active	Placebo	182/ [>182]	Grade 3/ Still Present	STUDY DRUG ACTION: (PERMANENTLY DISCONTINUED) SUBJECT ACTION: (D/C STUDY)/ Concomitant treatment-ddi	NO
A4001029 12[redacted]30001 (M/ 3[redacted](YEARS)/ [redacted])							

Age is at screening.
++ Day relative to first day of each treatment period. First day of each treatment period = day 1
* Treatment-emergent
[] Values in brackets are imputed from incomplete dates and times.
SAE = Serious Adverse Event (according to Investigators assessment).
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Table 3.1.3.2
Maraviroc Summary of Clinical Safety
Discontinuations from Study due to Adverse Events
Phase 2b/3 Treatment Experienced Studies

Treatment Group: Placebo

System Organ Class	MedDRA (v9.0) Preferred Term/ INVESTIGATOR ENTRY	Trt Phase	Treatment At Onset	Adverse Event ------- Start Day++/ Stop Day++	SEVERITY/ Outcome	ACTION/ Causality	SAE
GASTROINTESTINAL DISORDERS	Diarrhoea*/ DIARRHOEA	Active	Placebo	7/ [>7]	Grade 1/ Still Present	STUDY DRUG ACTION: (PERMANENTLY DISCONTINUED) SUBJECT ACTION: (D/C STUDY)/ Study drug	NO
	Nausea*/ NAUSEA	Active	Placebo	7/ [>7]	Grade 1/ Still Present	STUDY DRUG ACTION: (PERMANENTLY DISCONTINUED) SUBJECT ACTION: (D/C STUDY)/ Study drug	NO
NERVOUS SYSTEM DISORDERS	Lethargy*/ LETHARGY	Active	Placebo	7/ [>7]	Grade 1/ Still Present	STUDY DRUG ACTION: (PERMANENTLY DISCONTINUED) SUBJECT ACTION: (D/C STUDY)/ Study drug	NO

Age is at screening.
++ Day relative to first day of each treatment period. First day of each treatment period = day 1
* Treatment-emergent
[] Values in brackets are imputed from incomplete dates and times.
SAE = Serious Adverse Event (according to Investigators assessment).
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Table 3.1.3.3
Maraviroc Summary of Clinical Safety
Temporary Discontinuations or Dose Reductions Due to Adverse Events
Phase 2b/3 Treatment Experienced Studies

Treatment Group: maraviroc QD

System Organ Class	MedDRA (v9.0) Preferred Term/ INVESTIGATOR ENTRY	Trt Phase	Treatment At Onset	Adverse Event ------- Start Day++/ Stop Day++	SEVERITY/ Outcome	ACTION/ Causality	SAE
A4001027 1C[redacted]50002 (M/ 5[redacted](YEARS)/ [redacted]							
GASTROINTESTINAL DISORDERS	Diverticulum intestinal h aemorrhagic*/ COLON DIVERTICULAR BLEED	Active	maraviroc QD	95/ 104	Grade 4/ Resolved (19JUN2C[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Other event-diverticulitis	YES
A4001027 1C[redacted]70004 (M/ 4[redacted](YEARS)/ [redacted]							
GASTROINTESTINAL DISORDERS	Nausea*/ NAUSEA	Active	maraviroc QD	1/ 29	Grade 2/ Resolved (04MAY2C[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Study drug	NO
	Vomiting*/ VOMITING	Active	maraviroc QD	1/ 29	Grade 2/ Resolved (04MAY2C[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Study drug	NO
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	Chills*/ RIGORS	Active	maraviroc QD	13/ 13	Grade 1/ Resolved (18APR2C[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Other event-due to fever	NO

Age is at screening
* Treatment-emergent
++ Start Day and Stop Day are start and stop of AE relative to the start of treatment: First day of treatment = Day 1
[] Days in brackets are imputed days derived from incomplete dates.
SAE = Serious Adverse Event (according to Investigators assessment).
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Treatment Group: maraviroc QD

System Organ Class	MedDRA (v9.0) Preferred Term/ INVESTIGATOR ENTRY	Trt Phase	Treatment At Onset	Adverse Event ------- Start Day++/ Stop Day++	SEVERITY/ Outcome	ACTION/ Causality	SAE
METABOLISM AND NUTRITION DISORDERS	Dehydration*/ DEHYDRATION	Active	maraviroc QD	13/ 13	Grade 2/ Resolved (18APR20[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Other event-due to vomitting and diarrhea	NO
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	Rash*/ RASH	Active	maraviroc QD	1/ 29	Grade 2/ Resolved (04MAY20[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Study drug	NO
A4001027 10[redacted]70008 (M/ 4[redacted](YEARS)/ [redacted]							
GASTROINTESTINAL DISORDERS	Abdominal pain*/ ABDOMINAL PAIN	Active	maraviroc QD	121/ 136	Grade 2/ Resolved (31AUG20[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Disease under study	NO
A4001027 10[redacted]10005 (M/ 4[redacted](YEARS)/ [redacted]							
EYE DISORDERS	Eye pain*/ EYE PAIN	Active	maraviroc QD	8/ 16	Grade 2/ Resolved (31MAY20[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Study drug	NO
	Ocular hyperaemia*/ EYE REDNESS (BLOODSHOT)	Active	maraviroc QD	8/ 16	Grade 2/ Resolved (31MAY20[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Study drug	NO

Age is at screening
* Treatment-emergent
++ Start Day and Stop Day are start and stop of AE relative to the start of treatment: First day of treatment = Day 1
[] Days in brackets are imputed days derived from incomplete dates.
SAE = Serious Adverse Event (according to Investigators assessment).
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Table 3.1.3.3
Maraviroc Summary of Clinical Safety
Temporary Discontinuations or Dose Reductions Due to Adverse Events
Phase 2b/3 Treatment Experienced Studies

Treatment Group: maraviroc QD

System Organ Class	MedDRA (v9.0) Preferred Term/ INVESTIGATOR ENTRY	Trt Phase	Treatment At Onset	Adverse Event ------- Start Day++/ Stop Day++	SEVERITY/ Outcome	ACTION/ Causality	SAE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	Pyrexia*/ FEVER	Active	maraviroc QD	8/ 16	Grade 2/ Resolved (31MAY2C[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Study drug	NO
HEPATOBILIARY DISORDERS	Hyperbilirubinaemia*/ HYPERBILIRUBINEMIA	Active	maraviroc QD	8/ 16	Grade 2/ Resolved (31MAY2C[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Concomitant treatment-atazanavir sulfate#	NO
NERVOUS SYSTEM DISORDERS	Headache*/ HEADACHE	Active	maraviroc QD	8/ 16	Grade 2/ Resolved (31MAY2C[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Study drug	NO
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	Rash*/ RASH ON STOMACH	Active	maraviroc QD	8/ 16	Grade 2/ Resolved (31MAY2C[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Study drug	NO
A4001027 1C[redacted]20009 (M/ 5[redacted](YEARS)/ [redacted]							
GASTROINTESTINAL DISORDERS	Abdominal pain*/ ABDOMINAL PAIN	Active	maraviroc QD	306/ 308	Grade 2/ Resolved (10MAY2C[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Disease under study	YES

Age is at screening
* Treatment-emergent
++ Start Day and Stop Day are start and stop of AE relative to the start of treatment: First day of treatment = Day 1
[] Days in brackets are imputed days derived from incomplete dates.
SAE = Serious Adverse Event (according to Investigators assessment).
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.
PFIZER CONFIDENTIAL Includes Protocols:A4001027, A4001028, A4001029. Date of Table Generation: 01NOV2006 (06:38)

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Table 3.1.3.3
Maraviroc Summary of Clinical Safety
Temporary Discontinuations or Dose Reductions Due to Adverse Events
Phase 2b/3 Treatment Experienced Studies

Treatment Group: maraviroc QD

System Organ Class	MedDRA (v9.0) Preferred Term/ INVESTIGATOR ENTRY	Trt Phase	Treatment At Onset	Adverse Event Start Day++/ Stop Day++	SEVERITY/ Outcome	ACTION/ Causality	SAE
A4001027 10[redacted]40024 (F/ 6[redacted](YEARS)/ [redacted])							
INFECTIONS AND INFESTATIONS	Gastroenteritis*/ GASTROENTERITIS	Active	maraviroc QD	64/ [>64]	Grade 2/ Still Present	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Other event-virus	NO
A4001027 10[redacted]60005 (M/ 4[redacted](YEARS)/ [redacted])							
INVESTIGATIONS	Alanine aminotransferase increased*/ ELEVATED ALT	Active	maraviroc QD	114/ 117	Grade 3/ Resolved (23DEC2[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Other event-unknown etiology	NO
A4001027 10[redacted]60013 (M/ 5[redacted](YEARS)/ [redacted])							
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	Pyrexia*/ FEVER	Active	maraviroc QD	55/ 61	Grade 2/ Resolved (17FEB2[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Other event-possible bacterial infection	YES

Age is at screening
* Treatment-emergent
++ Start Day and Stop Day are start and stop of AE relative to the start of treatment: First day of treatment = Day 1
[] Days in brackets are imputed days derived from incomplete dates.
SAE = Serious Adverse Event (according to Investigators assessment).
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Table 3.1.3.3
Maraviroc Summary of Clinical Safety
Temporary Discontinuations or Dose Reductions Due to Adverse Events
Phase 2b/3 Treatment Experienced Studies

Treatment Group: maraviroc QD

System Organ Class	MedDRA (v9.0) Preferred Term/ INVESTIGATOR ENTRY	Trt Phase	Treatment At Onset	Adverse Event ------- Start Day++/ Stop Day++	SEVERITY/ Outcome	ACTION/ Causality	SAE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	Pyrexia*/ LOW GRADE FEVER	Active	maraviroc QD	54/ 55	Grade 1/ Resolved (11FEB2C[redacted]	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Other event-viral infection	NO
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	Dyspnoea*/ SHORTNESS OF BREATH	Active	maraviroc QD	57/ 61	Grade 3/ Resolved (17FEB2C[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Disease under study	YES
A4001027 1C[redacted]30009 (F/ 4[redacted](YEARS)/ [redacted]							
INFECTIONS AND INFESTATIONS	Pneumonia*/ PNEUMONIA	Active	maraviroc QD	57/ 66	Grade 3/ Resolved (12JAN2C[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Other event-community acquired pneumonia	YES
A4001027 1C[redacted]30014 (M/ 6[redacted](YEARS)/ [redacted]							

Age is at screening
* Treatment-emergent
++ Start Day and Stop Day are start and stop of AE relative to the start of treatment: First day of treatment = Day 1
[] Days in brackets are imputed days derived from incomplete dates.
SAE = Serious Adverse Event (according to Investigators assessment).
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Table 3.1.3.3
Maraviroc Summary of Clinical Safety
Temporary Discontinuations or Dose Reductions Due to Adverse Events
Phase 2b/3 Treatment Experienced Studies

Treatment Group: maraviroc QD

System Organ Class	MedDRA (v9.0) Preferred Term/ INVESTIGATOR ENTRY	Trt Phase	Treatment At Onset	Adverse Event Start Day++/ Stop Day++	SEVERITY/ Outcome	ACTION/ Causality	SAE
GASTROINTESTINAL DISORDERS	Nausea*/ NAUSEA	Active	maraviroc QD	18/ 43	Grade 3/ Resolved (03MAY2[redacted])	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Concomitant treatment-possibly azt	NO
A4001027 1[redacted]30006 (M/ 4[redacted](YEARS)/ [redacted])							
GASTROINTESTINAL DISORDERS	Abdominal pain*/ ABDOMINAL PAIN	Active	maraviroc QD	123/ 128	Grade 3/ Resolved (18JUL2[redacted])	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Study drug	YES
	Haematochezia*/ BLOOD IN STOOL	Active	maraviroc QD	124/ 128	Grade 3/ Resolved (18JUL2[redacted])	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Concomitant treatment-beptobismo	YES
	Nausea*/ NAUSEA	Active	maraviroc QD	2/ 72	Grade 1/ Resolved (23MAY2[redacted])	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study drug	NO
	Nausea*/ NAUSEA	Active	maraviroc QD	123/ 128	Grade 3/ Resolved (18JUL2[redacted])	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Concomitant treatment-peptobismo	YES

Age is at screening
* Treatment-emergent
++ Start Day and Stop Day are start and stop of AE relative to the start of treatment: First day of treatment = Day 1
[] Days in brackets are imputed days derived from incomplete dates.
SAE = Serious Adverse Event (according to Investigators assessment).
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Table 3.1.3.3
Maraviroc Summary of Clinical Safety
Temporary Discontinuations or Dose Reductions Due to Adverse Events
Phase 2b/3 Treatment Experienced Studies

Treatment Group: maraviroc QD

System Organ Class	MedDRA (v9.0) Preferred Term/ INVESTIGATOR ENTRY	Trt Phase	Treatment At Onset	Adverse Event ------- Start Day++/ Stop Day++	SEVERITY/ Outcome	ACTION/ Causality	SAE
NERVOUS SYSTEM DISORDERS	Dizziness*/ LIGHTHEADEDNESS	Active	maraviroc QD	125/ 128	Grade 1/ Resolved (18JUL20[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Study drug	NO
A4001027 11[redacted]40002 (M/ 4[redacted](YEARS)/ [redacted]							
GASTROINTESTINAL DISORDERS	Abdominal pain upper*/ EPIGASTRIC PAIN	Active	maraviroc QD	51/ 53	Grade 3/ Resolved (21AUG20[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Concomitant treatment-emtricitabine/tenofovir disoproxil fumarate# and epivir	YES
	Diarrhoea*/ DIARRHEA	Active	maraviroc QD	51/ 53	Grade 3/ Resolved (21AUG20[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Concomitant treatment-emtricitabine/tenofovir disoproxil fumarate# and epivir	YES
	Vomiting*/ VOMITING	Active	maraviroc QD	51/ 51	Grade 3/ Resolved (19AUG20[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Concomitant treatment-emtricitabine/tenofovir disoproxil fumarate# and epivir	YES

Age is at screening
* Treatment-emergent
++ Start Day and Stop Day are start and stop of AE relative to the start of treatment: First day of treatment = Day 1
[] Days in brackets are imputed days derived from incomplete dates.
SAE = Serious Adverse Event (according to Investigators assessment).
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

新薬承認情報提供時に置換えた。

Table 3.1.3.3
Maraviroc Summary of Clinical Safety
Temporary Discontinuations or Dose Reductions Due to Adverse Events
Phase 2b/3 Treatment Experienced Studies

Treatment Group: maraviroc QD

System Organ Class	MedDRA (v9.0) Preferred Term/ INVESTIGATOR ENTRY	Trt Phase	Treatment At Onset	Adverse Event ------- Start Day++/ Stop Day++	SEVERITY/ Outcome	ACTION/ Causality	SAE
A4001027 11[redacted]0004 (M/ 4[redacted](YEARS)/ [redacted])							
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	Injection site reaction*/ INJECTION SITE REACTIONS	Active	maraviroc QD	1/ 21	Grade 2/ Resolved (21AUG2C[redacted])	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Concomitant treatment-enfuvirtide#	NO
A4001027 11[redacted]0008 (M/ 4[redacted](YEARS)/ [redacted])							
GASTROINTESTINAL DISORDERS	Pancreatitis*/ PANCREATITIS	Active	maraviroc QD	89/ 97	Grade 1/ Resolved (15MAY2C[redacted])	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Study drug	YES
A4001028 1C[redacted]0005 (M/ 6[redacted](YEARS)/ [redacted])							
INFECTIONS AND INFESTATIONS	Pyelonephritis*/ PYELONEPHRITIS	Active	maraviroc QD	9/ 17	Grade 1/ Resolved (30JUL2C[redacted])	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Concomitant treatment-indinavir	NO

Age is at screening
* Treatment-emergent
++ Start Day and Stop Day are start and stop of AE relative to the start of treatment: First day of treatment = Day 1
[] Days in brackets are imputed days derived from incomplete dates.
SAE = Serious Adverse Event (according to Investigators assessment).
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

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Table 3.1.3.3
Maraviroc Summary of Clinical Safety
Temporary Discontinuations or Dose Reductions Due to Adverse Events
Phase 2b/3 Treatment Experienced Studies

Treatment Group: maraviroc QD

System Organ Class	MedDRA (v9.0) Preferred Term/ INVESTIGATOR ENTRY	Trt Phase	Treatment At Onset	Adverse Event ------- Start Day++/ Stop Day++	SEVERITY/ Outcome	ACTION/ Causality	SAE
RENAL AND URINARY DISORDERS	Renal pain*/ RENAL PAIN	Active	maraviroc QD	9/ 17	Grade 1/ Resolved (30JUL2[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Concomitant treatment-indinavir	NO
A4001028 1[redacted]0006 (M/ 2[redacted](YEARS)/ [redacted]							
GASTROINTESTINAL DISORDERS	Dysphagia*/ SWALLOW - PROBLEMS	Active	maraviroc QD	27/ 155	Grade 2/ Resolved (12OCT2[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Other event-suspected psychological problems with intake of pills	NO
A4001028 11[redacted]0002 (M/ 3[redacted](YEARS)/ [redacted]							
INVESTIGATIONS	Alanine aminotransferase increased*/ ALT ELEVATION	Active	maraviroc QD	59/ 65	Grade 3/ Resolved (05JAN2[redacted]	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study drug	NO
	Alanine aminotransferase increased*/ ALT ELEVATION	Active	maraviroc QD	85/ 93	Grade 4/ Resolved (02FEB2[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Study drug	NO

Age is at screening
* Treatment-emergent
++ Start Day and Stop Day are start and stop of AE relative to the start of treatment: First day of treatment = Day 1
[] Days in brackets are imputed days derived from incomplete dates.
SAE = Serious Adverse Event (according to Investigators assessment).
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Table 3.1.3.3
Maraviroc Summary of Clinical Safety
Temporary Discontinuations or Dose Reductions Due to Adverse Events
Phase 2b/3 Treatment Experienced Studies

Treatment Group: maraviroc QD

System Organ Class	MedDRA (v9.0) Preferred Term/ INVESTIGATOR ENTRY	Trt Phase	Treatment At Onset	Adverse Event ------- Start Day++/ Stop Day++	SEVERITY/ Outcome	ACTION/ Causality	SAE
INVESTIGATIONS	Aspartate aminotransferase increased*/ AST ELEVATION	Active	maraviroc QD	85/ 93	Grade 3/ Resolved (02FEB2[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Study drug	NO
A4001028 11[redacted]30025 (F/ 5[redacted](YEARS)/ [redacted]							
INFECTIONS AND INFESTATIONS	Herpes simplex*/ HSV INFECTION	Active	maraviroc QD	15/ 101	Grade 3/ Resolved (15OCT2[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Disease under study	YES
	Oral candidiasis*/ WORSENING OF ORAL CANDIDIASIS	Active	maraviroc QD	15/ 63	Grade 3/ Resolved (07SEP2[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Disease under study	YES
	Urinary tract infection*/ URINARY INFECTION	Active	maraviroc QD	15/ 28	Grade 2/ Resolved (03AUG2[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Other event-intercurrent infection	YES
A4001028 11[redacted]50008 (F/ 3[redacted](YEARS)/ [redacted]							
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	Fatigue*/ FATIGUE	Active	maraviroc QD	2/ 7	Grade 1/ Resolved (01MAR2[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Concomitant treatment-zidovudine/lamivudine#	NO

Age is at screening
* Treatment-emergent
++ Start Day and Stop Day are start and stop of AE relative to the start of treatment: First day of treatment = Day 1
[] Days in brackets are imputed days derived from incomplete dates.
SAE = Serious Adverse Event (according to Investigators assessment).
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.
PFIZER CONFIDENTIAL Includes Protocols:A4001027, A4001028, A4001029. Date of Table Generation: 01NOV2006 (06:38)

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Table 3.1.3.3
Maraviroc Summary of Clinical Safety
Temporary Discontinuations or Dose Reductions Due to Adverse Events
Phase 2b/3 Treatment Experienced Studies

Treatment Group: maraviroc QD

System Organ Class	MedDRA (v9.0) Preferred Term/ INVESTIGATOR ENTRY	Trt Phase	Treatment At Onset	Adverse Event ------- Start Day++/ Stop Day++	SEVERITY/ Outcome	ACTION/ Causality	SAE
NERVOUS SYSTEM DISORDERS	Dizziness*/ LIGHTHEADNESS	Active	maraviroc QD	2/ 7	Grade 1/ Resolved (01MAR2[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Concomitant treatment-azt componentof zidovudine/lamivudine#	NO
	Headache*/ HEADACHE	Active	maraviroc QD	2/ 7	Grade 1/ Resolved (01MAR2[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Concomitant treatment-azt component of zidovudine/lamivudine#	NO
A4001028 11[redacted]40011 (M/ 5[redacted](YEARS)/ [redacted]							
BLOOD AND LYMPHATIC SYSTEM DISORDERS	Neutropenia*/ NEUTROPENIA	Active	maraviroc QD	19/ [>19]	Grade 4/ Still Present	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Study drug	YES
INFECTIONS AND INFESTATIONS	Pneumonia bacterial*/ BACTERIAL PNEUMONIA RECURRENT	Active	maraviroc QD	43/ [>43]	Grade 4/ Still Present	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Other event-worsening pre existing condition	YES

Age is at screening
* Treatment-emergent
++ Start Day and Stop Day are start and stop of AE relative to the start of treatment: First day of treatment = Day 1
[] Days in brackets are imputed days derived from incomplete dates.
SAE = Serious Adverse Event (according to Investigators assessment).
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

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Maraviroc Summary of Clinical Safety
Temporary Discontinuations or Dose Reductions Due to Adverse Events
Phase 2b/3 Treatment Experienced Studies

Treatment Group: maraviroc QD

System Organ Class	MedDRA (v9.0) Preferred Term/ INVESTIGATOR ENTRY	Trt Phase	Treatment At Onset	Adverse Event ------- Start Day++/ Stop Day++	SEVERITY/ Outcome	ACTION/ Causality	SAE
A4001028 12[redacted]50003 (M/ 4[redacted](YEARS)/ [redacted]							
GASTROINTESTINAL DISORDERS	Diarrhoea*/ CHRONIC DIARRHEA GOT WORSENED	Active	maraviroc QD	22/ 90	Grade 2/ Resolved (25APR2C[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Study drug	NO
A4001028 12[redacted]50002 (M/ 3[redacted](YEARS)/ [redacted]							
INVESTIGATIONS	Gamma-glutamyltransferase increased*/ ELEVATED GGT	Active	maraviroc QD	86/ [>86]	Grade 4/ Still Present	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Other event-dilated intrahepatic ducts	NO
A4001029 10[redacted]30005 (M/ 4[redacted](YEARS)/ [redacted]							
GASTROINTESTINAL DISORDERS	Vomiting*/ VOMITING	Active	maraviroc QD	44/ 46	Grade 2/ Resolved (02APR2C[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Other event-reaction to surgical anesthesia.	NO

Age is at screening
* Treatment-emergent
++ Start Day and Stop Day are start and stop of AE relative to the start of treatment: First day of treatment = Day 1
[] Days in brackets are imputed days derived from incomplete dates.
SAE = Serious Adverse Event (according to Investigators assessment).
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Treatment Group: maraviroc QD

System Organ Class	MedDRA (v9.0) Preferred Term/ INVESTIGATOR ENTRY	Trt Phase	Treatment At Onset	Adverse Event ------- Start Day++/ Stop Day++	SEVERITY/ Outcome	ACTION/ Causality	SAE
A4001029 1[redacted]40001 (M/ 4[redacted](YEARS)/ [redacted]							
GASTROINTESTINAL DISORDERS	Vomiting*/ VOMITING	Active	maraviroc QD	78/ 80	Grade 1/ Resolved (30APR2[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Other event-possible food poisoning	NO
A4001029 1[redacted]90001 (M/ 4[redacted](YEARS)/ [redacted]							
INFECTIONS AND INFESTATIONS	Pneumocystis jiroveci pneumonia*/ PNEUMOCYSTIS PNEUMONIA	Active	maraviroc QD	30/ 42	Grade 4/ Resolved (13JUN2[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Disease under study	YES
METABOLISM AND NUTRITION DISORDERS	Hypoglycaemia*/ HYPOGLYCEMIA	Active	maraviroc QD	53/ 59	Grade 4/ Resolved (30JUN2[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Concomitant treatment-pentamidine	YES
A4001029 12[redacted]80003 (M/ 4[redacted](YEARS)/ [redacted]							

Age is at screening
* Treatment-emergent
++ Start Day and Stop Day are start and stop of AE relative to the start of treatment: First day of treatment = Day 1
[] Days in brackets are imputed days derived from incomplete dates.
SAE = Serious Adverse Event (according to Investigators assessment).
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Table 3.1.3.3
Maraviroc Summary of Clinical Safety
Temporary Discontinuations or Dose Reductions Due to Adverse Events
Phase 2b/3 Treatment Experienced Studies

Treatment Group: maraviroc QD

System Organ Class	MedDRA (v9.0) Preferred Term/ INVESTIGATOR ENTRY	Trt Phase	Treatment At Onset	Adverse Event ------- Start Day++/ Stop Day++	SEVERITY/ Outcome	ACTION/ Causality	SAE
RENAL AND URINARY DISORDERS	Nephrolithiasis*/ KIDNEY STONE	Active	maraviroc QD	89/ 90	Grade 3/ Resolved (01AUG20[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Other event-kidney stones	YES
A4001029 12[redacted]0007 (F/ 1[redacted](YEARS)/ [redacted]							
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	Pain in extremity*/ RIGHT ARM PAIN	Active	maraviroc QD	51/ 58	Grade 4/ Resolved (13JUL20[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Disease under study	YES
NERVOUS SYSTEM DISORDERS	Movement disorder*/ MOVEMENT DISORDER	Active	maraviroc QD	51/ 58	Grade 1/ Resolved (13JUL20[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Disease under study	YES

Age is at screening
* Treatment-emergent
++ Start Day and Stop Day are start and stop of AE relative to the start of treatment: First day of treatment = Day 1
[] Days in brackets are imputed days derived from incomplete dates.
SAE = Serious Adverse Event (according to Investigators assessment).
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Table 3.1.3.3
Maraviroc Summary of Clinical Safety
Temporary Discontinuations or Dose Reductions Due to Adverse Events
Phase 2b/3 Treatment Experienced Studies

Treatment Group: maraviroc BID

System Organ Class	MedDRA (v9.0) Preferred Term/ INVESTIGATOR ENTRY	Trt Phase	Treatment At Onset	Adverse Event ------- Start Day++/ Stop Day++	SEVERITY/ Outcome	ACTION/ Causality	SAE
A4001027 1[redacted]0003 (M/ 4[redacted](YEARS)/ [redacted]							
INVESTIGATIONS	Aspartate aminotransferase increased*/ ELEVATED AST	Active	maraviroc BID	15/ 22	Grade 3/ Resolved (20JAN20[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Study drug	NO
A4001027 1[redacted]0016 (M/ 4[redacted](YEARS)/ [redacted]							
IMMUNE SYSTEM DISORDERS	Drug hypersensitivity*/ NEVIRAPINE HYPERSENSITIVITY	Active	maraviroc BID	2/ 13	Grade 3/ Resolved (04FEB20[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Concomitant treatment-nevirapine	YES
A4001027 1[redacted]0004 (M/ 4[redacted](YEARS)/ [redacted]							
EAR AND LABYRINTH DISORDERS	Vertigo*/ VERTIGO	Active	maraviroc BID	1/ 8	Grade 3/ Resolved (24MAR20[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Concomitant treatment-efavirenz	NO

Age is at screening
* Treatment-emergent
++ Start Day and Stop Day are start and stop of AE relative to the start of treatment: First day of treatment = Day 1
[] Days in brackets are imputed days derived from incomplete dates.
SAE = Serious Adverse Event (according to Investigators assessment).
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Maraviroc Summary of Clinical Safety
Temporary Discontinuations or Dose Reductions Due to Adverse Events
Phase 2b/3 Treatment Experienced Studies

Treatment Group: maraviroc BID

System Organ Class	MedDRA (v9.0) Preferred Term/ INVESTIGATOR ENTRY	Trt Phase	Treatment At Onset	Adverse Event ------- Start Day++/ Stop Day++	SEVERITY/ Outcome	ACTION/ Causality	SAE
GASTROINTESTINAL DISORDERS	Vomiting*/ VOMITING	Active	maraviroc BID	1/ 8	Grade 3/ Resolved (24MAR2[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Concomitant treatment-efavirenz	NO
NERVOUS SYSTEM DISORDERS	Dizziness*/ DIZZINESS	Active	maraviroc BID	1/ 8	Grade 3/ Resolved (24MAR2[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Concomitant treatment-efavirenz	NO
	Tremor*/ SHAKINESS	Active	maraviroc BID	1/ 8	Grade 3/ Resolved (24MAR2[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Concomitant treatment-efavirenz	NO
A4001027 1C[redacted]40011 (M/ 5[redacted](YEARS)/ [redacted]							
GASTROINTESTINAL DISORDERS	Small intestinal obstruction*/ SMALL BOWEL OBSTRUCTION	Active	maraviroc BID	216/ 223	Grade 3/ Resolved (29JAN2[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Other event-unknown cause	YES
A4001027 1C[redacted]30016 (M/ 4[redacted](YEARS)/ [redacted]							

Age is at screening
* Treatment-emergent
++ Start Day and Stop Day are start and stop of AE relative to the start of treatment: First day of treatment = Day 1
[] Days in brackets are imputed days derived from incomplete dates.
SAE = Serious Adverse Event (according to Investigators assessment).
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Maraviroc Summary of Clinical Safety
Temporary Discontinuations or Dose Reductions Due to Adverse Events
Phase 2b/3 Treatment Experienced Studies

Treatment Group: maraviroc BID

System Organ Class	MedDRA (v9.0) Preferred Term/ INVESTIGATOR ENTRY	Trt Phase	Treatment At Onset	Adverse Event ------- Start Day++/ Stop Day++	SEVERITY/ Outcome	ACTION/ Causality	SAE
EYE DISORDERS	Dry eye*/ DRY EYES IRRITATED	Active	maraviroc BID	13/ 16	Grade 2/ Resolved (10MAR20[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Concomitant treatment-abacavir hypersensitivity	NO
GASTROINTESTINAL DISORDERS	Diarrhoea*/ DIARRHEA	Active	maraviroc BID	13/ 19	Grade 2/ Resolved (13MAR20[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Concomitant treatment-abacavir hypersensitivity	NO
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	Cough*/ DRY COUGH	Active	maraviroc BID	13/ 16	Grade 2/ Resolved (10MAR20[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Concomitant treatment-abacavir hypersensitivity	NO
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	Erythema*/ FACIAL ERYTHEMA	Active	maraviroc BID	13/ 19	Grade 1/ Resolved (13MAR20[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Concomitant treatment-abacavir hypersensitivity	NO
	Rash pruritic*/ ITCHING RASH	Active	maraviroc BID	4/ 19	Grade 2/ Resolved (13MAR20[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Concomitant treatment-abacavir hypersensitivity	NO

Age is at screening
* Treatment-emergent
++ Start Day and Stop Day are start and stop of AE relative to the start of treatment: First day of treatment = Day 1
[] Days in brackets are imputed days derived from incomplete dates.
SAE = Serious Adverse Event (according to Investigators assessment).
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Table 3.1.3.3
Maraviroc Summary of Clinical Safety
Temporary Discontinuations or Dose Reductions Due to Adverse Events
Phase 2b/3 Treatment Experienced Studies

Treatment Group: maraviroc BID

System Organ Class	MedDRA (v9.0) Preferred Term/ INVESTIGATOR ENTRY	Trt Phase	Treatment At Onset	Adverse Event ------- Start Day++/ Stop Day++	SEVERITY/ Outcome	ACTION/ Causality	SAE
A4001027 1[redacted]0018 (M/ 4[redacted](YEARS)/ [redacted]							
INFECTIONS AND INFESTATIONS	Candidiasis*/ CANDIDIASIS	Active	maraviroc BID	7/ 10	Grade 2/ Resolved (04FEB2[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Disease under study	NO
INVESTIGATIONS	Blood creatine phosphokinase increased*/ ELEVATED CK	Active	maraviroc BID	8/ 27	Grade 3/ Resolved (21FEB2[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Other event-rhabdomyolysis	NO
METABOLISM AND NUTRITION DISORDERS	Hyponatraemia*/ HYPONATREMIA	Active	maraviroc BID	7/ 10	Grade 3/ Resolved (04FEB2[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Concomitant treatment-enfuvirtide	NO
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	Rhabdomyolysis*/ RHABDOMYOLYSIS	Active	maraviroc BID	7/ 10	Grade 4/ Resolved (04FEB2[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Concomitant treatment-enfuvirtide#	YES
A4001027 1[redacted]0014 (M/ 4[redacted](YEARS)/ [redacted]							

Age is at screening
* Treatment-emergent
++ Start Day and Stop Day are start and stop of AE relative to the start of treatment: First day of treatment = Day 1
[] Days in brackets are imputed days derived from incomplete dates.
SAE = Serious Adverse Event (according to Investigators assessment).
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

#: 新薬承認情報提供時に置換えた。

Table 3.1.3.3
Maraviroc Summary of Clinical Safety
Temporary Discontinuations or Dose Reductions Due to Adverse Events
Phase 2b/3 Treatment Experienced Studies

Treatment Group: maraviroc BID

System Organ Class	MedDRA (v9.0) Preferred Term/ INVESTIGATOR ENTRY	Trt Phase	Treatment At Onset	Adverse Event ------- Start Day++/ Stop Day++	SEVERITY/ Outcome	ACTION/ Causality	SAE
INVESTIGATIONS	Blood creatine phosphokinase increased*/ ELEVATED CK	Active	maraviroc BID	335/ [>335]	Grade 4/ Still Present	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Study drug	NO
	Hepatic enzyme increased*/ ELEVATED LIVER ENZYMES	Active	maraviroc BID	335/ [>335]	Grade 3/ Still Present	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Study drug	NO
A4001027 1[redacted]20019 (M/ 3[redacted](YEARS)/ [redacted]							
GASTROINTESTINAL DISORDERS	Nausea*/ NAUSEA	Active	maraviroc BID	256/ 353	Grade 1/ Resolved (15JUL20[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Study drug	NO
	Vomiting*/ VOMITING	Active	maraviroc BID	256/ 353	Grade 1/ Resolved (15JUL20[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Study drug	NO
A4001027 1[redacted]30061 (M/ 4[redacted](YEARS)/ [redacted]							
INVESTIGATIONS	Haemoglobin decreased*/ DECREASED HEMOGLOBIN LEVEL (7.9)	Active	maraviroc BID	19/ 36	Grade 2/ Resolved (14OCT20[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Study drug	NO

Age is at screening
* Treatment-emergent
++ Start Day and Stop Day are start and stop of AE relative to the start of treatment: First day of treatment = Day 1
[] Days in brackets are imputed days derived from incomplete dates.
SAE = Serious Adverse Event (according to Investigators assessment).
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Table 3.1.3.3
Maraviroc Summary of Clinical Safety
Temporary Discontinuations or Dose Reductions Due to Adverse Events
Phase 2b/3 Treatment Experienced Studies

Treatment Group: maraviroc BID

System Organ Class	MedDRA (v9.0) Preferred Term/ INVESTIGATOR ENTRY	Trt Phase	Treatment At Onset	Adverse Event ------- Start Day++/ Stop Day++	SEVERITY/ Outcome	ACTION/ Causality	SAE
INVESTIGATIONS	Haemoglobin decreased*/ DECREASED HEMOGLOBIN LEVEL (8.0)	Active	maraviroc BID	1/ [>1]	Grade 1/ Still Present	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study drug	NO
A4001027 1[redacted]50010 (M/ 4[redacted](YEARS)/ [redacted]							
INFECTIONS AND INFESTATIONS	Meningitis viral*/ VIRAL MENINGITIS	Active	maraviroc BID	93/ 100	Grade 2/ Resolved (28JUN20[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Other event-viral meningitis	YES
A4001027 1[redacted]30002 (M/ 4[redacted](YEARS)/ [redacted]							
BLOOD AND LYMPHATIC SYSTEM DISORDERS	Anaemia*/ ANEMIA	Active	maraviroc BID	49/ 138	Grade 4/ Resolved (02SEP20[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Other event-hematemesis	YES
GASTROINTESTINAL DISORDERS	Varices oesophageal*/ ESOPHAGEAL VARICES	Active	maraviroc BID	49/ 102	Grade 4/ Resolved (28JUL20[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Other event-hematemesis	YES

Age is at screening
* Treatment-emergent
++ Start Day and Stop Day are start and stop of AE relative to the start of treatment: First day of treatment = Day 1
[] Days in brackets are imputed days derived from incomplete dates.
SAE = Serious Adverse Event (according to Investigators assessment).
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Table 3.1.3.3
Maraviroc Summary of Clinical Safety
Temporary Discontinuations or Dose Reductions Due to Adverse Events
Phase 2b/3 Treatment Experienced Studies

Treatment Group: maraviroc BID

System Organ Class	MedDRA (v9.0) Preferred Term/ INVESTIGATOR ENTRY	Trt Phase	Treatment At Onset	Adverse Event ------- Start Day++/ Stop Day++	SEVERITY/ Outcome	ACTION/ Causality	SAE
A4001027 10[redacted]40011 (M/ 5[redacted](YEARS)/ [redacted])							
BLOOD AND LYMPHATIC SYSTEM DISORDERS	Anaemia*/ ANEMIA	Active	maraviroc BID	307/ [>307]	Grade 2/ Still Present	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Concomitant treatment-lotrel, his anti-hypertensive medication	NO
NERVOUS SYSTEM DISORDERS	Dizziness*/ LIGHTHEADEDNESS	Active	maraviroc BID	307/ 342	Grade 2/ Resolved (27JUN20[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Concomitant treatment-lotrel, his anti-hypertensive medication	NO
A4001027 10[redacted]00002 (M/ 4[redacted](YEARS)/ [redacted])							
GASTROINTESTINAL DISORDERS	Dysphagia*/ DYSPHAGIA	Active	maraviroc BID	9/ [>9]	Grade 4/ Still Present	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Other event-unknown	YES

Age is at screening
* Treatment-emergent
++ Start Day and Stop Day are start and stop of AE relative to the start of treatment: First day of treatment = Day 1
[] Days in brackets are imputed days derived from incomplete dates.
SAE = Serious Adverse Event (according to Investigators assessment).
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Maraviroc Summary of Clinical Safety
Temporary Discontinuations or Dose Reductions Due to Adverse Events
Phase 2b/3 Treatment Experienced Studies

Treatment Group: maraviroc BID

System Organ Class	MedDRA (v9.0) Preferred Term/ INVESTIGATOR ENTRY	Trt Phase	Treatment At Onset	Adverse Event ------- Start Day++/ Stop Day++	SEVERITY/ Outcome	ACTION/ Causality	SAE
A4001027 1C[redacted]0025 (M/ 3[redacted](YEARS)/ [redacted])							
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	Rash*/ SKIN ERUPTIONS	Active	maraviroc BID	158/ 179	Grade 1/ Resolved (09JUN2C[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Study drug	NO
A4001027 1C[redacted]0022 (M/ 4[redacted](YEARS)/ [redacted])							
GASTROINTESTINAL DISORDERS	Pancreatitis*/ ASYMPTOMATIC PANCREATITIS	Active	maraviroc BID	57/ [>57]	Grade 2/ Still Present	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Study drug	NO
A4001027 1C[redacted]0025 (M/ 4[redacted](YEARS)/ [redacted])							
INVESTIGATIONS	Blood creatine increased*/ ELEVATED CREATINE	Active	maraviroc BID	112/ [>112]	Grade 2/ Still Present	STUDY DRUG ACTION: (REDUCED)/ Study drug	NO
	Blood potassium increased*/ ELEVATED POTASSIUM	Active	maraviroc BID	112/ [>112]	Grade 2/ Still Present	STUDY DRUG ACTION: (REDUCED)/ Study drug	NO

Age is at screening
* Treatment-emergent
++ Start Day and Stop Day are start and stop of AE relative to the start of treatment: First day of treatment = Day 1
[] Days in brackets are imputed days derived from incomplete dates.
SAE = Serious Adverse Event (according to Investigators assessment).
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Treatment Group: maraviroc BID

System Organ Class	MedDRA (v9.0) Preferred Term/ INVESTIGATOR ENTRY	Trt Phase	Treatment At Onset	Adverse Event ------- Start Day++/ Stop Day++	SEVERITY/ Outcome	ACTION/ Causality	SAE
A4001027 11[redacted]20001 (F/ 3[redacted](YEARS)/ [redacted])							
IMMUNE SYSTEM DISORDERS	Hypersensitivity*/ HYPERSENSITIVITY REACTION	Active	maraviroc BID	8/ 15	Grade 3/ Resolved (20APR2C[redacted])	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Concomitant treatment-abacavir	NO
A4001027 11[redacted]30011 (M/ 4[redacted](YEARS)/ [redacted])							
INVESTIGATIONS	Blood amylase increased*/ ELEVATED AMYLASE	Active	maraviroc BID	29/ 34	Grade 4/ Resolved (22AUG2C[redacted])	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Concomitant treatment-didanosine	YES
	Lipase increased*/ ELEVATED LIPASE	Active	maraviroc BID	29/ 34	Grade 4/ Resolved (22AUG2C[redacted])	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Concomitant treatment-didanosine	YES
A4001027 11[redacted]30001 (F/ 4[redacted](YEARS)/ [redacted])							

Age is at screening
* Treatment-emergent
++ Start Day and Stop Day are start and stop of AE relative to the start of treatment: First day of treatment = Day 1
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SAE = Serious Adverse Event (according to Investigators assessment).
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Table 3.1.3.3
Maraviroc Summary of Clinical Safety
Temporary Discontinuations or Dose Reductions Due to Adverse Events
Phase 2b/3 Treatment Experienced Studies

Treatment Group: maraviroc BID

System Organ Class	MedDRA (v9.0) Preferred Term/ INVESTIGATOR ENTRY	Trt Phase	Treatment At Onset	Adverse Event ------- Start Day++/ Stop Day++	SEVERITY/ Outcome	ACTION/ Causality	SAE
GASTROINTESTINAL DISORDERS	Nausea*/ HOSPITALIZED FOR WORSENING NAUSEA	Active	maraviroc BID	18/ 21	Grade 3/ Resolved (13MAR2[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Other event-progressive mulitfocal leukoencephalopathy	YES
INFECTIONS AND INFESTATIONS	Progressive multifocal leukoencephalopathy*/ PROGRESSIVE MULTIFOCAL LEUKOENCEPHALOPATHY	Active	maraviroc BID	11/ [>11]	Grade 3/ Still Present	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Disease under study	YES
METABOLISM AND NUTRITION DISORDERS	Dehydration*/ HOSPITALIZED FOR DEHYDRATION	Active	maraviroc BID	9/ [>9]	Grade 3/ Still Present	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Other event-progressive multifocal leukoencephalopathy	YES
A4001027 11[redacted]0009 (F/ 9[redacted](YEARS)/ [redacted]							
INVESTIGATIONS	Alanine aminotransferase increased*/ ELEVATED ALT	Active	maraviroc BID	147/ [>147]	Grade 3/ Still Present	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Study drug	NO
	Aspartate aminotransferase increased*/ ELEVATED AST	Active	maraviroc BID	147/ [>147]	Grade 3/ Still Present	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Study drug	NO

Age is at screening
* Treatment-emergent
++ Start Day and Stop Day are start and stop of AE relative to the start of treatment: First day of treatment = Day 1
[] Days in brackets are imputed days derived from incomplete dates.
SAE = Serious Adverse Event (according to Investigators assessment).
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Table 3.1.3.3
Maraviroc Summary of Clinical Safety
Temporary Discontinuations or Dose Reductions Due to Adverse Events
Phase 2b/3 Treatment Experienced Studies

Treatment Group: maraviroc BID

System Organ Class	MedDRA (v9.0) Preferred Term/ INVESTIGATOR ENTRY	Trt Phase	Treatment At Onset	Adverse Event ------- Start Day++/ Stop Day++	SEVERITY/ Outcome	ACTION/ Causality	SAE
INVESTIGATIONS	Gamma-glutamyltransferase increased*/ ELEVATED GGT	Active	maraviroc BID	147/ [>147]	Grade 4/ Still Present	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Study drug	NO
A4001028 1[redacted]0003 (M/ 5[redacted](YEARS)/ [redacted]							
GASTROINTESTINAL DISORDERS	Nausea*/ NAUSEA	Active	maraviroc BID	20/ 44	Grade 2/ Resolved (01JUN20[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Study drug	NO
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	Pyrexia*/ FEVER	Active	maraviroc BID	21/ 44	Grade 3/ Resolved (01JUN20[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Other event-mycobacterial infection	YES
INFECTIONS AND INFESTATIONS	Mycoplasma infection*/ MYCOPLASMA INFECTION	Active	maraviroc BID	20/ 58	Grade 3/ Resolved (15JUN20[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Other event-mycoplasma infection	YES
INVESTIGATIONS	Weight decreased*/ WEIGHT LOSS	Active	maraviroc BID	20/ 44	Grade 2/ Resolved (01JUN20[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Other event-mycobacterial infection	YES

Age is at screening
* Treatment-emergent
++ Start Day and Stop Day are start and stop of AE relative to the start of treatment: First day of treatment = Day 1
[] Days in brackets are imputed days derived from incomplete dates.
SAE = Serious Adverse Event (according to Investigators assessment).
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Maraviroc Summary of Clinical Safety
Temporary Discontinuations or Dose Reductions Due to Adverse Events
Phase 2b/3 Treatment Experienced Studies

Treatment Group: maraviroc BID

System Organ Class	MedDRA (v9.0) Preferred Term/ INVESTIGATOR ENTRY	Trt Phase	Treatment At Onset	Adverse Event ------- Start Day++/ Stop Day++	SEVERITY/ Outcome	ACTION/ Causality	SAE
METABOLISM AND NUTRITION DISORDERS	Anorexia*/ ANOREXIA	Active	maraviroc BID	20/ 44	Grade 2/ Resolved (01JUN2[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Study drug	NO
NERVOUS SYSTEM DISORDERS	Headache*/ HEADACHE	Active	maraviroc BID	20/ 23	Grade 1/ Resolved (11MAY2[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Study drug	NO
A4001028 1[redacted]10005 (F/ 3[redacted](YEARS)/ [redacted]							
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	Rash*/ SKIN RASH	Active	maraviroc BID	13/ 20	Grade 2/ Resolved (31JUL2[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Study drug	NO
A4001028 1[redacted]90003 (M/ 4[redacted](YEARS)/ [redacted]							
INVESTIGATIONS	Alanine aminotransferase increased*/ HIGH RESULTS OF ALT	Active	maraviroc BID	283/ [>283]	Grade 2/ Still Present	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Study drug	NO
	Aspartate aminotransferase increased*/ HIGH RESULTS OF AST	Active	maraviroc BID	283/ [>283]	Grade 2/ Still Present	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Study drug	NO

Age is at screening
* Treatment-emergent
++ Start Day and Stop Day are start and stop of AE relative to the start of treatment: First day of treatment = Day 1
[] Days in brackets are imputed days derived from incomplete dates.
SAE = Serious Adverse Event (according to Investigators assessment).
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Table 3.1.3.3
Maraviroc Summary of Clinical Safety
Temporary Discontinuations or Dose Reductions Due to Adverse Events
Phase 2b/3 Treatment Experienced Studies

Treatment Group: maraviroc BID

System Organ Class	MedDRA (v9.0) Preferred Term/ INVESTIGATOR ENTRY	Trt Phase	Treatment At Onset	Adverse Event ------- Start Day++/ Stop Day++	SEVERITY/ Outcome	ACTION/ Causality	SAE
INVESTIGATIONS	Gamma-glutamyltransferase increased*/ HIGH RESULTS OF GGT	Active	maraviroc BID	283/ [>283]	Grade 2/ Still Present	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Study drug	NO
A4001028 1[redacted]0001 (M/ 5[redacted](YEARS)/ [redacted]							
GASTROINTESTINAL DISORDERS	Nausea*/ INCREASED NAUSEA	Active	maraviroc BID	22/ 57	Grade 3/ Resolved (01JUN20[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Study drug	YES
	Vomiting*/ INCREASED VOMITING	Active	maraviroc BID	22/ 57	Grade 3/ Resolved (01JUN20[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Study drug	YES
A4001028 1[redacted]20001 (M/ 3[redacted](YEARS)/ [redacted]							
GASTROINTESTINAL DISORDERS	Vomiting*/ VOMITING	Active	maraviroc BID	300/ 308	Grade 1/ Resolved (13MAR20[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Other event-unknown	YES
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	Back pain*/ UPPER LUMBAR SACRAL TENDERNESS	Active	maraviroc BID	289/ [>289]	Grade 2/ Still Present	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Other event-unknown	NO

Age is at screening
* Treatment-emergent
++ Start Day and Stop Day are start and stop of AE relative to the start of treatment: First day of treatment = Day 1
[] Days in brackets are imputed days derived from incomplete dates.
SAE = Serious Adverse Event (according to Investigators assessment).
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Table 3.1.3.3
Maraviroc Summary of Clinical Safety
Temporary Discontinuations or Dose Reductions Due to Adverse Events
Phase 2b/3 Treatment Experienced Studies

Treatment Group: maraviroc BID

System Organ Class	MedDRA (v9.0) Preferred Term/ INVESTIGATOR ENTRY	Trt Phase	Treatment At Onset	Adverse Event ------- Start Day++/ Stop Day++	SEVERITY/ Outcome	ACTION/ Causality	SAE
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	Flank pain*/ FLANK PAIN	Active	maraviroc BID	289/ [>289]	Grade 4/ Still Present	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Other event-unknown	YES
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	Night sweats*/ NIGHT SWEATS	Active	maraviroc BID	296/ [>296]	Grade 1/ Still Present	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Study drug	NO
A4001028 1[redacted]10008 (M/ 4[redacted](YEARS)/ [redacted]							
RENAL AND URINARY DISORDERS	Renal colic*/ RENAL COLIC	Active	maraviroc BID	77/ 77	Grade 3/ Resolved (01SEP20[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Concomitant treatment-obt - intolerance to indinavir	NO
A4001028 11[redacted]0004 (M/ 6[redacted](YEARS)/ [redacted]							
INVESTIGATIONS	Hepatic enzyme increased* / ELEVATED LIVER ENZYMES	Active	maraviroc BID	150/ [>150]	Grade 2/ Still Present	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Study drug	YES

Age is at screening
* Treatment-emergent
++ Start Day and Stop Day are start and stop of AE relative to the start of treatment: First day of treatment = Day 1
[] Days in brackets are imputed days derived from incomplete dates.
SAE = Serious Adverse Event (according to Investigators assessment).
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Maraviroc Summary of Clinical Safety
Temporary Discontinuations or Dose Reductions Due to Adverse Events
Phase 2b/3 Treatment Experienced Studies

Treatment Group: maraviroc BID

System Organ Class	MedDRA (v9.0) Preferred Term/ INVESTIGATOR ENTRY	Trt Phase	Treatment At Onset	Adverse Event ------- Start Day++/ Stop Day++	SEVERITY/ Outcome	ACTION/ Causality	SAE
A4001028 11[redacted]0002 (M/ 4[redacted](YEARS)/ [redacted])							
INFECTIONS AND INFESTATIONS	Gastroenteritis*/ GASTROENTERITIS	Active	maraviroc BID	150/ 156	Grade 2/ Resolved (29OCT2[redacted])	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Other event-food poisoning	NO
A4001028 11[redacted]0013 (M/ 4[redacted](YEARS)/ [redacted])							
GASTROINTESTINAL DISORDERS	Abdominal pain upper*/ MID EPIGASTRIC PAIN	Active	maraviroc BID	40/ 42	Grade 2/ Resolved (10APR2[redacted])	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Study drug	NO
	Abdominal pain upper*/ STOMACH ACHE	Active	maraviroc BID	20/ 20	Grade 1/ Resolved (19MAR2[redacted])	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Other event-subject questions food he ate	NO
A4001028 11[redacted]0004 (M/ 4[redacted](YEARS)/ [redacted])							

Age is at screening
* Treatment-emergent
++ Start Day and Stop Day are start and stop of AE relative to the start of treatment: First day of treatment = Day 1
[] Days in brackets are imputed days derived from incomplete dates.
SAE = Serious Adverse Event (according to Investigators assessment).
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Table 3.1.3.3
Maraviroc Summary of Clinical Safety
Temporary Discontinuations or Dose Reductions Due to Adverse Events
Phase 2b/3 Treatment Experienced Studies

Treatment Group: maraviroc BID

System Organ Class	MedDRA (v9.0) Preferred Term/ INVESTIGATOR ENTRY	Trt Phase	Treatment At Onset	Adverse Event ------- Start Day++/ Stop Day++	SEVERITY/ Outcome	ACTION/ Causality	SAE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	Febrile neutropenia*/ FEBRILE NEUTROPENIA	Active	maraviroc BID	23/ 26	Grade 2/ Resolved (27MAR2[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Concomitant treatment-tipranovir	YES
	Neutropenia*/ NEUTROPENIA	Active	maraviroc BID	23/ 34	Grade 4/ Resolved (04APR2[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Concomitant treatment-tipranovir	YES
GASTROINTESTINAL DISORDERS	Diarrhoea*/ URGENT DIARRHEA	Active	maraviroc BID	23/ 29	Grade 2/ Resolved (30MAR2[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Other event-history of diarrhea that has increased in urgency	YES
INVESTIGATIONS	Weight decreased*/ WEIGHT LOSS	Active	maraviroc BID	23/ 29	Grade 1/ Resolved (30MAR2[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Other event-related to increased diarrhea	YES
A4001028 12[redacted]0004 (M/ 6[redacted](YEARS)/ [redacted]							
INVESTIGATIONS	Aspartate aminotransferase increased*/ AST ELEVATION	Active	maraviroc BID	15/ 22	Grade 4/ Resolved (04APR2[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Study drug	NO

Age is at screening
* Treatment-emergent
++ Start Day and Stop Day are start and stop of AE relative to the start of treatment: First day of treatment = Day 1
[] Days in brackets are imputed days derived from incomplete dates.
SAE = Serious Adverse Event (according to Investigators assessment).
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Maraviroc Summary of Clinical Safety
Temporary Discontinuations or Dose Reductions Due to Adverse Events
Phase 2b/3 Treatment Experienced Studies

Treatment Group: maraviroc BID

System Organ Class	MedDRA (v9.0) Preferred Term/ INVESTIGATOR ENTRY	Trt Phase	Treatment At Onset	Adverse Event ------- Start Day++/ Stop Day++	SEVERITY/ Outcome	ACTION/ Causality	SAE
INVESTIGATIONS	Blood creatine phosphokinase increased*/ ELEVATED CREATININE KINASE	Active	maraviroc BID	15/ 22	Grade 4/ Resolved (04APR20[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Study drug	NO
A4001028 12[redacted]50010 (M/ 5[redacted](YEARS)/ [redacted]							
BLOOD AND LYMPHATIC SYSTEM DISORDERS	Lymphadenopathy*/ ADENOPATHY	Active	maraviroc BID	10/ 21	Grade 2/ Resolved (16APR20[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Other event-viral syndrome	NO
INFECTIONS AND INFESTATIONS	Pharyngitis*/ PHARYNGITIS	Active	maraviroc BID	10/ 21	Grade 2/ Resolved (16APR20[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Other event-viral syndrome	NO
A4001029 10[redacted]30003 (M/ 4[redacted](YEARS)/ [redacted]							
CARDIAC DISORDERS	Myocardial infarction*/ MYOCARDIAL INFARCTION	Active	maraviroc BID	163/ 224	Grade 3/ Resolved (14NOV20[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Other event-related to atherosclerosis	YES

Age is at screening
* Treatment-emergent
++ Start Day and Stop Day are start and stop of AE relative to the start of treatment: First day of treatment = Day 1
[] Days in brackets are imputed days derived from incomplete dates.
SAE = Serious Adverse Event (according to Investigators assessment).
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Maraviroc Summary of Clinical Safety
Temporary Discontinuations or Dose Reductions Due to Adverse Events
Phase 2b/3 Treatment Experienced Studies

Treatment Group: maraviroc BID

System Organ Class	MedDRA (v9.0) Preferred Term/ INVESTIGATOR ENTRY	Trt Phase	Treatment At Onset	Adverse Event ------- Start Day++/ Stop Day++	SEVERITY/ Outcome	ACTION/ Causality	SAE
A4001029 11[redacted]30002 (M/ 4[redacted](YEARS)/ [redacted]							
INFECTIONS AND INFESTATIONS	Gastroenteritis viral*/ VIRAL GASTROENTERITIS	Active	maraviroc BID	19/ 27	Grade 2/ Resolved (26APR2[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Other event-probably food origin.	YES
A4001029 11[redacted]40002 (M/ 4[redacted](YEARS)/ [redacted]							
GASTROINTESTINAL DISORDERS	Oral mucosal blistering*/ MOUTH BLISTERS	Active	maraviroc BID	101/ [>101]	Grade 2/ Still Present	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Study drug	NO
A4001029 12[redacted]30002 (M/ 4[redacted](YEARS)/ [redacted]							
INFECTIONS AND INFESTATIONS	Candidiasis*/ THRUSH	Active	maraviroc BID	108/ 115	Grade 2/ Resolved (07MAY2[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Disease under study	NO

Age is at screening
* Treatment-emergent
++ Start Day and Stop Day are start and stop of AE relative to the start of treatment: First day of treatment = Day 1
[] Days in brackets are imputed days derived from incomplete dates.
SAE = Serious Adverse Event (according to Investigators assessment).
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Table 3.1.3.3
Maraviroc Summary of Clinical Safety
Temporary Discontinuations or Dose Reductions Due to Adverse Events
Phase 2b/3 Treatment Experienced Studies

Treatment Group: maraviroc BID

System Organ Class	MedDRA (v9.0) Preferred Term/ INVESTIGATOR ENTRY	Trt Phase	Treatment At Onset	Adverse Event ------- Start Day++/ Stop Day++	SEVERITY/ Outcome	ACTION/ Causality	SAE
A4001029 12[redacted]0005 (M/ 4[redacted](YEARS)/ [redacted])							
INFECTIONS AND INFESTATIONS	Pneumonia/ PNEUMONIA	Post	maraviroc BID	6/ 8	Grade 2/ Resolved (25JUN2[redacted])	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Disease under study	YES
A4001029 12[redacted]0006 (M/ 5[redacted](YEARS)/ [redacted])							
METABOLISM AND NUTRITION DISORDERS	Hypercholesterolaemia*/ HYPERCHOLESTEROLEMIA	Active	maraviroc BID	183/ 197	Grade 4/ Resolved (21NOV2[redacted])	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Concomitant treatment-lopinavir/ritonavir	NO
	Hypertriglyceridaemia*/ HYPERTRIGLYCERIDEMIA	Active	maraviroc BID	183/ 197	Grade 4/ Resolved (21NOV2[redacted])	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Concomitant treatment-lopinavir/ritonavir	NO

Age is at screening
* Treatment-emergent
++ Start Day and Stop Day are start and stop of AE relative to the start of treatment: First day of treatment = Day 1
[] Days in brackets are imputed days derived from incomplete dates.
SAE = Serious Adverse Event (according to Investigators assessment).
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Maraviroc Summary of Clinical Safety
Temporary Discontinuations or Dose Reductions Due to Adverse Events
Phase 2b/3 Treatment Experienced Studies

Treatment Group: Placebo

System Organ Class	MedDRA (v9.0) Preferred Term/ INVESTIGATOR ENTRY	Trt Phase	Treatment At Onset	Adverse Event ------- Start Day++/ Stop Day++	SEVERITY/ Outcome	ACTION/ Causality	SAE
A4001027 1C[redacted]70022 (M/ 5[redacted](YEARS)/ [redacted])							
INFECTIONS AND INFESTATIONS	Lobar pneumonia*/ LOWER LOBE PNEUMONIA	Active	Placebo	19/ 28	Grade 3/ Resolved (02MAR20[redacted])	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Disease under study	YES
A4001027 1C[redacted]00015 (F/ 5[redacted](YEARS)/ [redacted])							
NERVOUS SYSTEM DISORDERS	Memory impairment*/ LOSS OF SOME MEMORY FUNCTION	Active	Placebo	4/ 23	Grade 2/ Resolved (02MAR20[redacted])	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Concomitant treatment-multiple medications	YES
A4001027 1C[redacted]10009 (F/ 4[redacted](YEARS)/ [redacted])							
GASTROINTESTINAL DISORDERS	Pancreatitis*/ PANCREATITIS	Active	Placebo	56/ 63	Grade 4/ Resolved (07SEP20[redacted])	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Concomitant treatment-TM2# and ddi ec	YES

Age is at screening
* Treatment-emergent
++ Start Day and Stop Day are start and stop of AE relative to the start of treatment: First day of treatment = Day 1
[] Days in brackets are imputed days derived from incomplete dates.
SAE = Serious Adverse Event (according to Investigators assessment).
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

#:新薬承認情報提供時に置換えた。
TM2#はlopinavir/ritonavirを示す。

Table 3.1.3.3
Maraviroc Summary of Clinical Safety
Temporary Discontinuations or Dose Reductions Due to Adverse Events
Phase 2b/3 Treatment Experienced Studies

Treatment Group: Placebo

System Organ Class	MedDRA (v9.0) Preferred Term/ INVESTIGATOR ENTRY	Trt Phase	Treatment At Onset	Adverse Event ------- Start Day++/ Stop Day++	SEVERITY/ Outcome	ACTION/ Causality	SAE
A4001027 1C[redacted]0001 (M/ 3[redacted](YEARS)/ [redacted]							
BLOOD AND LYMPHATIC SYSTEM DISORDERS	Anaemia*/ ANEMIA	Active	Placebo	30/ 57	Grade 2/ Resolved (15MAR2C[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Other event-anemia of chronic disease	YES
A4001028 1C[redacted]0005 (M/ 4[redacted](YEARS)/ [redacted]							
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	Overdose*/ OVERDOSE	Active	Placebo	1/ 58	Grade 3/ Resolved (17NOV2C[redacted]	STUDY DRUG ACTION: (REDUCED)/ Other event-pt was on dose of 300 mg instead of 150 mg till wk 8.	YES
A4001028 1C[redacted]0003 (M/ 3[redacted](YEARS)/ [redacted]							
INFECTIONS AND INFESTATIONS	Pneumonia bacterial*/ BACTERIAL PNEUMONIA	Active	Placebo	10/ 17	Grade 4/ Resolved (05DEC2C[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Other event-bacterial pneumonia	YES

Age is at screening
* Treatment-emergent
++ Start Day and Stop Day are start and stop of AE relative to the start of treatment: First day of treatment = Day 1
[] Days in brackets are imputed days derived from incomplete dates.
SAE = Serious Adverse Event (according to Investigators assessment).
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Maraviroc Summary of Clinical Safety
Temporary Discontinuations or Dose Reductions Due to Adverse Events
Phase 2b/3 Treatment Experienced Studies

Treatment Group: Placebo

System Organ Class	MedDRA (v9.0) Preferred Term/ INVESTIGATOR ENTRY	Trt Phase	Treatment At Onset	Adverse Event ------- Start Day++/ Stop Day++	SEVERITY/ Outcome	ACTION/ Causality	SAE
A4001028 1[redacted]10002 (M/ 3[redacted](YEARS)/ [redacted])							
GASTROINTESTINAL DISORDERS	Diarrhoea*/ WORSENING OF DIARRHOEA	Active	Placebo	5/ 6	Grade 2/ Resolved (23APR20[redacted])	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Concomitant treatment-ritonavir	NO
	Nausea*/ NAUSEA	Active	Placebo	1/ 12	Grade 1/ Resolved (29APR20[redacted])	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Concomitant treatment-ritonavir	NO
	Vomiting*/ VOMITING	Active	Placebo	5/ 6	Grade 2/ Resolved (23APR20[redacted])	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Concomitant treatment-ritonavir	NO
A4001028 1[redacted]10003 (M/ 4[redacted](YEARS)/ [redacted])							
HEPATOBILIARY DISORDERS	Cytolytic hepatitis*/ HEPATIC CYTOLYSIS	Active	Placebo	28/ 37	Grade 3/ Resolved (01DEC20[redacted])	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Study drug	NO

Age is at screening
* Treatment-emergent
++ Start Day and Stop Day are start and stop of AE relative to the start of treatment: First day of treatment = Day 1
[] Days in brackets are imputed days derived from incomplete dates.
SAE = Serious Adverse Event (according to Investigators assessment).
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Treatment Group: Placebo

System Organ Class	MedDRA (v9.0) Preferred Term/ INVESTIGATOR ENTRY	Trt Phase	Treatment At Onset	Adverse Event ------- Start Day++/ Stop Day++	SEVERITY/ Outcome	ACTION/ Causality	SAE
A4001028 1C[redacted]0013 (M/ 4[redacted](YEARS)/ [redacted])							
CARDIAC DISORDERS	Aortic valve disease*/ WORSENING AORTIC VALVULAR DEFECT	Active	Placebo	186/ [>186]	Grade 3/ Still Present	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Other event-patient history aortic valvula defect	YES
A4001028 1C[redacted]0014 (M/ 4[redacted](YEARS)/ [redacted])							
HEPATOBILIARY DISORDERS	Hyperbilirubinaemia*/ HYPERBILIRUBINEMIA	Active	Placebo	12/ 200	Grade 4/ Resolved (13MAR20[redacted])	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Concomitant treatment-obt-atazanavir and ritonavir	NO
A4001028 1C[redacted]0004 (M/ 5[redacted](YEARS)/ [redacted])							
GASTROINTESTINAL DISORDERS	Flatulence*/ FLATULENCE	Active	Placebo	145/ 188	Grade 2/ Resolved (14FEB20[redacted])	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Study drug	NO

Age is at screening
* Treatment-emergent
++ Start Day and Stop Day are start and stop of AE relative to the start of treatment: First day of treatment = Day 1
[] Days in brackets are imputed days derived from incomplete dates.
SAE = Serious Adverse Event (according to Investigators assessment).
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Table 3.1.3.3
Maraviroc Summary of Clinical Safety
Temporary Discontinuations or Dose Reductions Due to Adverse Events
Phase 2b/3 Treatment Experienced Studies

Treatment Group: Placebo

System Organ Class	MedDRA (v9.0) Preferred Term/ INVESTIGATOR ENTRY	Trt Phase	Treatment At Onset	Adverse Event ------- Start Day++/ Stop Day++	SEVERITY/ Outcome	ACTION/ Causality	SAE
A4001028 1[redacted]0015 (F/ 4[redacted](YEARS)/ [redacted])							
HEPATOBILIARY DISORDERS	Hepatitis toxic*/ TOXIC HEPATITIS	Active	Placebo	58/ 149	Grade 4/ Resolved (24AUG20[redacted])	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Concomitant treatment-tipranavir	NO
A4001028 1[redacted]0005 (M/ 9[redacted](YEARS)/ [redacted])							
GASTROINTESTINAL DISORDERS	Diarrhoea*/ DIARRHOEA	Active	Placebo	274/ 278	Grade 1/ Resolved (09APR20[redacted])	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Study drug	NO
	Vomiting*/ VOMITING	Active	Placebo	274/ 274	Grade 1/ Resolved (05APR20[redacted])	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Other event-viral cause	NO
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	Pyrexia*/ FEVER	Active	Placebo	142/ 163	Grade 1/ Resolved (15DEC20[redacted])	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Disease under study	NO

Age is at screening
* Treatment-emergent
++ Start Day and Stop Day are start and stop of AE relative to the start of treatment: First day of treatment = Day 1
[] Days in brackets are imputed days derived from incomplete dates.
SAE = Serious Adverse Event (according to Investigators assessment).
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Table 3.1.3.3
Maraviroc Summary of Clinical Safety
Temporary Discontinuations or Dose Reductions Due to Adverse Events
Phase 2b/3 Treatment Experienced Studies

Treatment Group: Placebo

System Organ Class	MedDRA (v9.0) Preferred Term/ INVESTIGATOR ENTRY	Trt Phase	Treatment At Onset	Adverse Event ------- Start Day++/ Stop Day++	SEVERITY/ Outcome	ACTION/ Causality	SAE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	Pyrexia*/ FEVER	Active	Placebo	263/ 264	Grade 3/ Resolved (26MAR20[redacted])	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Disease under study	YES
INFECTIONS AND INFESTATIONS	Gastroenteritis*/ GASTROENTERITIS	Active	Placebo	274/ 280	Grade 3/ Resolved (11APR20[redacted])	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Other event-viral	NO
RENAL AND URINARY DISORDERS	Renal failure acute*/ ACUTE RENAL FAILURE	Active	Placebo	263/ 283	Grade 4/ Resolved (14APR20[redacted])	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Study drug	YES
A4001028 12[redacted]50005 (M/ 4[redacted](YEARS)/ [redacted]							
EAR AND LABYRINTH DISORDERS	Ear disorder*/ THROBBING IN EARS	Active	Placebo	21/ 38	Grade 2/ Resolved (30APR20[redacted])	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Concomitant treatment-secondary to obt, efavirenz	NO
NERVOUS SYSTEM DISORDERS	Dizziness*/ LIGHTHEADEDNESS	Active	Placebo	21/ 38	Grade 2/ Resolved (30APR20[redacted])	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Concomitant treatment-secondary to obt, efavirenz	NO

Age is at screening
* Treatment-emergent
++ Start Day and Stop Day are start and stop of AE relative to the start of treatment: First day of treatment = Day 1
[] Days in brackets are imputed days derived from incomplete dates.
SAE = Serious Adverse Event (according to Investigators assessment).
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Table 3.1.3.3
Maraviroc Summary of Clinical Safety
Temporary Discontinuations or Dose Reductions Due to Adverse Events
Phase 2b/3 Treatment Experienced Studies

Treatment Group: Placebo

System Organ Class	MedDRA (v9.0) Preferred Term/ INVESTIGATOR ENTRY	Trt Phase	Treatment At Onset	Adverse Event ------- Start Day++/ Stop Day++	SEVERITY/ Outcome	ACTION/ Causality	SAE
A4001029 1C[redacted]0004 (M/ 5[redacted](YEARS)/ [redacted]							
GASTROINTESTINAL DISORDERS	Diarrhoea*/ DIARRHEA	Active	Placebo	8/ 15	Grade 4/ Resolved (10MAY20[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Concomitant treatment-other arv (lopinavir/ritonavir#)	YES
METABOLISM AND NUTRITION DISORDERS	Anorexia*/ ANOREXIA	Active	Placebo	8/ [>8]	Grade 4/ Still Present	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Other event-candidiasis	YES
A4001029 1C[redacted]0003 (M/ 3[redacted](YEARS)/ [redacted]							
BLOOD AND LYMPHATIC SYSTEM DISORDERS	Neutropenia*/ NEUTROPENIA	Active	Placebo	28/ 32	Grade 2/ Resolved (21APR20[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Disease under study	YES
A4001029 1C[redacted]0002 (M/ 4[redacted](YEARS)/ [redacted]							

Age is at screening
* Treatment-emergent
++ Start Day and Stop Day are start and stop of AE relative to the start of treatment: First day of treatment = Day 1
[] Days in brackets are imputed days derived from incomplete dates.
SAE = Serious Adverse Event (according to Investigators assessment).
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

※ 新薬承認情報提供時に置換えた。

Maraviroc Summary of Clinical Safety
Temporary Discontinuations or Dose Reductions Due to Adverse Events
Phase 2b/3 Treatment Experienced Studies

Treatment Group: Placebo

System Organ Class	MedDRA (v9.0) Preferred Term/ INVESTIGATOR ENTRY	Trt Phase	Treatment At Onset	Adverse Event ------- Start Day++/ Stop Day++	SEVERITY/ Outcome	ACTION/ Causality	SAE
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	Swelling face*/ FACIAL SWELLING	Active	Placebo	100/ 107	Grade 2/ Resolved (17AUG20[redacted])	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Other event-response to allergic reaction	NO
A4001029 11[redacted]10001 (M/ 4[redacted](YEARS)/ [redacted])							
GASTROINTESTINAL DISORDERS	Aphthous stomatitis*/ ORAL APHTHA	Active	Placebo	12/ 20	Grade 1/ Resolved (19JUL20[redacted])	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Study drug	NO
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	Malaise*/ MALAISE	Active	Placebo	12/ 15	Grade 1/ Resolved (14JUL20[redacted])	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Study drug	NO
	Pyrexia*/ FEVER	Active	Placebo	12/ 15	Grade 1/ Resolved (14JUL20[redacted])	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Study drug	NO
NERVOUS SYSTEM DISORDERS	Paraesthesia oral*/ PERIORAL PARESTHESIA	Active	Placebo	12/ 20	Grade 1/ Resolved (19JUL20[redacted])	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Study drug	NO
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	Pruritus*/ PRURITUS	Active	Placebo	12/ 20	Grade 1/ Resolved (19JUL20[redacted])	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Study drug	NO

Age is at screening
* Treatment-emergent
++ Start Day and Stop Day are start and stop of AE relative to the start of treatment: First day of treatment = Day 1
[] Days in brackets are imputed days derived from incomplete dates.
SAE = Serious Adverse Event (according to Investigators assessment).
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Table 3.1.3.3
Maraviroc Summary of Clinical Safety
Temporary Discontinuations or Dose Reductions Due to Adverse Events
Phase 2b/3 Treatment Experienced Studies

Treatment Group: Placebo

System Organ Class	MedDRA (v9.0) Preferred Term/ INVESTIGATOR ENTRY	Trt Phase	Treatment At Onset	Adverse Event ------- Start Day++/ Stop Day++	SEVERITY/ Outcome	ACTION/ Causality	SAE
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	Rash*/ RASH	Active	Placebo	12/ 20	Grade 2/ Resolved (19JUL2[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Study drug	NO
A4001029 12[redacted]40001 (M/ 9[redacted](YEARS)/ [redacted]							
GASTROINTESTINAL DISORDERS	Abdominal discomfort*/ INTERMITTENT ABDOMINAL DISCOMFORT	Active	Placebo	170/ [>170]	Grade 2/ Still Present	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Concomitant treatment-ddi	NO
	Dry mouth*/ DRY MOUTH	Active	Placebo	170/ [>170]	Grade 2/ Still Present	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Study drug	NO
	Nausea*/ INTERMITTENT NAUSEA	Active	Placebo	170/ [>170]	Grade 2/ Still Present	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Concomitant treatment-ddi	NO

Age is at screening
* Treatment-emergent
++ Start Day and Stop Day are start and stop of AE relative to the start of treatment: First day of treatment = Day 1
[] Days in brackets are imputed days derived from incomplete dates.
SAE = Serious Adverse Event (according to Investigators assessment).
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Maraviroc Summary of Clinical Safety
Discontinuation from Study
Phase 3 Treatment Experienced CCR5 Tropic Studies

Number (%) of Subjects	maraviroc QD 414		maraviroc BID 426		Placebo 209	
Discontinuations						
Subject Died	3	(0.7)	5	(1.2)	1	(0.5)
Related to Study Drug	93	(22.5)	101	(23.7)	111	(53.1)
Adverse event	12	(2.9)	10	(2.3)	5	(2.4)
Lack of efficacy	81	(19.6)	91	(21.4)	106	(50.7)
Not Related to Study Drug	47	(11.4)	32	(7.5)	21	(10.0)
Adverse event	4	(1.0)	6	(1.4)	3	(1.4)
Other	12	(2.9)	4	(0.9)	5	(2.4)
Subject defaulted	31	(7.5)	22	(5.2)	13	(6.2)
Total	143	(34.5)	138	(32.4)	133	(63.6)

Subject defaulted means Subject no longer willing to participate in study or Lost to follow-up.

Maraviroc Summary of Clinical Safety
Discontinuations from Study due to Adverse Events
Phase 3 Treatment Experienced CCR5 Tropic Studies

Treatment Group: maraviroc QD

System Organ Class	MedDRA (v9.0) Preferred Term/ INVESTIGATOR ENTRY	Trt Phase	Treatment At Onset	Adverse Event ------- Start Day++/ Stop Day++	SEVERITY/ Outcome	ACTION/ Causality	SAE
A4001027 1[redacted]0001 (F/ [redacted](YEARS)/ [redacted])							
GASTROINTESTINAL DISORDERS	Abdominal distension*/ ABDOMINAL BLOATING	Active	maraviroc QD	1/ 111	Grade 2/ Resolved (01AUG2[redacted])	STUDY DRUG ACTION: (PERMANENTLY DISCONTINUED) SUBJECT ACTION: (D/C STUDY)/ Study drug	NO
A4001027 1[redacted]0008 (M/ [redacted](YEARS)/ [redacted])							
HEPATOBILIARY DISORDERS	Hepatic failure*/ HEPATIC FAILURE	Active	maraviroc QD	35/ 42	Grade 4/ Resolved (13JAN2[redacted])	STUDY DRUG ACTION: (PERMANENTLY DISCONTINUED) SUBJECT ACTION: (D/C STUDY)/ Other event-possibly r/t to recreational drug use interaction with arv's	YES

Age is at screening.
++ Day relative to first day of each treatment period. First day of each treatment period = day 1
* Treatment-emergent
[] Values in brackets are imputed from incomplete dates and times.
SAE = Serious Adverse Event (according to Investigators assessment).
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Table 3.1.4.2
Maraviroc Summary of Clinical Safety
Discontinuations from Study due to Adverse Events
Phase 3 Treatment Experienced CCR5 Tropic Studies

Treatment Group: maraviroc QD

System Organ Class	MedDRA (v9.0) Preferred Term/ INVESTIGATOR ENTRY	Trt Phase	Treatment At Onset	Adverse Event ------- Start Day++/ Stop Day++	SEVERITY/ Outcome	ACTION/ Causality	SAE
A4001027 10[redacted]0014 (M/ 6[redacted](YEARS)/ [redacted]							
INVESTIGATIONS	Alanine aminotransferase increased*/ ELEVATED ALT	Active	maraviroc QD	58/ 66	Grade 3/ Resolved (05JUN2[redacted])	STUDY DRUG ACTION: (PERMANENTLY DISCONTINUED) SUBJECT ACTION: (D/C STUDY)/ Concomitant treatment-obt: possibly tipranavir.	NO
A4001027 10[redacted]0008 (M/ 5[redacted](YEARS)/ [redacted]							
INVESTIGATIONS	Aspartate aminotransferase increased*/ ELEVATED AST	Active	maraviroc QD	28/ [>28]	Grade 3/ Still Present	STUDY DRUG ACTION: (PERMANENTLY DISCONTINUED) SUBJECT ACTION: (D/C STUDY)/ Study drug	NO

Age is at screening.
++ Day relative to first day of each treatment period. First day of each treatment period = day 1
* Treatment-emergent
[] Values in brackets are imputed from incomplete dates and times.
SAE = Serious Adverse Event (according to Investigators assessment).
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Maraviroc Summary of Clinical Safety
Discontinuations from Study due to Adverse Events
Phase 3 Treatment Experienced CCR5 Tropic Studies

Treatment Group: maraviroc QD

System Organ Class	MedDRA (v9.0) Preferred Term/ INVESTIGATOR ENTRY	Trt Phase	Treatment At Onset	Adverse Event ------- Start Day++/ Stop Day++	SEVERITY/ Outcome	ACTION/ Causality	SAE
A4001027 10[redacted]0001 (M/ 7[redacted](YEARS)/ [redacted])							
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	Intervertebral disc degeneration*/ DEGENERATIVE DISC DISEASE	Active	maraviroc QD	291/ [>291]	Grade 3/ Still Present	STUDY DRUG ACTION: (PERMANENTLY DISCONTINUED) SUBJECT ACTION: (D/C STUDY)/ Other event-degenerative disease	YES
	Spinal disorder*/ CERVICAL SPINE DISEASE	Active	maraviroc QD	291/ [>291]	Grade 3/ Still Present	STUDY DRUG ACTION: (PERMANENTLY DISCONTINUED) SUBJECT ACTION: (D/C STUDY)/ Other event-degenerative disease	YES
A4001027 10[redacted]0003 (M/ 5[redacted](YEARS)/ [redacted])							

Age is at screening.
++ Day relative to first day of each treatment period. First day of each treatment period = day 1
* Treatment-emergent
[] Values in brackets are imputed from incomplete dates and times.
SAE = Serious Adverse Event (according to Investigators assessment).
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Table 3.1.4.2
Maraviroc Summary of Clinical Safety
Discontinuations from Study due to Adverse Events
Phase 3 Treatment Experienced CCR5 Tropic Studies

Treatment Group: maraviroc QD

System Organ Class	MedDRA (v9.0) Preferred Term/ INVESTIGATOR ENTRY	Trt Phase	Treatment At Onset	Adverse Event ------- Start Day++/ Stop Day++	SEVERITY/ Outcome	ACTION/ Causality	SAE
RENAL AND URINARY DISORDERS	Renal failure*/ RENAL FAILURE	Active	maraviroc QD	12/ [>12]	Grade 3/ Still Present	STUDY DRUG ACTION: (PERMANENTLY DISCONTINUED) SUBJECT ACTION: (D/C STUDY)/ Study drug	YES
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	Rash*/ RASH	Active	maraviroc QD	10/ 17	Grade 3/ Resolved (20APR2[redacted]	STUDY DRUG ACTION: (PERMANENTLY DISCONTINUED) SUBJECT ACTION: (D/C STUDY)/ Study drug	YES
A4001027 11[redacted]40002 (M/ 4[redacted](YEARS)/ [redacted]							
GASTROINTESTINAL DISORDERS	Abdominal pain upper*/ EPIGASTRIC PAIN	Active	maraviroc QD	51/ 53	Grade 3/ Resolved (21AUG2[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Concomitant treatment-emtricitabine/tenofovir disoproxil fumarate# and epivir	YES

Age is at screening.
++ Day relative to first day of each treatment period. First day of each treatment period = day 1
# 新薬承認情報提供時に置換えた。
* Treatment-emergent
[] Values in brackets are imputed from incomplete dates and times.
SAE = Serious Adverse Event (according to Investigators assessment).
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Table 3.1.4.2
Maraviroc Summary of Clinical Safety
Discontinuations from Study due to Adverse Events
Phase 3 Treatment Experienced CCR5 Tropic Studies

Treatment Group: maraviroc QD

System Organ Class	MedDRA (v9.0) Preferred Term/ INVESTIGATOR ENTRY	Trt Phase	Treatment At Onset	Adverse Event ------- Start Day++/ Stop Day++	SEVERITY/ Outcome	ACTION/ Causality	SAE
GASTROINTESTINAL DISORDERS	Abdominal pain upper*/ EPIGASTRIC PAIN	Active	maraviroc QD	187/ 194	Grade 3/ Resolved (20JAN2[redacted])	STUDY DRUG ACTION: (PERMANENTLY DISCONTINUED) SUBJECT ACTION: (D/C STUDY)/ Study drug	YES
A4001027 11[redacted]60006 (M/ 3[redacted](YEARS)/ [redacted])							
BLOOD AND LYMPHATIC SYSTEM DISORDERS	Anaemia*/ WORSENING ANEMIA	Active	maraviroc QD	16/ 47	Grade 2/ Resolved (24AUG2[redacted])	STUDY DRUG ACTION: (PERMANENTLY DISCONTINUED) SUBJECT ACTION: (D/C STUDY)/ Study drug	YES
A4001027 11[redacted]10018 (M/ 5[redacted](YEARS)/ [redacted])							

Age is at screening.
++ Day relative to first day of each treatment period. First day of each treatment period = day 1
* Treatment-emergent
[] Values in brackets are imputed from incomplete dates and times.
SAE = Serious Adverse Event (according to Investigators assessment).
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Table 3.1.4.2
Maraviroc Summary of Clinical Safety
Discontinuations from Study due to Adverse Events
Phase 3 Treatment Experienced CCR5 Tropic Studies

Treatment Group: maraviroc QD

System Organ Class	MedDRA (v9.0) Preferred Term/ INVESTIGATOR ENTRY	Trt Phase	Treatment At Onset	Adverse Event ------- Start Day++/ Stop Day++	SEVERITY/ Outcome	ACTION/ Causality	SAE
INVESTIGATIONS	Lipase increased*/ LIPASE INCREASED	Active	maraviroc QD	15/ 61	Grade 3/ Resolved (22AUG2[redacted])	STUDY DRUG ACTION: (PERMANENTLY DISCONTINUED) SUBJECT ACTION: (D/C STUDY)/ Disease under study	NO
	Lipase increased*/ LIPASE INCREASED	Active	maraviroc QD	62/ 64	Grade 4/ Resolved (11OCT2[redacted])	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Disease under study	NO
A4001028 1C[redacted]30007 (F/ 3[redacted](YEARS)/ [redacted]							
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	Muscular weakness*/ WEAKNESS IN BOTH LEGS	Active	maraviroc QD	79/ [>79]	Grade 3/ Still Present	STUDY DRUG ACTION: (PERMANENTLY DISCONTINUED) SUBJECT ACTION: (D/C STUDY)/ Study drug	NO
A4001028 1C[redacted]10035 (M/ 4[redacted](YEARS)/ [redacted]							

Age is at screening.
++ Day relative to first day of each treatment period. First day of each treatment period = day 1
* Treatment-emergent
[] Values in brackets are imputed from incomplete dates and times.
SAE = Serious Adverse Event (according to Investigators assessment).
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Treatment Group: maraviroc QD

System Organ Class	MedDRA (v9.0) Preferred Term/ INVESTIGATOR ENTRY	Trt Phase	Treatment At Onset	Adverse Event ------- Start Day++/ Stop Day++	SEVERITY/ Outcome	ACTION/ Causality	SAE
INVESTIGATIONS	Alanine aminotransferase increased*/ INCREASE OF ALT	Active	maraviroc QD	139/ [>139]	Grade 2/ Still Present	STUDY DRUG ACTION: (PERMANENTLY DISCONTINUED) SUBJECT ACTION: (D/C STUDY)/ Study drug	NO
	Aspartate aminotransferase increased*/ INCREASE OF AST	Active	maraviroc QD	139/ [>139]	Grade 2/ Still Present	STUDY DRUG ACTION: (PERMANENTLY DISCONTINUED) SUBJECT ACTION: (D/C STUDY)/ Study drug	NO
A4001028 1[redacted]0001 (M/ 4[redacted](YEARS)/ [redacted])							
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	Oedema peripheral*/ SWOLLEN HANDS	Active	maraviroc QD	113/ [>113]	Grade 1/ Still Present	STUDY DRUG ACTION: (PERMANENTLY DISCONTINUED) SUBJECT ACTION: (D/C STUDY)/ Study drug	NO

Age is at screening.
++ Day relative to first day of each treatment period. First day of each treatment period = day 1
* Treatment-emergent
[] Values in brackets are imputed from incomplete dates and times.
SAE = Serious Adverse Event (according to Investigators assessment).
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Table 3.1.4.2
Maraviroc Summary of Clinical Safety
Discontinuations from Study due to Adverse Events
Phase 3 Treatment Experienced CCR5 Tropic Studies

Treatment Group: maraviroc QD

System Organ Class	MedDRA (v9.0) Preferred Term/ INVESTIGATOR ENTRY	Trt Phase	Treatment At Onset	Adverse Event ------- Start Day++/ Stop Day++	SEVERITY/ Outcome	ACTION/ Causality	SAE
A4001028 11[redacted]50001 (M/ 5[redacted](YEARS)/ [redacted]							
BLOOD AND LYMPHATIC SYSTEM DISORDERS	Anaemia*/ ANEMIA	Active	maraviroc QD	31/ [>31]	Grade 1/ Still Present	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Concomitant treatment-voriconazol	NO
	Anaemia*/ WORSENING OF ANEMIA	Active	maraviroc QD	56/ 70	Grade 3/ Resolved (27DEC2[redacted])	STUDY DRUG ACTION: (PERMANENTLY DISCONTINUED) SUBJECT ACTION: (D/C STUDY)/ Study drug	YES
A4001028 11[redacted]70011 (M/ 4[redacted](YEARS)/ [redacted]							

Age is at screening.
++ Day relative to first day of each treatment period. First day of each treatment period = day 1
* Treatment-emergent
[] Values in brackets are imputed from incomplete dates and times.
SAE = Serious Adverse Event (according to Investigators assessment).
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Maraviroc Summary of Clinical Safety
Discontinuations from Study due to Adverse Events
Phase 3 Treatment Experienced CCR5 Tropic Studies

Treatment Group: maraviroc QD

System Organ Class	MedDRA (v9.0) Preferred Term/ INVESTIGATOR ENTRY	Trt Phase	Treatment At Onset	Adverse Event ------- Start Day++/ Stop Day++	SEVERITY/ Outcome	ACTION/ Causality	SAE
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	Myalgia*/ MUSCLE ACHES	Active	maraviroc QD	37/ 63	Grade 3/ Resolved (11APR2[redacted])	STUDY DRUG ACTION: (PERMANENTLY DISCONTINUED) SUBJECT ACTION: (D/C STUDY)/ Study drug	NO
A4001028 11[redacted]0001 (M/ 4[redacted](YEARS)/ [redacted])							
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	Myalgia*/ MYALGIA	Active	maraviroc QD	77/ 89	Grade 1/ Resolved (28MAY2[redacted])	STUDY DRUG ACTION: (PERMANENTLY DISCONTINUED) SUBJECT ACTION: (D/C STUDY)/ Study drug	NO
A4001028 11[redacted]0003 (M/ 4[redacted](YEARS)/ [redacted])							

Age is at screening.
++ Day relative to first day of each treatment period. First day of each treatment period = day 1
* Treatment-emergent
[] Values in brackets are imputed from incomplete dates and times.
SAE = Serious Adverse Event (according to Investigators assessment).
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Maraviroc Summary of Clinical Safety
Discontinuations from Study due to Adverse Events
Phase 3 Treatment Experienced CCR5 Tropic Studies

Treatment Group: maraviroc QD

System Organ Class	MedDRA (v9.0) Preferred Term/ INVESTIGATOR ENTRY	Trt Phase	Treatment At Onset	Adverse Event ------- Start Day++/ Stop Day++	SEVERITY/ Outcome	ACTION/ Causality	SAE
GASTROINTESTINAL DISORDERS	Diarrhoea*/ DIARRHEA	Active	maraviroc QD	6/ 23	Grade 2/ Resolved (18APR2[redacted])	STUDY DRUG ACTION: (PERMANENTLY DISCONTINUED) SUBJECT ACTION: (D/C STUDY)/ Study drug	NO

Age is at screening.
++ Day relative to first day of each treatment period. First day of each treatment period = day 1
* Treatment-emergent
[] Values in brackets are imputed from incomplete dates and times.
SAE = Serious Adverse Event (according to Investigators assessment).
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Table 3.1.4.2
Maraviroc Summary of Clinical Safety
Discontinuations from Study due to Adverse Events
Phase 3 Treatment Experienced CCR5 Tropic Studies

Treatment Group: maraviroc BID

System Organ Class	MedDRA (v9.0) Preferred Term/ INVESTIGATOR ENTRY	Trt Phase	Treatment At Onset	Adverse Event ------- Start Day++/ Stop Day++	SEVERITY/ Outcome	ACTION/ Causality	SAE
A4001027 1[redacted]40016 (M/ [redacted](YEARS)/ [redacted])							
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	Heat exhaustion*/ HEAT EXHAUSTION	Active	maraviroc BID	184/ 193	Grade 3/ Resolved (03AUG2[redacted])	STUDY DRUG ACTION: (PERMANENTLY DISCONTINUED) SUBJECT ACTION: (D/C STUDY)/ Other event-heat, dehydration	YES
INVESTIGATIONS	Transaminases increased*/ ELEVATED TRANSAMINASES	Active	maraviroc BID	187/ 193	Grade 4/ Resolved (03AUG2[redacted])	STUDY DRUG ACTION: (PERMANENTLY DISCONTINUED) SUBJECT ACTION: (D/C STUDY)/ Study drug	YES
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	Rhabdomyolysis*/ RHABDOMYOLYSIS	Active	maraviroc BID	184/ 193	Grade 3/ Resolved (03AUG2[redacted])	STUDY DRUG ACTION: (PERMANENTLY DISCONTINUED) SUBJECT ACTION: (D/C STUDY)/ Other event-heat, dehydration	YES

Age is at screening.
++ Day relative to first day of each treatment period. First day of each treatment period = day 1
* Treatment-emergent
[] Values in brackets are imputed from incomplete dates and times.
SAE = Serious Adverse Event (according to Investigators assessment).
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Maraviroc Summary of Clinical Safety
Discontinuations from Study due to Adverse Events
Phase 3 Treatment Experienced CCR5 Tropic Studies

Treatment Group: maraviroc BID

System Organ Class	MedDRA (v9.0) Preferred Term/ INVESTIGATOR ENTRY	Trt Phase	Treatment At Onset	Adverse Event ------- Start Day++/ Stop Day++	SEVERITY/ Outcome	ACTION/ Causality	SAE
A4001027 10[redacted]0005 (M/ 4[redacted](YEARS)/ [redacted]							
INVESTIGATIONS	Aspartate aminotransferase increased*/ ELEVATED AST	Active	maraviroc BID	15/ 29	Grade 4/ Resolved (10MAR2C[redacted])	STUDY DRUG ACTION: (PERMANENTLY DISCONTINUED) SUBJECT ACTION: (D/C STUDY)/ Concomitant treatment-anaesthesia	NO
A4001027 10[redacted]0021 (M/ 3[redacted](YEARS)/ [redacted]							
GASTROINTESTINAL DISORDERS	Abdominal pain upper*/ RUQ PAIN	Active	maraviroc BID	32/ 34	Grade 2/ Resolved (17JAN2C[redacted])	STUDY DRUG ACTION: (PERMANENTLY DISCONTINUED) SUBJECT ACTION: (D/C STUDY)/ Study drug	NO

Age is at screening.
++ Day relative to first day of each treatment period. First day of each treatment period = day 1
* Treatment-emergent
[] Values in brackets are imputed from incomplete dates and times.
SAE = Serious Adverse Event (according to Investigators assessment).
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Table 3.1.4.2
Maraviroc Summary of Clinical Safety
Discontinuations from Study due to Adverse Events
Phase 3 Treatment Experienced CCR5 Tropic Studies

Treatment Group: maraviroc BID

System Organ Class	MedDRA (v9.0) Preferred Term/ INVESTIGATOR ENTRY	Trt Phase	Treatment At Onset	Adverse Event ------- Start Day++/ Stop Day++	SEVERITY/ Outcome	ACTION/ Causality	SAE
INVESTIGATIONS	Liver function test abnormal*/ ELEVATED LFT'S	Active	maraviroc BID	32/ [>32]	Grade 4/ Still Present	STUDY DRUG ACTION: (PERMANENTLY DISCONTINUED) SUBJECT ACTION: (D/C STUDY)/ Study drug	NO
A4001027 1C[redacted]50010 (M/ 4[redacted](YEARS)/ [redacted]							
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	Anal cancer*/ CARCINOMA OF ANUS	Active	maraviroc BID	161/ [>161]	Grade 2/ Still Present	STUDY DRUG ACTION: (PERMANENTLY DISCONTINUED) SUBJECT ACTION: (D/C STUDY)/ Other event-cancer	YES
A4001027 1C[redacted]70009 (M/ 5[redacted](YEARS)/ [redacted]							

Age is at screening.
++ Day relative to first day of each treatment period. First day of each treatment period = day 1
* Treatment-emergent
[] Values in brackets are imputed from incomplete dates and times.
SAE = Serious Adverse Event (according to Investigators assessment).
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Table 3.1.4.2
Maraviroc Summary of Clinical Safety
Discontinuations from Study due to Adverse Events
Phase 3 Treatment Experienced CCR5 Tropic Studies

Treatment Group: maraviroc BID

System Organ Class	MedDRA (v9.0) Preferred Term/ INVESTIGATOR ENTRY	Trt Phase	Treatment At Onset	Adverse Event Start Day++/ Stop Day++	SEVERITY/ Outcome	ACTION/ Causality	SAE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	Pyrexia*/ FEVER	Active	maraviroc BID	11/ 23	Grade 2/ Resolved (04JUL2[redacted])	STUDY DRUG ACTION: (PERMANENTLY DISCONTINUED) SUBJECT ACTION: (D/C STUDY)/ Study drug	YES
A4001027 1[redacted]0003 (M/ 4[redacted](YEARS)/ [redacted])							
NERVOUS SYSTEM DISORDERS	Convulsion*/ LOSS OF CONSCIOUSNESS, POSSIBLE SEIZURE	Active	maraviroc BID	93/ 94	Grade 4/ Resolved (21SEP2[redacted])	STUDY DRUG ACTION: (PERMANENTLY DISCONTINUED) SUBJECT ACTION: (D/C STUDY)/ Study drug	YES
A4001027 1[redacted]0002 (M/ 4[redacted](YEARS)/ [redacted])							

Age is at screening.
++ Day relative to first day of each treatment period. First day of each treatment period = day 1
* Treatment-emergent
[] Values in brackets are imputed from incomplete dates and times.
SAE = Serious Adverse Event (according to Investigators assessment).
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Maraviroc Summary of Clinical Safety
Discontinuations from Study due to Adverse Events
Phase 3 Treatment Experienced CCR5 Tropic Studies

Treatment Group: maraviroc BID

System Organ Class	MedDRA (v9.0) Preferred Term/ INVESTIGATOR ENTRY	Trt Phase	Treatment At Onset	Adverse Event ------- Start Day++/ Stop Day++	SEVERITY/ Outcome	ACTION/ Causality	SAE
GASTROINTESTINAL DISORDERS	Abdominal pain upper*/ EPIGASTRIC PAIN	Active	maraviroc BID	9/ [>9]	Grade 4/ Still Present	STUDY DRUG ACTION: (PERMANENTLY DISCONTINUED) SUBJECT ACTION: (D/C STUDY)/ Other event-unknown	YES
	Diarrhoea*/ DIARRHEA	Active	maraviroc BID	9/ 16	Grade 2/ Resolved (06FEB2[redacted]	STUDY DRUG ACTION: (PERMANENTLY DISCONTINUED) SUBJECT ACTION: (D/C STUDY)/ Other event-unknown etiology	YES
	Odynophagia*/ ODYNOPHAGIA	Active	maraviroc BID	9/ [>9]	Grade 4/ Still Present	STUDY DRUG ACTION: (PERMANENTLY DISCONTINUED) SUBJECT ACTION: (D/C STUDY)/ Other event-unknown	YES
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	Arthralgia*/ INCREASED LEFT HIP PAIN	Active	maraviroc BID	9/ [>9]	Grade 4/ Still Present	STUDY DRUG ACTION: (PERMANENTLY DISCONTINUED) SUBJECT ACTION: (D/C STUDY)/ Other event-arthritis	YES

Age is at screening.
++ Day relative to first day of each treatment period. First day of each treatment period = day 1
* Treatment-emergent
[] Values in brackets are imputed from incomplete dates and times.
SAE = Serious Adverse Event (according to Investigators assessment).
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Maraviroc Summary of Clinical Safety
Discontinuations from Study due to Adverse Events
Phase 3 Treatment Experienced CCR5 Tropic Studies

Treatment Group: maraviroc BID

System Organ Class	MedDRA (v9.0) Preferred Term/ INVESTIGATOR ENTRY	Trt Phase	Treatment At Onset	Adverse Event ------- Start Day++/ Stop Day++	SEVERITY/ Outcome	ACTION/ Causality	SAE
A4001027 11[redacted]0007 (M/ 4[redacted](YEARS)/ [redacted])							
HEPATOBILIARY DISORDERS	Hyperbilirubinaemia*/ HYPERBILIRUBINEMIA	Active	maraviroc BID	42/ [>42]	Grade 3/ Still Present	STUDY DRUG ACTION: (PERMANENTLY DISCONTINUED) SUBJECT ACTION: (D/C STUDY)/ Other event-other illness-hcv/etoh	YES
A4001027 11[redacted]0003 (F/ 2[redacted](YEARS)/ [redacted])							
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	Rash generalised*/ GENERALIZED RASH	Active	maraviroc BID	8/ 13	Grade 3/ Resolved (26MAR2[redacted])	STUDY DRUG ACTION: (PERMANENTLY DISCONTINUED) SUBJECT ACTION: (D/C STUDY)/ Study drug	YES
A4001028 10[redacted]0003 (M/ 5[redacted](YEARS)/ [redacted])							

Age is at screening.
++ Day relative to first day of each treatment period. First day of each treatment period = day 1
* Treatment-emergent
[] Values in brackets are imputed from incomplete dates and times.
SAE = Serious Adverse Event (according to Investigators assessment).
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Table 3.1.4.2
Maraviroc Summary of Clinical Safety
Discontinuations from Study due to Adverse Events
Phase 3 Treatment Experienced CCR5 Tropic Studies

Treatment Group: maraviroc BID

System Organ Class	MedDRA (v9.0) Preferred Term/ INVESTIGATOR ENTRY	Trt Phase	Treatment At Onset	Adverse Event ------- Start Day++/ Stop Day++	SEVERITY/ Outcome	ACTION/ Causality	SAE
INVESTIGATIONS	Viral load increased*/ VIRAL LOAD INCREASED	Active	maraviroc BID	72/ 80	Grade 1/ Resolved (21JUL2[redacted])	STUDY DRUG ACTION: (PERMANENTLY DISCONTINUED) SUBJECT ACTION: (D/C STUDY)/ Study drug	NO
A4001028 1[redacted]30006 (M/ 4[redacted](YEARS)/ [redacted])							
INVESTIGATIONS	Alanine aminotransferase increased*/ ELEVATED ALT	Active	maraviroc BID	127/ 135	Grade 4/ Resolved (22MAR2[redacted])	STUDY DRUG ACTION: (PERMANENTLY DISCONTINUED) SUBJECT ACTION: (D/C STUDY)/ Study drug	YES
	Aspartate aminotransferase increased*/ INCREASED AST G4	Active	maraviroc BID	127/ 134	Grade 4/ Resolved (15MAR2[redacted])	STUDY DRUG ACTION: (PERMANENTLY DISCONTINUED) SUBJECT ACTION: (D/C STUDY)/ Study drug	YES

Age is at screening.
++ Day relative to first day of each treatment period. First day of each treatment period = day 1
* Treatment-emergent
[] Values in brackets are imputed from incomplete dates and times.
SAE = Serious Adverse Event (according to Investigators assessment).
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Table 3.1.4.2
Maraviroc Summary of Clinical Safety
Discontinuations from Study due to Adverse Events
Phase 3 Treatment Experienced CCR5 Tropic Studies

Treatment Group: maraviroc BID

System Organ Class	MedDRA (v9.0) Preferred Term/ INVESTIGATOR ENTRY	Trt Phase	Treatment At Onset	Adverse Event ------- Start Day++/ Stop Day++	SEVERITY/ Outcome	ACTION/ Causality	SAE
A4001028 11[redacted]20002 (M/ 4[redacted](YEARS)/ [redacted])							
NERVOUS SYSTEM DISORDERS	Syncope*/ SYNCOPAL EPISODE	Active	maraviroc BID	65/ 65	Grade 4/ Resolved (28FEB2C[redacted])	STUDY DRUG ACTION: (PERMANENTLY DISCONTINUED) SUBJECT ACTION: (D/C STUDY)/ Study drug	YES
A4001028 11[redacted]10004 (M/ 5[redacted](YEARS)/ [redacted])							
VASCULAR DISORDERS	Orthostatic hypotension*/ ORTHOSTATIC HYPOTENSION	Active	maraviroc BID	98/ 100	Grade 3/ Resolved (05JUL2C[redacted])	STUDY DRUG ACTION: (PERMANENTLY DISCONTINUED) SUBJECT ACTION: (D/C STUDY)/ Study drug	YES
A4001028 11[redacted]50002 (M/ 6[redacted](YEARS)/ [redacted])							

Age is at screening.
++ Day relative to first day of each treatment period. First day of each treatment period = day 1
* Treatment-emergent
[] Values in brackets are imputed from incomplete dates and times.
SAE = Serious Adverse Event (according to Investigators assessment).
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Table 3.1.4.2
Maraviroc Summary of Clinical Safety
Discontinuations from Study due to Adverse Events
Phase 3 Treatment Experienced CCR5 Tropic Studies

Treatment Group: maraviroc BID

System Organ Class	MedDRA (v9.0) Preferred Term/ INVESTIGATOR ENTRY	Trt Phase	Treatment At Onset	Adverse Event ------- Start Day++/ Stop Day++	SEVERITY/ Outcome	ACTION/ Causality	SAE
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	Tongue neoplasm malignant stage unspecified*/ SQUAMOUS CELL CARCINOMA OF THE L TONGUE BASE.	Active	maraviroc BID	49/ [>49]	Grade 3/ Still Present	STUDY DRUG ACTION: (PERMANENTLY DISCONTINUED) SUBJECT ACTION: (D/C STUDY)/ Other event-diagnosis of squamous cell carcinoma of the left tongue base.	YES
A4001028 12[redacted]50011 (M/ 4[redacted](YEARS)/ [redacted]							
INFECTIONS AND INFESTATIONS	Gastrointestinal infectio n*/ GASTROINTESTINAL INFECTION	Active	maraviroc BID	33/ 57	Grade 2/ Resolved (18APR2[redacted]	STUDY DRUG ACTION: (PERMANENTLY DISCONTINUED) SUBJECT ACTION: (D/C STUDY)/ Other event-norovirus infection	NO

Age is at screening.
++ Day relative to first day of each treatment period. First day of each treatment period = day 1
* Treatment-emergent
[] Values in brackets are imputed from incomplete dates and times.
SAE = Serious Adverse Event (according to Investigators assessment).
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Maraviroc Summary of Clinical Safety
Discontinuations from Study due to Adverse Events
Phase 3 Treatment Experienced CCR5 Tropic Studies

Treatment Group: Placebo

System Organ Class	MedDRA (v9.0) Preferred Term/ INVESTIGATOR ENTRY	Trt Phase	Treatment At Onset	Adverse Event ------- Start Day++/ Stop Day++	SEVERITY/ Outcome	ACTION/ Causality	SAE
A4001027 1C[redacted]30004 (M/ 4[redacted](YEARS)/ [redacted])							
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	Pyrexia*/ MILD FEVER	Active	Placebo	10/ 15	Grade 1/ Resolved (31AUG2C[redacted])	STUDY DRUG ACTION: (PERMANENTLY DISCONTINUED) SUBJECT ACTION: (D/C STUDY)/ Study drug	NO
A4001027 1C[redacted]10001 (M/ 5[redacted](YEARS)/ [redacted])							
INVESTIGATIONS	Liver function test abnormal*/ ELEVATED LFT TEST	Active	Placebo	232/ [>232]	Grade 4/ Still Present	STUDY DRUG ACTION: (PERMANENTLY DISCONTINUED) SUBJECT ACTION: (D/C STUDY)/ Study drug	NO

Age is at screening.
++ Day relative to first day of each treatment period. First day of each treatment period = day 1
* Treatment-emergent
[] Values in brackets are imputed from incomplete dates and times.
SAE = Serious Adverse Event (according to Investigators assessment).
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Treatment Group: Placebo

System Organ Class	MedDRA (v9.0) Preferred Term/ INVESTIGATOR ENTRY	Trt Phase	Treatment At Onset	Adverse Event ------- Start Day++/ Stop Day++	SEVERITY/ Outcome	ACTION/ Causality	SAE
INVESTIGATIONS	White blood cell count decreased*/ LOW WHITE BLOOD CELL COUNT	Active	Placebo	294/ [>294]	Grade 1/ Still Present	STUDY DRUG ACTION: (PERMANENTLY DISCONTINUED) SUBJECT ACTION: (D/C STUDY)/ Concomitant treatment-neupogen 480mcg sq for 5 days	NO
A4001027 10[redacted]20015 (M/ 5[redacted](YEARS)/ [redacted]							
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	Chest pain*/ CHEST PAIN	Active	Placebo	69/ 75	Grade 3/ Resolved (17JUN2[redacted])	STUDY DRUG ACTION: (PERMANENTLY DISCONTINUED) SUBJECT ACTION: (D/C STUDY)/ Other event-unknown	YES
A4001027 10[redacted]30019 (M/ 4[redacted](YEARS)/ [redacted]							

Age is at screening.
++ Day relative to first day of each treatment period. First day of each treatment period = day 1
* Treatment-emergent
[] Values in brackets are imputed from incomplete dates and times.
SAE = Serious Adverse Event (according to Investigators assessment).
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Table 3.1.4.2
Maraviroc Summary of Clinical Safety
Discontinuations from Study due to Adverse Events
Phase 3 Treatment Experienced CCR5 Tropic Studies

Treatment Group: Placebo

System Organ Class	MedDRA (v9.0) Preferred Term/ INVESTIGATOR ENTRY	Trt Phase	Treatment At Onset	Adverse Event ------- Start Day++/ Stop Day++	SEVERITY/ Outcome	ACTION/ Causality	SAE
GASTROINTESTINAL DISORDERS	Gingivitis*/ GINIVITIS	Active	Placebo	7/ 72	Grade 2/ Resolved (31OCT2[redacted])	STUDY DRUG ACTION: (PERMANENTLY DISCONTINUED) SUBJECT ACTION: (D/C STUDY)/ Study drug	NO
A4001027 1[redacted]0012 (F/ [redacted](YEARS)/ [redacted])							
INFECTIONS AND INFESTATIONS	Pneumonia*/ PNEUMONIA	Active	Placebo	5/ 14	Grade 4/ Resolved (13JAN2[redacted])	STUDY DRUG ACTION: (PERMANENTLY DISCONTINUED) SUBJECT ACTION: (D/C STUDY)/ Disease under study	YES
A4001027 1[redacted]0012 (F/ [redacted](YEARS)/ [redacted])							

Age is at screening.
++ Day relative to first day of each treatment period. First day of each treatment period = day 1
* Treatment-emergent
[] Values in brackets are imputed from incomplete dates and times.
SAE = Serious Adverse Event (according to Investigators assessment).
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Maraviroc Summary of Clinical Safety
Discontinuations from Study due to Adverse Events
Phase 3 Treatment Experienced CCR5 Tropic Studies

Treatment Group: Placebo

System Organ Class	MedDRA (v9.0) Preferred Term/ INVESTIGATOR ENTRY	Trt Phase	Treatment At Onset	Adverse Event ------- Start Day++/ Stop Day++	SEVERITY/ Outcome	ACTION/ Causality	SAE
INFECTIONS AND INFESTATIONS	Mycobacterium avium complex infection/ MYCOBACTERIUM AVIUM COMPLEX INFECTION	Post	Placebo	63/ [>63]	Grade 3/ Still Present	STUDY DRUG ACTION: (PERMANENTLY DISCONTINUED) SUBJECT ACTION: (D/C STUDY)/ Disease under study	YES
METABOLISM AND NUTRITION DISORDERS	Lactic acidosis*/ LACTIC ACIDOSIS	Active	Placebo	96/ 101	Grade 3/ Resolved (01APR2[redacted])	STUDY DRUG ACTION: (PERMANENTLY DISCONTINUED) SUBJECT ACTION: (D/C STUDY)/ Other event-sepsis on drug induced ddi	YES
A4001028 1[redacted]10003 (M/ 4[redacted](YEARS)/ [redacted])							
HEPATOBILIARY DISORDERS	Cytolytic hepatitis*/ HEPATIC CYTOLYSIS	Active	Placebo	14/ 37	Grade 2/ Resolved (02DEC2[redacted])	STUDY DRUG ACTION: (PERMANENTLY DISCONTINUED) SUBJECT ACTION: (D/C STUDY)/ Study drug	NO

Age is at screening.
++ Day relative to first day of each treatment period. First day of each treatment period = day 1
* Treatment-emergent
[] Values in brackets are imputed from incomplete dates and times.
SAE = Serious Adverse Event (according to Investigators assessment).
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Table 3.1.4.2
Maraviroc Summary of Clinical Safety
Discontinuations from Study due to Adverse Events
Phase 3 Treatment Experienced CCR5 Tropic Studies

Treatment Group: Placebo

System Organ Class	MedDRA (v9.0) Preferred Term/ INVESTIGATOR ENTRY	Trt Phase	Treatment At Onset	Adverse Event ------- Start Day++/ Stop Day++	SEVERITY/ Outcome	ACTION/ Causality	SAE
A4001028 10[redacted]10034 (M/ 4[redacted](YEARS)/ [redacted]							
NERVOUS SYSTEM DISORDERS	Dizziness*/ DIZZINESS	Active	Placebo	2/ 22	Grade 2/ Resolved (30DEC2C[redacted])	STUDY DRUG ACTION: (PERMANENTLY DISCONTINUED) SUBJECT ACTION: (D/C STUDY)/ Study drug	NO

Age is at screening.
++ Day relative to first day of each treatment period. First day of each treatment period = day 1
* Treatment-emergent
[] Values in brackets are imputed from incomplete dates and times.
SAE = Serious Adverse Event (according to Investigators assessment).
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Table 3.1.4.3
Maraviroc Summary of Clinical Safety
Temporary Discontinuations or Dose Reductions Due to Adverse Events
Phase 3 Treatment Experienced CCR5 Tropic Studies

Treatment Group: maraviroc QD

System Organ Class	MedDRA (v9.0) Preferred Term/ INVESTIGATOR ENTRY	Trt Phase	Treatment At Onset	Adverse Event ------- Start Day++/ Stop Day++	SEVERITY/ Outcome	ACTION/ Causality	SAE
A4001027 1[redacted]50002 (M/ 5[redacted](YEARS)/ [redacted])							
GASTROINTESTINAL DISORDERS	Diverticulum intestinal h aemorrhagic*/ COLON DIVERTICULAR BLEED	Active	maraviroc QD	95/ 104	Grade 4/ Resolved (19JUN2C[redacted])	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Other event-diverticulitis	YES
A4001027 1[redacted]70004 (M/ 4[redacted](YEARS)/ [redacted])							
GASTROINTESTINAL DISORDERS	Nausea*/ NAUSEA	Active	maraviroc QD	1/ 29	Grade 2/ Resolved (04MAY2C[redacted])	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Study drug	NO
	Vomiting*/ VOMITING	Active	maraviroc QD	1/ 29	Grade 2/ Resolved (04MAY2C[redacted])	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Study drug	NO
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	Chills*/ RIGORS	Active	maraviroc QD	13/ 13	Grade 1/ Resolved (18APR2C[redacted])	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Other event-due to fever	NO
METABOLISM AND NUTRITION DISORDERS	Dehydration*/ DEHYDRATION	Active	maraviroc QD	13/ 13	Grade 2/ Resolved (18APR2C[redacted])	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Other event-due to vomitting and diarrhea	NO
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	Rash*/ RASH	Active	maraviroc QD	1/ 29	Grade 2/ Resolved (04MAY2C[redacted])	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Study drug	NO

Age is at screening
* Treatment-emergent
++ Start Day and Stop Day are start and stop of AE relative to the start of treatment: First day of treatment = Day 1
[] Days in brackets are imputed days derived from incomplete dates.
SAE = Serious Adverse Event (according to Investigators assessment).
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Table 3.1.4.3
Maraviroc Summary of Clinical Safety
Temporary Discontinuations or Dose Reductions Due to Adverse Events
Phase 3 Treatment Experienced CCR5 Tropic Studies

Treatment Group: maraviroc QD

System Organ Class	MedDRA (v9.0) Preferred Term/ INVESTIGATOR ENTRY	Trt Phase	Treatment At Onset	Adverse Event ------- Start Day++/ Stop Day++	SEVERITY/ Outcome	ACTION/ Causality	SAE
A4001027 1C[redacted]70008 (M/ 4[redacted](YEARS)/ [redacted]							
GASTROINTESTINAL DISORDERS	Abdominal pain*/ ABDOMINAL PAIN	Active	maraviroc QD	121/ 136	Grade 2/ Resolved (31AUG2C[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Disease under study	NO
A4001027 1C[redacted]10005 (M/ 4[redacted](YEARS)/ [redacted]							
EYE DISORDERS	Eye pain*/ EYE PAIN	Active	maraviroc QD	8/ 16	Grade 2/ Resolved (31MAY2C[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Study drug	NO
	Ocular hyperaemia*/ EYE REDNESS (BLOODSHOT)	Active	maraviroc QD	8/ 16	Grade 2/ Resolved (31MAY2C[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Study drug	NO
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	Pyrexia*/ FEVER	Active	maraviroc QD	8/ 16	Grade 2/ Resolved (31MAY2C[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Study drug	NO
HEPATOBILIARY DISORDERS	Hyperbilirubinaemia*/ HYPERBILIRUBINEMIA	Active	maraviroc QD	8/ 16	Grade 2/ Resolved (31MAY2C[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Concomitant treatment-atazanavir sulfate#	NO
NERVOUS SYSTEM DISORDERS	Headache*/ HEADACHE	Active	maraviroc QD	8/ 16	Grade 2/ Resolved (31MAY2C[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Study drug	NO

Age is at screening
* Treatment-emergent
++ Start Day and Stop Day are start and stop of AE relative to the start of treatment: First day of treatment = Day 1
[] Days in brackets are imputed days derived from incomplete dates.
SAE = Serious Adverse Event (according to Investigators assessment).
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

#: 新薬承認情報提供時に置換えた。

Maraviroc Summary of Clinical Safety
Temporary Discontinuations or Dose Reductions Due to Adverse Events
Phase 3 Treatment Experienced CCR5 Tropic Studies

Treatment Group: maraviroc QD

System Organ Class	MedDRA (v9.0) Preferred Term/ INVESTIGATOR ENTRY	Trt Phase	Treatment At Onset	Adverse Event ------- Start Day++/ Stop Day++	SEVERITY/ Outcome	ACTION/ Causality	SAE
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	Rash*/ RASH ON STOMACH	Active	maraviroc QD	8/ 16	Grade 2/ Resolved (31MAY2[redacted])	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Study drug	NO
A4001027 10[redacted]0009 (M/ 5[redacted](YEARS)/ [redacted])							
GASTROINTESTINAL DISORDERS	Abdominal pain*/ ABDOMINAL PAIN	Active	maraviroc QD	306/ 308	Grade 2/ Resolved (10MAY2[redacted])	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Disease under study	YES
A4001027 10[redacted]0024 (F/ 6[redacted](YEARS)/ [redacted])							
INFECTIONS AND INFESTATIONS	Gastroenteritis*/ GASTROENTERITIS	Active	maraviroc QD	64/ [>64]	Grade 2/ Still Present	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Other event-virus	NO
A4001027 10[redacted]0005 (M/ 4[redacted](YEARS)/ [redacted])							
INVESTIGATIONS	Alanine aminotransferase increased*/ ELEVATED ALT	Active	maraviroc QD	114/ 117	Grade 3/ Resolved (23DEC2[redacted])	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Other event-unknown etiology	NO
A4001027 10[redacted]0013 (M/ 5[redacted](YEARS)/ [redacted])							

Age is at screening
* Treatment-emergent
++ Start Day and Stop Day are start and stop of AE relative to the start of treatment: First day of treatment = Day 1
[] Days in brackets are imputed days derived from incomplete dates.
SAE = Serious Adverse Event (according to Investigators assessment).
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Table 3.1.4.3
Maraviroc Summary of Clinical Safety
Temporary Discontinuations or Dose Reductions Due to Adverse Events
Phase 3 Treatment Experienced CCR5 Tropic Studies

Treatment Group: maraviroc QD

System Organ Class	MedDRA (v9.0) Preferred Term/ INVESTIGATOR ENTRY	Trt Phase	Treatment At Onset	Adverse Event ------- Start Day++/ Stop Day++	SEVERITY/ Outcome	ACTION/ Causality	SAE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	Pyrexia*/ FEVER	Active	maraviroc QD	55/ 61	Grade 2/ Resolved (17FEB2[redacted])	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Other event-possible bacterial infection	YES
	Pyrexia*/ LOW GRADE FEVER	Active	maraviroc QD	54/ 55	Grade 1/ Resolved (11FEB2[redacted])	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Other event-viral infection	NO
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	Dyspnoea*/ SHORTNESS OF BREATH	Active	maraviroc QD	57/ 61	Grade 3/ Resolved (17FEB2[redacted])	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Disease under study	YES
A4001027 10[redacted]30009 (F/ 4[redacted](YEARS)/ [redacted])							
INFECTIONS AND INFESTATIONS	Pneumonia*/ PNEUMONIA	Active	maraviroc QD	57/ 66	Grade 3/ Resolved (12JAN2[redacted])	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Other event-community acquired pneumonia	YES
A4001027 10[redacted]30014 (M/ 6[redacted](YEARS)/ [redacted])							
GASTROINTESTINAL DISORDERS	Nausea*/ NAUSEA	Active	maraviroc QD	18/ 43	Grade 3/ Resolved (03MAY2[redacted])	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Concomitant treatment-possibly azt	NO

Age is at screening
* Treatment-emergent
++ Start Day and Stop Day are start and stop of AE relative to the start of treatment: First day of treatment = Day 1
[] Days in brackets are imputed days derived from incomplete dates.
SAE = Serious Adverse Event (according to Investigators assessment).
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Maraviroc Summary of Clinical Safety
Temporary Discontinuations or Dose Reductions Due to Adverse Events
Phase 3 Treatment Experienced CCR5 Tropic Studies

Treatment Group: maraviroc QD

System Organ Class	MedDRA (v9.0) Preferred Term/ INVESTIGATOR ENTRY	Trt Phase	Treatment At Onset	Adverse Event ------- Start Day++/ Stop Day++	SEVERITY/ Outcome	ACTION/ Causality	SAE
A4001027 1[redacted]0006 (M/ 4[redacted](YEARS)/ [redacted]							
GASTROINTESTINAL DISORDERS	Abdominal pain*/ ABDOMINAL PAIN	Active	maraviroc QD	123/ 128	Grade 3/ Resolved (18JUL2[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Study drug	YES
	Haematochezia*/ BLOOD IN STOOL	Active	maraviroc QD	124/ 128	Grade 3/ Resolved (18JUL2[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Concomitant treatment-beptobismo	YES
	Nausea*/ NAUSEA	Active	maraviroc QD	2/ 72	Grade 1/ Resolved (23MAY2[redacted]	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study drug	NO
	Nausea*/ NAUSEA	Active	maraviroc QD	123/ 128	Grade 3/ Resolved (18JUL2[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Concomitant treatment-peptobismo	YES
NERVOUS SYSTEM DISORDERS	Dizziness*/ LIGHTHEADEDNESS	Active	maraviroc QD	125/ 128	Grade 1/ Resolved (18JUL2[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Study drug	NO
A4001027 11[redacted]0002 (M/ 4[redacted](YEARS)/ [redacted]							

Age is at screening
* Treatment-emergent
++ Start Day and Stop Day are start and stop of AE relative to the start of treatment: First day of treatment = Day 1
[] Days in brackets are imputed days derived from incomplete dates.
SAE = Serious Adverse Event (according to Investigators assessment).
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Maraviroc Summary of Clinical Safety
Temporary Discontinuations or Dose Reductions Due to Adverse Events
Phase 3 Treatment Experienced CCR5 Tropic Studies

Treatment Group: maraviroc QD

System Organ Class	MedDRA (v9.0) Preferred Term/ INVESTIGATOR ENTRY	Trt Phase	Treatment At Onset	Adverse Event ------- Start Day++/ Stop Day++	SEVERITY/ Outcome	ACTION/ Causality	SAE
GASTROINTESTINAL DISORDERS	Abdominal pain upper*/ EPIGASTRIC PAIN	Active	maraviroc QD	51/ 53	Grade 3/ Resolved (21AUG2[redacted])	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Concomitant treatment-TM12# and epivir	YES
	Diarrhoea*/ DIARRHEA	Active	maraviroc QD	51/ 53	Grade 3/ Resolved (21AUG2[redacted])	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Concomitant treatment-TM12# and epivir	YES
	Vomiting*/ VOMITING	Active	maraviroc QD	51/ 51	Grade 3/ Resolved (19AUG2[redacted])	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Concomitant treatment-TM12# and epivir	YES
A4001027 11[redacted]0004 (M/ 4[redacted](YEARS)/ [redacted])							
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	Injection site reaction*/ INJECTION SITE REACTIONS	Active	maraviroc QD	1/ 21	Grade 2/ Resolved (21AUG2[redacted])	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Concomitant treatment-enfuvirtide#	NO
A4001027 11[redacted]0008 (M/ 4[redacted](YEARS)/ [redacted])							
GASTROINTESTINAL DISORDERS	Pancreatitis*/ PANCREATITIS	Active	maraviroc QD	89/ 97	Grade 1/ Resolved (15MAY2[redacted])	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Study drug	YES

Age is at screening
* Treatment-emergent
++ Start Day and Stop Day are start and stop of AE relative to the start of treatment: First day of treatment = Day 1
[] Days in brackets are imputed days derived from incomplete dates.
SAE = Serious Adverse Event (according to Investigators assessment).
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

#:新薬承認情報提供時に置換えた。
TM12#はemtricitabine/tenofovir disoproxil fumarateを示す。

Table 3.1.4.3
Maraviroc Summary of Clinical Safety
Temporary Discontinuations or Dose Reductions Due to Adverse Events
Phase 3 Treatment Experienced CCR5 Tropic Studies

Treatment Group: maraviroc QD

System Organ Class	MedDRA (v9.0) Preferred Term/ INVESTIGATOR ENTRY	Trt Phase	Treatment At Onset	Adverse Event ------- Start Day++/ Stop Day++	SEVERITY/ Outcome	ACTION/ Causality	SAE
A4001028 1[redacted]40005 (M/ 6[redacted](YEARS)/ [redacted])							
INFECTIONS AND INFESTATIONS	Pyelonephritis*/ PYELONEPHRITIS	Active	maraviroc QD	9/ 17	Grade 1/ Resolved (30JUL2[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Concomitant treatment-indinavir	NO
RENAL AND URINARY DISORDERS	Renal pain*/ RENAL PAIN	Active	maraviroc QD	9/ 17	Grade 1/ Resolved (30JUL2[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Concomitant treatment-indinavir	NO
A4001028 1[redacted]90006 (M/ 3[redacted](YEARS)/ [redacted])							
GASTROINTESTINAL DISORDERS	Dysphagia*/ SWALLOW - PROBLEMS	Active	maraviroc QD	27/ 155	Grade 2/ Resolved (12OCT2[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Other event-suspected psychological problems with intake of pills	NO
A4001028 11[redacted]70002 (M/ 3[redacted](YEARS)/ [redacted])							
INVESTIGATIONS	Alanine aminotransferase increased*/ ALT ELEVATION	Active	maraviroc QD	59/ 65	Grade 3/ Resolved (05JAN2[redacted]	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study drug	NO

Age is at screening
* Treatment-emergent
++ Start Day and Stop Day are start and stop of AE relative to the start of treatment: First day of treatment = Day 1
[] Days in brackets are imputed days derived from incomplete dates.
SAE = Serious Adverse Event (according to Investigators assessment).
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Table 3.1.4.3
Maraviroc Summary of Clinical Safety
Temporary Discontinuations or Dose Reductions Due to Adverse Events
Phase 3 Treatment Experienced CCR5 Tropic Studies

Treatment Group: maraviroc QD

System Organ Class	MedDRA (v9.0) Preferred Term/ INVESTIGATOR ENTRY	Trt Phase	Treatment At Onset	Adverse Event ------- Start Day++/ Stop Day++	SEVERITY/ Outcome	ACTION/ Causality	SAE
INVESTIGATIONS	Alanine aminotransferase increased*/ ALT ELEVATION	Active	maraviroc QD	85/ 93	Grade 4/ Resolved (02FEB2[redacted])	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Study drug	NO
	Aspartate aminotransferase increased*/ AST ELEVATION	Active	maraviroc QD	85/ 93	Grade 3/ Resolved (02FEB2[redacted])	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Study drug	NO
A4001028 11[redacted]30025 (F/ 5[redacted](YEARS)/ [redacted])							
INFECTIONS AND INFESTATIONS	Herpes simplex*/ HSV INFECTION	Active	maraviroc QD	15/ 101	Grade 3/ Resolved (15OCT2[redacted])	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Disease under study	YES
	Oral candidiasis*/ WORSENING OF ORAL CANDIDIASIS	Active	maraviroc QD	15/ 63	Grade 3/ Resolved (07SEP2[redacted])	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Disease under study	YES
	Urinary tract infection*/ URINARY INFECTION	Active	maraviroc QD	15/ 28	Grade 2/ Resolved (03AUG2[redacted])	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Other event-intercurrent infection	YES
A4001028 11[redacted]60008 (F/ 3[redacted](YEARS)/ [redacted])							
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	Fatigue*/ FATIGUE	Active	maraviroc QD	2/ 7	Grade 1/ Resolved (01MAR2[redacted])	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Concomitant treatment-zidovudine/lamivudine#	NO

Age is at screening
* Treatment-emergent
++ Start Day and Stop Day are start and stop of AE relative to the start of treatment: First day of treatment = Day 1
[] Days in brackets are imputed days derived from incomplete dates.
SAE = Serious Adverse Event (according to Investigators assessment).
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.
PFIZER CONFIDENTIAL Includes Protocols:A4001027, A4001028. Date of Table Generation: 01NOV2006 (23:50)

#: 新薬承認情報提供時に置換えた。

Table 3.1.4.3
Maraviroc Summary of Clinical Safety
Temporary Discontinuations or Dose Reductions Due to Adverse Events
Phase 3 Treatment Experienced CCR5 Tropic Studies

Treatment Group: maraviroc QD

System Organ Class	MedDRA (v9.0) Preferred Term/ INVESTIGATOR ENTRY	Trt Phase	Treatment At Onset	Adverse Event ------- Start Day++/ Stop Day++	SEVERITY/ Outcome	ACTION/ Causality	SAE
NERVOUS SYSTEM DISORDERS	Dizziness*/ LIGHTHEADNESS	Active	maraviroc QD	2/ 7	Grade 1/ Resolved (01MAR2[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Concomitant treatment-azt componentof zidovudine/lamivudine#	NO
	Headache*/ HEADACHE	Active	maraviroc QD	2/ 7	Grade 1/ Resolved (01MAR2[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Concomitant treatment-azt component of zidovudine/lamivudine#	NO
A4001028 1[redacted]40011 (M/ 5[redacted](YEARS)/ [redacted]							
BLOOD AND LYMPHATIC SYSTEM DISORDERS	Neutropenia*/ NEUTROPENIA	Active	maraviroc QD	19/ [>19]	Grade 4/ Still Present	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Study drug	YES
INFECTIONS AND INFESTATIONS	Pneumonia bacterial*/ BACTERIAL PNEUMONIA RECURRENT	Active	maraviroc QD	43/ [>43]	Grade 4/ Still Present	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Other event-worsening pre existing condition	YES
A4001028 12[redacted]50003 (M/ 4[redacted](YEARS)/ [redacted]							
GASTROINTESTINAL DISORDERS	Diarrhoea*/ CHRONIC DIARRHEA GOT WORSENED	Active	maraviroc QD	22/ 90	Grade 2/ Resolved (25APR2[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Study drug	NO

Age is at screening
* Treatment-emergent
++ Start Day and Stop Day are start and stop of AE relative to the start of treatment: First day of treatment = Day 1
[] Days in brackets are imputed days derived from incomplete dates.
SAE = Serious Adverse Event (according to Investigators assessment).
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

※ 新薬承認情報提供時に置換えた。

Maraviroc Summary of Clinical Safety
Temporary Discontinuations or Dose Reductions Due to Adverse Events
Phase 3 Treatment Experienced CCR5 Tropic Studies

Treatment Group: maraviroc QD

System Organ Class	MedDRA (v9.0) Preferred Term/ INVESTIGATOR ENTRY	Trt Phase	Treatment At Onset	Adverse Event ------- Start Day++/ Stop Day++	SEVERITY/ Outcome	ACTION/ Causality	SAE
A4001028 12[redacted]50002 (M/ 3[redacted](YEARS)/ [redacted]							
INVESTIGATIONS	Gamma-glutamyltransferase increased*/ ELEVATED GGT	Active	maraviroc QD	86/ [>86]	Grade 4/ Still Present	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Other event-dilated intrahepatic ducts	NO

Age is at screening
* Treatment-emergent
++ Start Day and Stop Day are start and stop of AE relative to the start of treatment: First day of treatment = Day 1
[] Days in brackets are imputed days derived from incomplete dates.
SAE = Serious Adverse Event (according to Investigators assessment).
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Table 3.1.4.3
Maraviroc Summary of Clinical Safety
Temporary Discontinuations or Dose Reductions Due to Adverse Events
Phase 3 Treatment Experienced CCR5 Tropic Studies

Treatment Group: maraviroc BID

System Organ Class	MedDRA (v9.0) Preferred Term/ INVESTIGATOR ENTRY	Trt Phase	Treatment At Onset	Adverse Event ------- Start Day++/ Stop Day++	SEVERITY/ Outcome	ACTION/ Causality	SAE
A4001027 10[redacted]10003 (M/ 4[redacted](YEARS)/ [redacted])							
INVESTIGATIONS	Aspartate aminotransferase increased*/ ELEVATED AST	Active	maraviroc BID	15/ 22	Grade 3/ Resolved (20JAN2C[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Study drug	NO
A4001027 10[redacted]40016 (M/ 6[redacted](YEARS)/ [redacted])							
IMMUNE SYSTEM DISORDERS	Drug hypersensitivity*/ NEVIRAPINE HYPERSENSITIVITY	Active	maraviroc BID	2/ 13	Grade 3/ Resolved (04FEB2C[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Concomitant treatment-nevirapine	YES
A4001027 10[redacted]00004 (M/ 4[redacted](YEARS)/ [redacted])							
EAR AND LABYRINTH DISORDERS	Vertigo*/ VERTIGO	Active	maraviroc BID	1/ 8	Grade 3/ Resolved (24MAR2C[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Concomitant treatment-efavirenz	NO
GASTROINTESTINAL DISORDERS	Vomiting*/ VOMITING	Active	maraviroc BID	1/ 8	Grade 3/ Resolved (24MAR2C[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Concomitant treatment-efavirenz	NO

Age is at screening
* Treatment-emergent
++ Start Day and Stop Day are start and stop of AE relative to the start of treatment: First day of treatment = Day 1
[] Days in brackets are imputed days derived from incomplete dates.
SAE = Serious Adverse Event (according to Investigators assessment).
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Treatment Group: maraviroc BID

System Organ Class	MedDRA (v9.0) Preferred Term/ INVESTIGATOR ENTRY	Trt Phase	Treatment At Onset	Adverse Event ------- Start Day++/ Stop Day++	SEVERITY/ Outcome	ACTION/ Causality	SAE
NERVOUS SYSTEM DISORDERS	Dizziness*/ DIZZINESS	Active	maraviroc BID	1/ 8	Grade 3/ Resolved (24MAR2[redacted])	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Concomitant treatment-efavirenz	NO
	Tremor*/ SHAKINESS	Active	maraviroc BID	1/ 8	Grade 3/ Resolved (24MAR2[redacted])	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Concomitant treatment-efavirenz	NO
A4001027 1[redacted]40011 (M/ 5[redacted](YEARS)/ [redacted])							
GASTROINTESTINAL DISORDERS	Small intestinal obstruction*/ SMALL BOWEL OBSTRUCTION	Active	maraviroc BID	216/ 223	Grade 3/ Resolved (29JAN2[redacted])	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Other event-unknown cause	YES
A4001027 1[redacted]30016 (M/ 4[redacted](YEARS)/ [redacted])							
EYE DISORDERS	Dry eye*/ DRY EYES IRRITATED	Active	maraviroc BID	13/ 16	Grade 2/ Resolved (10MAR2[redacted])	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Concomitant treatment-abacavir hypersensitivity	NO
GASTROINTESTINAL DISORDERS	Diarrhoea*/ DIARRHEA	Active	maraviroc BID	13/ 19	Grade 2/ Resolved (13MAR2[redacted])	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Concomitant treatment-abacavir hypersensitivity	NO

Age is at screening
* Treatment-emergent
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[] Days in brackets are imputed days derived from incomplete dates.
SAE = Serious Adverse Event (according to Investigators assessment).
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Maraviroc Summary of Clinical Safety
Temporary Discontinuations or Dose Reductions Due to Adverse Events
Phase 3 Treatment Experienced CCR5 Tropic Studies

Treatment Group: maraviroc BID

System Organ Class	MedDRA (v9.0) Preferred Term/ INVESTIGATOR ENTRY	Trt Phase	Treatment At Onset	Adverse Event Start Day++/ Stop Day++	SEVERITY/ Outcome	ACTION/ Causality	SAE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	Cough*/ DRY COUGH	Active	maraviroc BID	13/ 16	Grade 2/ Resolved (10MAR2[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Concomitant treatment-abacavir hypersensitivity	NO
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	Erythema*/ FACIAL ERYTHEMA	Active	maraviroc BID	13/ 19	Grade 1/ Resolved (13MAR2[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Concomitant treatment-abacavir hypersensitivity	NO
	Rash pruritic*/ ITCHING RASH	Active	maraviroc BID	4/ 19	Grade 2/ Resolved (13MAR2[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Concomitant treatment-abacavir hypersensitivity	NO
A4001027 1[redacted]0018 (M/ 4[redacted](YEARS)/ [redacted]							
INFECTIONS AND INFESTATIONS	Candidiasis*/ CANDIDIASIS	Active	maraviroc BID	7/ 10	Grade 2/ Resolved (04FEB2[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Disease under study	NO
INVESTIGATIONS	Blood creatine phosphokinase increased*/ ELEVATED CK	Active	maraviroc BID	8/ 27	Grade 3/ Resolved (21FEB2[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Other event-rhabdomyolysis	NO
METABOLISM AND NUTRITION DISORDERS	Hyponatraemia*/ HYPONATREMIA	Active	maraviroc BID	7/ 10	Grade 3/ Resolved (04FEB2[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Concomitant treatment-enfuvirtide	NO

Age is at screening
* Treatment-emergent
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[] Days in brackets are imputed days derived from incomplete dates.
SAE = Serious Adverse Event (according to Investigators assessment).
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Table 3.1.4.3
Maraviroc Summary of Clinical Safety
Temporary Discontinuations or Dose Reductions Due to Adverse Events
Phase 3 Treatment Experienced CCR5 Tropic Studies

Treatment Group: maraviroc BID

System Organ Class	MedDRA (v9.0) Preferred Term/ INVESTIGATOR ENTRY	Trt Phase	Treatment At Onset	Adverse Event ------- Start Day++/ Stop Day++	SEVERITY/ Outcome	ACTION/ Causality	SAE
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	Rhabdomyolysis*/ RHABDOMYOLYSIS	Active	maraviroc BID	7/ 10	Grade 4/ Resolved (04FEB2[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Concomitant treatment-enfuvirtide#	YES
A4001027 1[redacted]20014 (M/ 4[redacted](YEARS)/ [redacted]							
INVESTIGATIONS	Blood creatine phosphokinase increased*/ ELEVATED CK	Active	maraviroc BID	335/ [>335]	Grade 4/ Still Present	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Study drug	NO
	Hepatic enzyme increased*/ ELEVATED LIVER ENZYMES	Active	maraviroc BID	335/ [>335]	Grade 3/ Still Present	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Study drug	NO
A4001027 1[redacted]20019 (M/ 3[redacted](YEARS)/ [redacted]							
GASTROINTESTINAL DISORDERS	Nausea*/ NAUSEA	Active	maraviroc BID	256/ 353	Grade 1/ Resolved (15JUL2[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Study drug	NO
	Vomiting*/ VOMITING	Active	maraviroc BID	256/ 353	Grade 1/ Resolved (15JUL2[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Study drug	NO
A4001027 1[redacted]30061 (M/ 4[redacted](YEARS)/ [redacted]							

Age is at screening
* Treatment-emergent
++ Start Day and Stop Day are start and stop of AE relative to the start of treatment: First day of treatment = Day 1
[] Days in brackets are imputed days derived from incomplete dates.
SAE = Serious Adverse Event (according to Investigators assessment).
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

#: 新薬承認情報提供時に置換えた。

Maraviroc Summary of Clinical Safety
Temporary Discontinuations or Dose Reductions Due to Adverse Events
Phase 3 Treatment Experienced CCR5 Tropic Studies

Treatment Group: maraviroc BID

System Organ Class	MedDRA (v9.0) Preferred Term/ INVESTIGATOR ENTRY	Trt Phase	Treatment At Onset	Adverse Event ------- Start Day++/ Stop Day++	SEVERITY/ Outcome	ACTION/ Causality	SAE
INVESTIGATIONS	Haemoglobin decreased*/ DECREASED HEMOGLOBIN LEVEL (7.9)	Active	maraviroc BID	19/ 36	Grade 2/ Resolved (14OCT2[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Study drug	NO
	Haemoglobin decreased*/ DECREASED HEMOGLOBIN LEVEL (8.0)	Active	maraviroc BID	1/ [>1]	Grade 1/ Still Present	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Study drug	NO
A4001027 1[redacted]50010 (M/ 4[redacted](YEARS)/ [redacted]							
INFECTIONS AND INFESTATIONS	Meningitis viral*/ VIRAL MENINGITIS	Active	maraviroc BID	93/ 100	Grade 2/ Resolved (28JUN2[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Other event-viral meningitis	YES
A4001027 1[redacted]30002 (M/ 4[redacted](YEARS)/ [redacted]							
BLOOD AND LYMPHATIC SYSTEM DISORDERS	Anaemia*/ ANEMIA	Active	maraviroc BID	49/ 138	Grade 4/ Resolved (02SEP2[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Other event-hematemesis	YES
GASTROINTESTINAL DISORDERS	Varices oesophageal*/ ESOPHAGEAL VARICES	Active	maraviroc BID	49/ 102	Grade 4/ Resolved (28JUL2[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Other event-hematemesis	YES

Age is at screening
* Treatment-emergent
++ Start Day and Stop Day are start and stop of AE relative to the start of treatment: First day of treatment = Day 1
[] Days in brackets are imputed days derived from incomplete dates.
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ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Maraviroc Summary of Clinical Safety
Temporary Discontinuations or Dose Reductions Due to Adverse Events
Phase 3 Treatment Experienced CCR5 Tropic Studies

Treatment Group: maraviroc BID

System Organ Class	MedDRA (v9.0) Preferred Term/ INVESTIGATOR ENTRY	Trt Phase	Treatment At Onset	Adverse Event ------- Start Day++/ Stop Day++	SEVERITY/ Outcome	ACTION/ Causality	SAE
A4001027 10[redacted]40011 (M/ 5[redacted](YEARS)/ [redacted])							
BLOOD AND LYMPHATIC SYSTEM DISORDERS	Anaemia*/ ANEMIA	Active	maraviroc BID	307/ [>307]	Grade 2/ Still Present	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Concomitant treatment-lotrel, his anti-hypertensive medication	NO
NERVOUS SYSTEM DISORDERS	Dizziness*/ LIGHTHEADEDNESS	Active	maraviroc BID	307/ 342	Grade 2/ Resolved (27JUN20[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Concomitant treatment-lotrel, his anti-hypertensive medication	NO
A4001027 10[redacted]00002 (M/ 4[redacted](YEARS)/ [redacted])							
GASTROINTESTINAL DISORDERS	Dysphagia*/ DYSPHAGIA	Active	maraviroc BID	9/ [>9]	Grade 4/ Still Present	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Other event-unknown	YES
A4001027 10[redacted]30025 (M/ 3[redacted](YEARS)/ [redacted])							

Age is at screening
* Treatment-emergent
++ Start Day and Stop Day are start and stop of AE relative to the start of treatment: First day of treatment = Day 1
[] Days in brackets are imputed days derived from incomplete dates.
SAE = Serious Adverse Event (according to Investigators assessment).
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Maraviroc Summary of Clinical Safety
Temporary Discontinuations or Dose Reductions Due to Adverse Events
Phase 3 Treatment Experienced CCR5 Tropic Studies

Treatment Group: maraviroc BID

System Organ Class	MedDRA (v9.0) Preferred Term/ INVESTIGATOR ENTRY	Trt Phase	Treatment At Onset	Adverse Event ------- Start Day++/ Stop Day++	SEVERITY/ Outcome	ACTION/ Causality	SAE
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	Rash*/ SKIN ERUPTIONS	Active	maraviroc BID	158/ 179	Grade 1/ Resolved (09JUN2[redacted])	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Study drug	NO
A4001027 1[redacted]10022 (M/ 4[redacted](YEARS)/ [redacted])							
GASTROINTESTINAL DISORDERS	Pancreatitis*/ ASYMPTOMATIC PANCREATITIS	Active	maraviroc BID	57/ [>57]	Grade 2/ Still Present	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Study drug	NO
A4001027 1[redacted]10025 (M/ 4[redacted](YEARS)/ [redacted])							
INVESTIGATIONS	Blood creatine increased*/ ELEVATED CREATINE	Active	maraviroc BID	112/ [>112]	Grade 2/ Still Present	STUDY DRUG ACTION: (REDUCED)/ Study drug	NO
	Blood potassium increased*/ ELEVATED POTASSIUM	Active	maraviroc BID	112/ [>112]	Grade 2/ Still Present	STUDY DRUG ACTION: (REDUCED)/ Study drug	NO
A4001027 11[redacted]20001 (F/ 3[redacted](YEARS)/ [redacted])							
IMMUNE SYSTEM DISORDERS	Hypersensitivity*/ HYPERSENSITIVITY REACTION	Active	maraviroc BID	8/ 15	Grade 3/ Resolved (20APR2[redacted])	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Concomitant treatment-abacavir	NO

Age is at screening
* Treatment-emergent
++ Start Day and Stop Day are start and stop of AE relative to the start of treatment: First day of treatment = Day 1
[] Days in brackets are imputed days derived from incomplete dates.
SAE = Serious Adverse Event (according to Investigators assessment).
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Table 3.1.4.3
Maraviroc Summary of Clinical Safety
Temporary Discontinuations or Dose Reductions Due to Adverse Events
Phase 3 Treatment Experienced CCR5 Tropic Studies

Treatment Group: maraviroc BID

System Organ Class	MedDRA (v9.0) Preferred Term/ INVESTIGATOR ENTRY	Trt Phase	Treatment At Onset	Adverse Event ------- Start Day++/ Stop Day++	SEVERITY/ Outcome	ACTION/ Causality	SAE
A4001027 11[redacted]0011 (M/ 4[redacted](YEARS)/ [redacted])							
INVESTIGATIONS	Blood amylase increased*/ ELEVATED AMYLASE	Active	maraviroc BID	29/ 34	Grade 4/ Resolved (22AUG2C[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Concomitant treatment-didanosine	YES
	Lipase increased*/ ELEVATED LIPASE	Active	maraviroc BID	29/ 34	Grade 4/ Resolved (22AUG2C[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Concomitant treatment-didanosine	YES
A4001027 11[redacted]0001 (F/ 4[redacted](YEARS)/ [redacted])							
GASTROINTESTINAL DISORDERS	Nausea*/ HOSPITALIZED FOR WORSENING NAUSEA	Active	maraviroc BID	18/ 21	Grade 3/ Resolved (13MAR2C[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Other event-progressive mulitfocal leukoencephalopathy	YES
INFECTIONS AND INFESTATIONS	Progressive multifocal leukoencephalopathy*/ PROGRESSIVE MULTIFOCAL LEUKOENCEPHALOPATHY	Active	maraviroc BID	11/ [>11]	Grade 3/ Still Present	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Disease under study	YES
METABOLISM AND NUTRITION DISORDERS	Dehydration*/ HOSPITALIZED FOR DEHYDRATION	Active	maraviroc BID	9/ [>9]	Grade 3/ Still Present	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Other event-progressive multifocal leukoencephalopathy	YES

Age is at screening
* Treatment-emergent
++ Start Day and Stop Day are start and stop of AE relative to the start of treatment: First day of treatment = Day 1
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SAE = Serious Adverse Event (according to Investigators assessment).
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Maraviroc Summary of Clinical Safety
Temporary Discontinuations or Dose Reductions Due to Adverse Events
Phase 3 Treatment Experienced CCR5 Tropic Studies

Treatment Group: maraviroc BID

System Organ Class	MedDRA (v9.0) Preferred Term/ INVESTIGATOR ENTRY	Trt Phase	Treatment At Onset	Adverse Event ------- Start Day++/ Stop Day++	SEVERITY/ Outcome	ACTION/ Causality	SAE
A4001027 11[redacted]0009 (F/ 5[redacted](YEARS)/ [redacted])							
INVESTIGATIONS	Alanine aminotransferase increased*/ ELEVATED ALT	Active	maraviroc BID	147/ [>147]	Grade 3/ Still Present	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Study drug	NO
	Aspartate aminotransferase increased*/ ELEVATED AST	Active	maraviroc BID	147/ [>147]	Grade 3/ Still Present	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Study drug	NO
	Gamma-glutamyltransferase increased*/ ELEVATED GGT	Active	maraviroc BID	147/ [>147]	Grade 4/ Still Present	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Study drug	NO
A4001028 10[redacted]0003 (M/ 5[redacted](YEARS)/ [redacted])							
GASTROINTESTINAL DISORDERS	Nausea*/ NAUSEA	Active	maraviroc BID	20/ 44	Grade 2/ Resolved (01JUN20[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Study drug	NO
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	Pyrexia*/ FEVER	Active	maraviroc BID	21/ 44	Grade 3/ Resolved (01JUN20[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Other event-mycobacterial infection	YES
INFECTIONS AND INFESTATIONS	Mycoplasma infection*/ MYCOPLASMA INFECTION	Active	maraviroc BID	20/ 58	Grade 3/ Resolved (15JUN20[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Other event-mycoplasma infection	YES

Age is at screening
* Treatment-emergent
++ Start Day and Stop Day are start and stop of AE relative to the start of treatment: First day of treatment = Day 1
[] Days in brackets are imputed days derived from incomplete dates.
SAE = Serious Adverse Event (according to Investigators assessment).
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Maraviroc Summary of Clinical Safety
Temporary Discontinuations or Dose Reductions Due to Adverse Events
Phase 3 Treatment Experienced CCR5 Tropic Studies

Treatment Group: maraviroc BID

System Organ Class	MedDRA (v9.0) Preferred Term/ INVESTIGATOR ENTRY	Trt Phase	Treatment At Onset	Adverse Event ------- Start Day++/ Stop Day++	SEVERITY/ Outcome	ACTION/ Causality	SAE
INVESTIGATIONS	Weight decreased*/ WEIGHT LOSS	Active	maraviroc BID	20/ 44	Grade 2/ Resolved (01JUN2C[redacted])	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Other event-mycobacterial infection	YES
METABOLISM AND NUTRITION DISORDERS	Anorexia*/ ANOREXIA	Active	maraviroc BID	20/ 44	Grade 2/ Resolved (01JUN2C[redacted])	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Study drug	NO
NERVOUS SYSTEM DISORDERS	Headache*/ HEADACHE	Active	maraviroc BID	20/ 23	Grade 1/ Resolved (11MAY2C[redacted])	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Study drug	NO
A4001028 1C[redacted]10005 (F/ 3[redacted](YEARS)/ [redacted])							
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	Rash*/ SKIN RASH	Active	maraviroc BID	13/ 20	Grade 2/ Resolved (31JUL2C[redacted])	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Study drug	NO
A4001028 1C[redacted]90003 (M/ 4[redacted](YEARS)/ [redacted])							
INVESTIGATIONS	Alanine aminotransferase increased*/ HIGH RESULTS OF ALT	Active	maraviroc BID	283/ [>283]	Grade 2/ Still Present	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Study drug	NO
	Aspartate aminotransferase increased*/ HIGH RESULTS OF AST	Active	maraviroc BID	283/ [>283]	Grade 2/ Still Present	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Study drug	NO

Age is at screening
* Treatment-emergent
++ Start Day and Stop Day are start and stop of AE relative to the start of treatment: First day of treatment = Day 1
[] Days in brackets are imputed days derived from incomplete dates.
SAE = Serious Adverse Event (according to Investigators assessment).
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Table 3.1.4.3
Maraviroc Summary of Clinical Safety
Temporary Discontinuations or Dose Reductions Due to Adverse Events
Phase 3 Treatment Experienced CCR5 Tropic Studies

Treatment Group: maraviroc BID

System Organ Class	MedDRA (v9.0) Preferred Term/ INVESTIGATOR ENTRY	Trt Phase	Treatment At Onset	Adverse Event ------- Start Day++/ Stop Day++	SEVERITY/ Outcome	ACTION/ Causality	SAE
INVESTIGATIONS	Gamma-glutamyltransferase increased*/ HIGH RESULTS OF GGT	Active	maraviroc BID	283/ [>283]	Grade 2/ Still Present	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Study drug	NO
A4001028 1C[redacted]0001 (M/ 5[redacted](YEARS)/ [redacted]							
GASTROINTESTINAL DISORDERS	Nausea*/ INCREASED NAUSEA	Active	maraviroc BID	22/ 57	Grade 3/ Resolved (01JUN2C[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Study drug	YES
	Vomiting*/ INCREASED VOMITING	Active	maraviroc BID	22/ 57	Grade 3/ Resolved (01JUN2C[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Study drug	YES
A4001028 1C[redacted]20001 (M/ 3[redacted](YEARS)/ [redacted]							
GASTROINTESTINAL DISORDERS	Vomiting*/ VOMITING	Active	maraviroc BID	300/ 308	Grade 1/ Resolved (13MAR2C[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Other event-unknown	YES
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	Back pain*/ UPPER LUMBAR SACRAL TENDERNESS	Active	maraviroc BID	289/ [>289]	Grade 2/ Still Present	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Other event-unknown	NO
	Flank pain*/ FLANK PAIN	Active	maraviroc BID	289/ [>289]	Grade 4/ Still Present	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Other event-unknown	YES

Age is at screening
* Treatment-emergent
++ Start Day and Stop Day are start and stop of AE relative to the start of treatment: First day of treatment = Day 1
[] Days in brackets are imputed days derived from incomplete dates.
SAE = Serious Adverse Event (according to Investigators assessment).
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Maraviroc Summary of Clinical Safety
Temporary Discontinuations or Dose Reductions Due to Adverse Events
Phase 3 Treatment Experienced CCR5 Tropic Studies

Treatment Group: maraviroc BID

System Organ Class	MedDRA (v9.0) Preferred Term/ INVESTIGATOR ENTRY	Trt Phase	Treatment At Onset	Adverse Event ------- Start Day++/ Stop Day++	SEVERITY/ Outcome	ACTION/ Causality	SAE
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	Night sweats*/ NIGHT SWEATS	Active	maraviroc BID	296/ [>296]	Grade 1/ Still Present	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Study drug	NO
A4001028 1C[redacted]10008 (M/ 4[redacted](YEARS)/ [redacted]							
RENAL AND URINARY DISORDERS	Renal colic*/ RENAL COLIC	Active	maraviroc BID	77/ 77	Grade 3/ Resolved (01SEP2C[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Concomitant treatment-obt - intolerance to indinavir	NO
A4001028 11[redacted]30004 (M/ 6[redacted](YEARS)/ [redacted]							
INVESTIGATIONS	Hepatic enzyme increased* / ELEVATED LIVER ENZYMES	Active	maraviroc BID	150/ [>150]	Grade 2/ Still Present	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Study drug	YES
A4001028 11[redacted]30002 (M/ 4[redacted](YEARS)/ [redacted]							
INFECTIONS AND INFESTATIONS	Gastroenteritis*/ GASTROENTERITIS	Active	maraviroc BID	150/ 156	Grade 2/ Resolved (29OCT2C[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Other event-food poisoning	NO

Age is at screening
* Treatment-emergent
++ Start Day and Stop Day are start and stop of AE relative to the start of treatment: First day of treatment = Day 1
[] Days in brackets are imputed days derived from incomplete dates.
SAE = Serious Adverse Event (according to Investigators assessment).
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Table 3.1.4.3
Maraviroc Summary of Clinical Safety
Temporary Discontinuations or Dose Reductions Due to Adverse Events
Phase 3 Treatment Experienced CCR5 Tropic Studies

Treatment Group: maraviroc BID

System Organ Class	MedDRA (v9.0) Preferred Term/ INVESTIGATOR ENTRY	Trt Phase	Treatment At Onset	Adverse Event ------- Start Day++/ Stop Day++	SEVERITY/ Outcome	ACTION/ Causality	SAE
A4001028 11[redacted]0013 (M/ 4[redacted]YEARS)/ [redacted]							
GASTROINTESTINAL DISORDERS	Abdominal pain upper*/ MID EPIGASTRIC PAIN	Active	maraviroc BID	40/ 42	Grade 2/ Resolved (10APR2[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Study drug	NO
	Abdominal pain upper*/ STOMACH ACHE	Active	maraviroc BID	20/ 20	Grade 1/ Resolved (19MAR2[redacted]	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Other event-subject questions food he ate	NO
A4001028 11[redacted]0004 (M/ 4[redacted]YEARS)/ [redacted]							
BLOOD AND LYMPHATIC SYSTEM DISORDERS	Febrile neutropenia*/ FEBRILE NEUTROPENIA	Active	maraviroc BID	23/ 26	Grade 2/ Resolved (27MAR2[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Concomitant treatment-tipranovir	YES
	Neutropenia*/ NEUTROPENIA	Active	maraviroc BID	23/ 34	Grade 4/ Resolved (04APR2[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Concomitant treatment-tipranovir	YES
GASTROINTESTINAL DISORDERS	Diarrhoea*/ URGENT DIARRHEA	Active	maraviroc BID	23/ 29	Grade 2/ Resolved (30MAR2[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Other event-history of diarrhea that has increased in urgency	YES

Age is at screening
* Treatment-emergent
++ Start Day and Stop Day are start and stop of AE relative to the start of treatment: First day of treatment = Day 1
[] Days in brackets are imputed days derived from incomplete dates.
SAE = Serious Adverse Event (according to Investigators assessment).
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Table 3.1.4.3
Maraviroc Summary of Clinical Safety
Temporary Discontinuations or Dose Reductions Due to Adverse Events
Phase 3 Treatment Experienced CCR5 Tropic Studies

Treatment Group: maraviroc BID

System Organ Class	MedDRA (v9.0) Preferred Term/ INVESTIGATOR ENTRY	Trt Phase	Treatment At Onset	Adverse Event ------- Start Day++/ Stop Day++	SEVERITY/ Outcome	ACTION/ Causality	SAE
INVESTIGATIONS	Weight decreased*/ WEIGHT LOSS	Active	maraviroc BID	23/ 29	Grade 1/ Resolved (30MAR2[redacted])	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Other event-related to increased diarrhea	YES
A4001028 12[redacted]50004 (M/ 6[redacted](YEARS)/ [redacted])							
INVESTIGATIONS	Aspartate aminotransferase increased*/ AST ELEVATION	Active	maraviroc BID	15/ 22	Grade 4/ Resolved (04APR2[redacted])	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Study drug	NO
	Blood creatine phosphokinase increased*/ ELEVATED CREATININE KINASE	Active	maraviroc BID	15/ 22	Grade 4/ Resolved (04APR2[redacted])	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Study drug	NO
A4001028 12[redacted]50010 (M/ 5[redacted](YEARS)/ [redacted])							
BLOOD AND LYMPHATIC SYSTEM DISORDERS	Lymphadenopathy*/ ADENOPATHY	Active	maraviroc BID	10/ 21	Grade 2/ Resolved (16APR2[redacted])	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Other event-viral syndrome	NO
INFECTIONS AND INFESTATIONS	Pharyngitis*/ PHARYNGITIS	Active	maraviroc BID	10/ 21	Grade 2/ Resolved (16APR2[redacted])	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Other event-viral syndrome	NO

Age is at screening
* Treatment-emergent
++ Start Day and Stop Day are start and stop of AE relative to the start of treatment: First day of treatment = Day 1
[] Days in brackets are imputed days derived from incomplete dates.
SAE = Serious Adverse Event (according to Investigators assessment).
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Maraviroc Summary of Clinical Safety
Temporary Discontinuations or Dose Reductions Due to Adverse Events
Phase 3 Treatment Experienced CCR5 Tropic Studies

Treatment Group: Placebo

System Organ Class	MedDRA (v9.0) Preferred Term/ INVESTIGATOR ENTRY	Trt Phase	Treatment At Onset	Adverse Event ------- Start Day++/ Stop Day++	SEVERITY/ Outcome	ACTION/ Causality	SAE
A4001027 1[redacted]70022 (M/ 5[redacted](YEARS)/ [redacted])							
INFECTIONS AND INFESTATIONS	Lobar pneumonia*/ LOWER LOBE PNEUMONIA	Active	Placebo	19/ 28	Grade 3/ Resolved (02MAR2[redacted])	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Disease under study	YES
A4001027 1[redacted]00015 (F/ 5[redacted](YEARS)/ [redacted])							
NERVOUS SYSTEM DISORDERS	Memory impairment*/ LOSS OF SOME MEMORY FUNCTION	Active	Placebo	4/ 23	Grade 2/ Resolved (02MAR2[redacted])	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Concomitant treatment-multiple medications	YES
A4001027 1[redacted]10009 (F/ 4[redacted](YEARS)/ [redacted])							
GASTROINTESTINAL DISORDERS	Pancreatitis*/ PANCREATITIS	Active	Placebo	56/ 63	Grade 4/ Resolved (07SEP2[redacted])	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Concomitant treatment-lopinavir/ritonavir# and ddi ec	YES
A4001027 1[redacted]80001 (M/ 3[redacted](YEARS)/ [redacted])							

Age is at screening
* Treatment-emergent
++ Start Day and Stop Day are start and stop of AE relative to the start of treatment: First day of treatment = Day 1
[] Days in brackets are imputed days derived from incomplete dates.
SAE = Serious Adverse Event (according to Investigators assessment).
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

#: 新薬承認情報提供時に置換え。

Maraviroc Summary of Clinical Safety
Temporary Discontinuations or Dose Reductions Due to Adverse Events
Phase 3 Treatment Experienced CCR5 Tropic Studies

Treatment Group: Placebo

System Organ Class	MedDRA (v9.0) Preferred Term/ INVESTIGATOR ENTRY	Trt Phase	Treatment At Onset	Adverse Event ------- Start Day++/ Stop Day++	SEVERITY/ Outcome	ACTION/ Causality	SAE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	Anaemia*/ ANEMIA	Active	Placebo	30/ 57	Grade 2/ Resolved (15MAR2[redacted])	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Other event-anemia of chronic disease	YES
A4001028 1[redacted]20005 (M/ 4[redacted](YEARS)/ [redacted])							
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	Overdose*/ OVERDOSE	Active	Placebo	1/ 58	Grade 3/ Resolved (17NOV2[redacted])	STUDY DRUG ACTION: (REDUCED)/ Other event-pt was on dose of 300 mg instead of 150 mg till wk 8.	YES
A4001028 1[redacted]50003 (M/ 3[redacted](YEARS)/ [redacted])							
INFECTIONS AND INFESTATIONS	Pneumonia bacterial*/ BACTERIAL PNEUMONIA	Active	Placebo	10/ 17	Grade 4/ Resolved (05DEC2[redacted])	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Other event-bacterial pneumonia	YES
A4001028 1[redacted]10002 (M/ 3[redacted](YEARS)/ [redacted])							
GASTROINTESTINAL DISORDERS	Diarrhoea*/ WORSENING OF DIARRHOEA	Active	Placebo	5/ 6	Grade 2/ Resolved (23APR2[redacted])	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Concomitant treatment-ritonavir	NO

Age is at screening
* Treatment-emergent
++ Start Day and Stop Day are start and stop of AE relative to the start of treatment: First day of treatment = Day 1
[] Days in brackets are imputed days derived from incomplete dates.
SAE = Serious Adverse Event (according to Investigators assessment).
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Table 3.1.4.3
Maraviroc Summary of Clinical Safety
Temporary Discontinuations or Dose Reductions Due to Adverse Events
Phase 3 Treatment Experienced CCR5 Tropic Studies

Treatment Group: Placebo

System Organ Class	MedDRA (v9.0) Preferred Term/ INVESTIGATOR ENTRY	Trt Phase	Treatment At Onset	Adverse Event ------- Start Day++/ Stop Day++	SEVERITY/ Outcome	ACTION/ Causality	SAE
GASTROINTESTINAL DISORDERS	Nausea*/ NAUSEA	Active	Placebo	1/ 12	Grade 1/ Resolved (29APR2C[redacted])	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Concomitant treatment-ritonavir	NO
	Vomiting*/ VOMITING	Active	Placebo	5/ 6	Grade 2/ Resolved (23APR2C[redacted])	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Concomitant treatment-ritonavir	NO
A4001028 1C[redacted]40003 (M/ 4[redacted](YEARS)/ [redacted])							
HEPATOBILIARY DISORDERS	Cytolytic hepatitis*/ HEPATIC CYTOLYSIS	Active	Placebo	28/ 37	Grade 3/ Resolved (01DEC2C[redacted])	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Study drug	NO
A4001028 1C[redacted]50013 (M/ 4[redacted](YEARS)/ [redacted])							
CARDIAC DISORDERS	Aortic valve disease*/ WORSENING AORTIC VALVULAR DEFECT	Active	Placebo	186/ [>186]	Grade 3/ Still Present	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Other event-patient history aortic valvula defect	YES
A4001028 1C[redacted]10014 (M/ 4[redacted](YEARS)/ [redacted])							

Age is at screening
* Treatment-emergent
++ Start Day and Stop Day are start and stop of AE relative to the start of treatment: First day of treatment = Day 1
[] Days in brackets are imputed days derived from incomplete dates.
SAE = Serious Adverse Event (according to Investigators assessment).
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Table 3.1.4.3
Maraviroc Summary of Clinical Safety
Temporary Discontinuations or Dose Reductions Due to Adverse Events
Phase 3 Treatment Experienced CCR5 Tropic Studies

Treatment Group: Placebo

System Organ Class	MedDRA (v9.0) Preferred Term/ INVESTIGATOR ENTRY	Trt Phase	Treatment At Onset	Adverse Event ------- Start Day++/ Stop Day++	SEVERITY/ Outcome	ACTION/ Causality	SAE
HEPATOBILIARY DISORDERS	Hyperbilirubinaemia*/ HYPERBILIRUBINEMIA	Active	Placebo	12/ 200	Grade 4/ Resolved (13MAR2C[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Concomitant treatment-obt-atazanavir and ritonavir	NO
A4001028 1C[redacted]50004 (M/ 5[redacted](YEARS)/ [redacted]							
GASTROINTESTINAL DISORDERS	Flatulence*/ FLATULENCE	Active	Placebo	145/ 188	Grade 2/ Resolved (14FEB2C[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Study drug.	NO
A4001028 1C[redacted]90015 (F/ 4[redacted](YEARS)/ [redacted]							
HEPATOBILIARY DISORDERS	Hepatitis toxic*/ TOXIC HEPATITIS	Active	Placebo	58/ 149	Grade 4/ Resolved (24AUG2C[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Concomitant treatment-tipranavir	NO
A4001028 1C[redacted]00005 (M/ 5[redacted](YEARS)/ [redacted]							
GASTROINTESTINAL DISORDERS	Diarrhoea*/ DIARRHOEA	Active	Placebo	274/ 278	Grade 1/ Resolved (09APR2C[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Study drug	NO
	Vomiting*/ VOMITING	Active	Placebo	274/ 274	Grade 1/ Resolved (05APR2C[redacted]	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Other event-viral cause	NO

Age is at screening
* Treatment-emergent
++ Start Day and Stop Day are start and stop of AE relative to the start of treatment: First day of treatment = Day 1
[] Days in brackets are imputed days derived from incomplete dates.
SAE = Serious Adverse Event (according to Investigators assessment).
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Table 3.1.4.3
Maraviroc Summary of Clinical Safety
Temporary Discontinuations or Dose Reductions Due to Adverse Events
Phase 3 Treatment Experienced CCR5 Tropic Studies

Treatment Group: Placebo

System Organ Class	MedDRA (v9.0) Preferred Term/ INVESTIGATOR ENTRY	Trt Phase	Treatment At Onset	Adverse Event ------- Start Day++/ Stop Day++	SEVERITY/ Outcome	ACTION/ Causality	SAE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	Pyrexia*/ FEVER	Active	Placebo	142/ 163	Grade 1/ Resolved (15DEC2[redacted])	STUDY DRUG ACTION: (NO ACTION TAKEN) SUBJECT ACTION: (NO ACTION)/ Disease under study	NO
	Pyrexia*/ FEVER	Active	Placebo	263/ 264	Grade 3/ Resolved (26MAR2[redacted])	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Disease under study	YES
INFECTIONS AND INFESTATIONS	Gastroenteritis*/ GASTROENTERITIS	Active	Placebo	274/ 280	Grade 3/ Resolved (11APR2[redacted])	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Other event-viral	NO
RENAL AND URINARY DISORDERS	Renal failure acute*/ ACUTE RENAL FAILURE	Active	Placebo	263/ 283	Grade 4/ Resolved (14APR2[redacted])	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Study drug	YES
A4001028 12[redacted]50005 (M/ 4[redacted](YEARS)/ [redacted]							
EAR AND LABYRINTH DISORDERS	Ear disorder*/ THROBBING IN EARS	Active	Placebo	21/ 38	Grade 2/ Resolved (30APR2[redacted])	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Concomitant treatment-secondary to obt, efavirenz	NO
NERVOUS SYSTEM DISORDERS	Dizziness*/ LIGHTHEADEDNESS	Active	Placebo	21/ 38	Grade 2/ Resolved (30APR2[redacted])	STUDY DRUG ACTION: (STOPPED TEMPORARILY)/ Concomitant treatment-secondary to obt, efavirenz	NO

Age is at screening
* Treatment-emergent
++ Start Day and Stop Day are start and stop of AE relative to the start of treatment: First day of treatment = Day 1
[] Days in brackets are imputed days derived from incomplete dates.
SAE = Serious Adverse Event (according to Investigators assessment).
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Table 3.1.5.1
Maraviroc Summary of Clinical Safety
Discontinuation from Study by Sex
Phase 2b/3 Treatment Experienced Studies

Sex: MALE

Number (%) of Subjects	maraviroc QD 416		maraviroc BID 437		Placebo 238	
Discontinuations						
Subject Died	5	(1.2)	6	(1.4)	2	(0.8)
Related to Study Drug	113	(27.2)	114	(26.1)	125	(52.5)
Adverse event	10	(2.4)	10	(2.3)	7	(2.9)
Lack of efficacy	103	(24.8)	104	(23.8)	118	(49.6)
Not Related to Study Drug	40	(9.6)	33	(7.6)	24	(10.1)
Adverse event	4	(1.0)	7	(1.6)	3	(1.3)
Other	9	(2.2)	3	(0.7)	8	(3.4)
Subject defaulted	27	(6.5)	23	(5.3)	13	(5.5)
Total	158	(38.0)	153	(35.0)	151	(63.4)

Subject defaulted means Subject no longer willing to participate in study or Lost to follow-up.

Table 3.1.5.1
Maraviroc Summary of Clinical Safety
Discontinuation from Study by Sex
Phase 2b/3 Treatment Experienced Studies

Sex: FEMALE

Number (%) of Subjects	maraviroc QD 61		maraviroc BID 50		Placebo 33	
Discontinuations						
Subject Died	0		0		1	(3.0)
Related to Study Drug	15	(24.6)	12	(24.0)	12	(36.4)
Adverse event	2	(3.3)	1	(2.0)	0	
Lack of efficacy	13	(21.3)	11	(22.0)	12	(36.4)
Not Related to Study Drug	8	(13.1)	5	(10.0)	7	(21.2)
Adverse event	0		0		2	(6.1)
Other	4	(6.6)	2	(4.0)	2	(6.1)
Subject defaulted	4	(6.6)	3	(6.0)	3	(9.1)
Total	23	(37.7)	17	(34.0)	20	(60.6)

Subject defaulted means Subject no longer willing to participate in study or Lost to follow-up.

Table 3.1.5.2
Maraviroc Summary of Clinical Safety
Discontinuation from Study by Age
Phase 2b/3 Treatment Experienced Studies

Age category: 16-44

Number (%) of Subjects	maraviroc QD 209		maraviroc BID 200		Placebo 119	
Discontinuations						
Subject Died	1	(0.5)	0		1	(0.8)
Related to Study Drug	59	(28.2)	55	(27.5)	51	(42.9)
Adverse event	4	(1.9)	4	(2.0)	2	(1.7)
Lack of efficacy	55	(26.3)	51	(25.5)	49	(41.2)
Not Related to Study Drug	23	(11.0)	16	(8.0)	19	(16.0)
Adverse event	1	(0.5)	2	(1.0)	1	(0.8)
Other	8	(3.8)	2	(1.0)	8	(6.7)
Subject defaulted	14	(6.7)	12	(6.0)	10	(8.4)
Total	83	(39.7)	71	(35.5)	71	(59.7)

Subject defaulted means Subject no longer willing to participate in study or Lost to follow-up.

Table 3.1.5.2
Maraviroc Summary of Clinical Safety
Discontinuation from Study by Age
Phase 2b/3 Treatment Experienced Studies

Age category: 45-64

Number (%) of Subjects	maraviroc QD 258		maraviroc BID 282		Placebo 148	
Discontinuations						
Subject Died	4	(1.6)	6	(2.1)	2	(1.4)
Related to Study Drug	69	(26.7)	69	(24.5)	85	(57.4)
Adverse event	8	(3.1)	7	(2.5)	5	(3.4)
Lack of efficacy	61	(23.6)	62	(22.0)	80	(54.1)
Not Related to Study Drug	21	(8.1)	22	(7.8)	11	(7.4)
Adverse event	1	(0.4)	5	(1.8)	4	(2.7)
Other	5	(1.9)	3	(1.1)	2	(1.4)
Subject defaulted	15	(5.8)	14	(5.0)	5	(3.4)
Total	94	(36.4)	97	(34.4)	98	(66.2)

Subject defaulted means Subject no longer willing to participate in study or Lost to follow-up.

Table 3.1.5.2
Maraviroc Summary of Clinical Safety
Discontinuation from Study by Age
Phase 2b/3 Treatment Experienced Studies

Age category: 65 and over

Number (%) of Subjects	maraviroc QD 10		maraviroc BID 5		Placebo 4	
Discontinuations						
Subject Died	0		0		0	
Related to Study Drug	0		2	(40.0)	1	(25.0)
Adverse event	0		0		0	
Lack of efficacy	0		2	(40.0)	1	(25.0)
Not Related to Study Drug	4	(40.0)	0		1	(25.0)
Adverse event	2	(20.0)	0		0	
Other	0		0		0	
Subject defaulted	2	(20.0)	0		1	(25.0)
Total	4	(40.0)	2	(40.0)	2	(50.0)

Subject defaulted means Subject no longer willing to participate in study or Lost to follow-up.

Table 3.1.5.3
Maraviroc Summary of Clinical Safety
Discontinuation from Study by Race
Phase 2b/3 Treatment Experienced Studies

Race: WHITE

Number (%) of Subjects	maraviroc QD 382		maraviroc BID 407		Placebo 218	
Discontinuations						
Subject Died	4	(1.0)	5	(1.2)	3	(1.4)
Related to Study Drug	103	(27.0)	101	(24.8)	115	(52.8)
Adverse event	11	(2.9)	9	(2.2)	6	(2.8)
Lack of efficacy	92	(24.1)	92	(22.6)	109	(50.0)
Not Related to Study Drug	29	(7.6)	30	(7.4)	23	(10.6)
Adverse event	2	(0.5)	6	(1.5)	2	(0.9)
Other	7	(1.8)	4	(1.0)	7	(3.2)
Subject defaulted	20	(5.2)	20	(4.9)	14	(6.4)
Total	136	(35.6)	136	(33.4)	141	(64.7)

Subject defaulted means Subject no longer willing to participate in study or Lost to follow-up.

Table 3.1.5.3
Maraviroc Summary of Clinical Safety
Discontinuation from Study by Race
Phase 2b/3 Treatment Experienced Studies

Race: BLACK

Number (%) of Subjects	maraviroc QD 87		maraviroc BID 64		Placebo 44	
Discontinuations						
Subject Died	1	(1.1)	0		0	
Related to Study Drug	24	(27.6)	22	(34.4)	19	(43.2)
Adverse event	1	(1.1)	2	(3.1)	1	(2.3)
Lack of efficacy	23	(26.4)	20	(31.3)	18	(40.9)
Not Related to Study Drug	19	(21.8)	7	(10.9)	7	(15.9)
Adverse event	2	(2.3)	1	(1.6)	3	(6.8)
Other	6	(6.9)	1	(1.6)	3	(6.8)
Subject defaulted	11	(12.6)	5	(7.8)	1	(2.3)
Total	44	(50.6)	29	(45.3)	26	(59.1)

Subject defaulted means Subject no longer willing to participate in study or Lost to follow-up.

Table 3.1.5.3
Maraviroc Summary of Clinical Safety
Discontinuation from Study by Race
Phase 2b/3 Treatment Experienced Studies

Race: ASIAN

Number (%) of Subjects	maraviroc QD 3	maraviroc BID 6	Placebo 4
Discontinuations			
Subject Died	0	1 (16.7)	0
Related to Study Drug	0	0	1 (25.0)
Adverse event	0	0	0
Lack of efficacy	0	0	1 (25.0)
Not Related to Study Drug	0	0	0
Adverse event	0	0	0
Other	0	0	0
Subject defaulted	0	0	0
Total	0	1 (16.7)	1 (25.0)

Subject defaulted means Subject no longer willing to participate in study or Lost to follow-up.

Table 3.1.5.3
Maraviroc Summary of Clinical Safety
Discontinuation from Study by Race
Phase 2b/3 Treatment Experienced Studies

Race: OTHER

Number (%) of Subjects	maraviroc QD 4		maraviroc BID 10		Placebo 5	
Discontinuations						
Subject Died	0		0		0	
Related to Study Drug	1	(25.0)	3	(30.0)	2	(40.0)
Adverse event	0		0		0	
Lack of efficacy	1	(25.0)	3	(30.0)	2	(40.0)
Not Related to Study Drug	0		1	(10.0)	1	(20.0)
Adverse event	0		0		0	
Other	0		0		0	
Subject defaulted	0		1	(10.0)	1	(20.0)
Total	1	(25.0)	4	(40.0)	3	(60.0)

Subject defaulted means Subject no longer willing to participate in study or Lost to follow-up.

Table 3.1.5.3
Maraviroc Summary of Clinical Safety
Discontinuation from Study by Race
Phase 2b/3 Treatment Experienced Studies

Race: Unspecified

Number (%) of Subjects	maraviroc QD 1
Discontinuations	
Subject Died	0
Related to Study Drug	0
Adverse event	0
Lack of efficacy	0
Not Related to Study Drug	0
Adverse event	0
Other	0
Subject defaulted	0
Total	0

Subject defaulted means Subject no longer willing to participate in study or Lost to follow-up.

Table 3.1.7.1
Maraviroc Summary of Clinical Safety
Discontinuation from Study by Sex
Phase 3 Treatment Experienced CCR5 Tropic Studies

Group by: MALE

Number (%) of Subjects	maraviroc QD 363		maraviroc BID 382		Placebo 185	
Discontinuations						
Subject Died	3	(0.8)	5	(1.3)	0	
Related to Study Drug	84	(23.1)	92	(24.1)	103	(55.7)
Adverse event	10	(2.8)	9	(2.4)	5	(2.7)
Lack of efficacy	74	(20.4)	83	(21.7)	98	(53.0)
Not Related to Study Drug	39	(10.7)	28	(7.3)	15	(8.1)
Adverse event	4	(1.1)	6	(1.6)	1	(0.5)
Other	8	(2.2)	3	(0.8)	3	(1.6)
Subject defaulted	27	(7.4)	19	(5.0)	11	(5.9)
Total	126	(34.7)	125	(32.7)	118	(63.8)

Subject defaulted means Subject no longer willing to participate in study or Lost to follow-up.

Maraviroc Summary of Clinical Safety
Discontinuation from Study by Sex
Phase 3 Treatment Experienced CCR5 Tropic Studies

Group by: FEMALE

Number (%) of Subjects	maraviroc QD 51		maraviroc BID 44		Placebo 24	
Discontinuations						
Subject Died	0		0		1	(4.2)
Related to Study Drug	9	(17.6)	9	(20.5)	8	(33.3)
Adverse event	2	(3.9)	1	(2.3)	0	
Lack of efficacy	7	(13.7)	8	(18.2)	8	(33.3)
Not Related to Study Drug	8	(15.7)	4	(9.1)	6	(25.0)
Adverse event	0		0		2	(8.3)
Other	4	(7.8)	1	(2.3)	2	(8.3)
Subject defaulted	4	(7.8)	3	(6.8)	2	(8.3)
Total	17	(33.3)	13	(29.5)	15	(62.5)

Subject defaulted means Subject no longer willing to participate in study or Lost to follow-up.

Table 3.1.7.2
Maraviroc Summary of Clinical Safety
Discontinuation from Study by Age
Phase 3 Treatment Experienced CCR5 Tropic Studies

Group by: 16-44

Number (%) of Subjects	maraviroc QD 178		maraviroc BID 168		Placebo 88	
Discontinuations						
Subject Died	1	(0.6)	0		0	
Related to Study Drug	41	(23.0)	46	(27.4)	40	(45.5)
Adverse event	4	(2.2)	4	(2.4)	1	(1.1)
Lack of efficacy	37	(20.8)	42	(25.0)	39	(44.3)
Not Related to Study Drug	22	(12.4)	11	(6.5)	11	(12.5)
Adverse event	1	(0.6)	1	(0.6)	1	(1.1)
Other	7	(3.9)	1	(0.6)	3	(3.4)
Subject defaulted	14	(7.9)	9	(5.4)	7	(8.0)
Total	64	(36.0)	57	(33.9)	51	(58.0)

Subject defaulted means Subject no longer willing to participate in study or Lost to follow-up.

Table 3.1.7.2
Maraviroc Summary of Clinical Safety
Discontinuation from Study by Age
Phase 3 Treatment Experienced CCR5 Tropic Studies

Group by: 45-64

Number (%) of Subjects	maraviroc QD 226		maraviroc BID 253		Placebo 118	
Discontinuations						
Subject Died	2	(0.9)	5	(2.0)	1	(0.8)
Related to Study Drug	52	(23.0)	53	(20.9)	70	(59.3)
Adverse event	8	(3.5)	6	(2.4)	4	(3.4)
Lack of efficacy	44	(19.5)	47	(18.6)	66	(55.9)
Not Related to Study Drug	21	(9.3)	21	(8.3)	9	(7.6)
Adverse event	1	(0.4)	5	(2.0)	2	(1.7)
Other	5	(2.2)	3	(1.2)	2	(1.7)
Subject defaulted	15	(6.6)	13	(5.1)	5	(4.2)
Total	75	(33.2)	79	(31.2)	80	(67.8)

Subject defaulted means Subject no longer willing to participate in study or Lost to follow-up.

Maraviroc Summary of Clinical Safety
Discontinuation from Study by Age
Phase 3 Treatment Experienced CCR5 Tropic Studies

Group by: 65 and over

Number (%) of Subjects	maraviroc QD 10		maraviroc BID 5		Placebo 3	
Discontinuations						
Subject Died	0		0		0	
Related to Study Drug	0		2	(40.0)	1	(33.3)
Adverse event	0		0		0	
Lack of efficacy	0		2	(40.0)	1	(33.3)
Not Related to Study Drug	4	(40.0)	0		1	(33.3)
Adverse event	2	(20.0)	0		0	
Other	0		0		0	
Subject defaulted	2	(20.0)	0		1	(33.3)
Total	4	(40.0)	2	(40.0)	2	(66.7)

Subject defaulted means Subject no longer willing to participate in study or Lost to follow-up.

Maraviroc Summary of Clinical Safety
Discontinuation from Study by Race
Phase 3 Treatment Experienced CCR5 Tropic Studies

Group by: WHITE

Number (%) of Subjects	maraviroc QD 336		maraviroc BID 363		Placebo 178	
Discontinuations						
Subject Died	3	(0.9)	4	(1.1)	1	(0.6)
Related to Study Drug	78	(23.2)	83	(22.9)	97	(54.5)
Adverse event	11	(3.3)	8	(2.2)	4	(2.2)
Lack of efficacy	67	(19.9)	75	(20.7)	93	(52.2)
Not Related to Study Drug	28	(8.3)	25	(6.9)	16	(9.0)
Adverse event	2	(0.6)	5	(1.4)	1	(0.6)
Other	6	(1.8)	3	(0.8)	4	(2.2)
Subject defaulted	20	(6.0)	17	(4.7)	11	(6.2)
Total	109	(32.4)	112	(30.9)	114	(64.0)

Subject defaulted means Subject no longer willing to participate in study or Lost to follow-up.

Maraviroc Summary of Clinical Safety
Discontinuation from Study by Race
Phase 3 Treatment Experienced CCR5 Tropic Studies

Group by: BLACK

Number (%) of Subjects	maraviroc QD 70		maraviroc BID 51		Placebo 26	
Discontinuations						
Subject Died	0		0		0	
Related to Study Drug	14	(20.0)	17	(33.3)	11	(42.3)
Adverse event	1	(1.4)	2	(3.9)	1	(3.8)
Lack of efficacy	13	(18.6)	15	(29.4)	10	(38.5)
Not Related to Study Drug	19	(27.1)	6	(11.8)	4	(15.4)
Adverse event	2	(2.9)	1	(2.0)	2	(7.7)
Other	6	(8.6)	1	(2.0)	1	(3.8)
Subject defaulted	11	(15.7)	4	(7.8)	1	(3.8)
Total	33	(47.1)	23	(45.1)	15	(57.7)

Subject defaulted means Subject no longer willing to participate in study or Lost to follow-up.

Maraviroc Summary of Clinical Safety
Discontinuation from Study by Race
Phase 3 Treatment Experienced CCR5 Tropic Studies

Group by: ASIAN

Number (%) of Subjects	maraviroc QD 3	maraviroc BID 5	Placebo 1
Discontinuations			
Subject Died	0	1 (20.0)	0
Related to Study Drug	0	0	1 (100.0)
Adverse event	0	0	0
Lack of efficacy	0	0	1 (100.0)
Not Related to Study Drug	0	0	0
Adverse event	0	0	0
Other	0	0	0
Subject defaulted	0	0	0
Total	0	1 (20.0)	1 (100.0)

Subject defaulted means Subject no longer willing to participate in study or Lost to follow-up.

Maraviroc Summary of Clinical Safety
Discontinuation from Study by Race
Phase 3 Treatment Experienced CCR5 Tropic Studies

Group by: OTHER

Number (%) of Subjects	maraviroc QD 4		maraviroc BID 7		Placebo 4	
Discontinuations						
Subject Died	0		0		0	
Related to Study Drug	1	(25.0)	1	(14.3)	2	(50.0)
Adverse event	0		0		0	
Lack of efficacy	1	(25.0)	1	(14.3)	2	(50.0)
Not Related to Study Drug	0		1	(14.3)	1	(25.0)
Adverse event	0		0		0	
Other	0		0		0	
Subject defaulted	0		1	(14.3)	1	(25.0)
Total	1	(25.0)	2	(28.6)	3	(75.0)

Subject defaulted means Subject no longer willing to participate in study or Lost to follow-up.

Table 3.1.7.3
Maraviroc Summary of Clinical Safety
Discontinuation from Study by Race
Phase 3 Treatment Experienced CCR5 Tropic Studies

Group by: Unspecified

Number (%) of Subjects	maraviroc QD 1
Discontinuations	
Subject Died	0
Related to Study Drug	0
Adverse event	0
Lack of efficacy	0
Not Related to Study Drug	0
Adverse event	0
Other	0
Subject defaulted	0
Total	0

Subject defaulted means Subject no longer willing to participate in study or Lost to follow-up.

Table 3.2.1.1
Maraviroc Summary of Clinical Safety
Duration of Maraviroc Therapy (Days)
Phase 2b/3 Studies All Maraviroc Therapy

	maraviroc
Number of Subjects	1212
Duration Category (Days)	
<=1	3
2-14	16
15-28	16
29-90	182
91-180	313
181-364	668
>=365	14
Median Duration (Days)	200.5
Total Duration (Years)	691.7
Range (Days)	1-460

NOTE: The duration is defined as the total number of dosing days from first to and including last day of each study treatment.
For protocol 1026 only the QD arm is included. For 1027 and 1028 both blinded and open label treatment are included.

Table 3.2.1.2
Maraviroc Summary of Clinical Safety
Duration of Maraviroc Blinded Therapy (Days)
Phase 3 Treatment Experienced CCR5 Tropic Studies

	maraviroc QD	maraviroc BID	Placebo
Number of Subjects	414	426	209
Duration Category (Days)			
<=1	0	1	0
2-14	5	5	2
15-28	1	11	2
29-90	51	53	64
91-180	104	92	60
181-364	248	262	80
>=365	5	2	1
Median Duration (Days)	235.5	238.5	145.0
Total Duration (Years)	258.7	266.8	99.3
Range (Days)	2-381	1-366	7-427

NOTE: The duration of treatment is defined as the total number of dosing days from first to and including last day of each study treatment.
The total duration of treatment is the overall sum of each subjects duration of treatment, given in years.

Table 3.2.1.3
Maraviroc Summary of Clinical Safety
Duration of Maraviroc Blinded Therapy (Days)
Combined Maraviroc, Phase 3 Treatment Experienced CCR5 Tropic Studies

	Combined maraviroc	Placebo
Number of Subjects	840	209
Duration Category (Days)		
<=1	1	0
2-14	10	2
15-28	12	2
29-90	104	64
91-180	196	60
181-364	510	80
>=365	7	1
Median Duration (Days)	237.0	145.0
Total Duration (Years)	525.5	99.3
Range (Days)	1-381	7-427

NOTE: The duration of treatment is defined as the total number of dosing days from first to and including last day of each study treatment.
The total duration of treatment is the overall sum of each subjects duration of treatment, given in years.

Table 3.2.1.4
Maraviroc Summary of Clinical Safety
Treatment Compliance (%) on Blinded Therapy
Phase 3 Treatment Experienced CCR5 Tropic Studies

	maraviroc QD N=414	maraviroc BID N=426	Placebo N=209
Number of Subjects	403	419	204
Mean	95.88	97.91	97.81
Standard Deviation	12.035	13.210	10.077
Median	98.81	99.11	99.38
Min-Max	4.9-150.0	26.3-270.0	50.9-140.6

Compliance is calculated as (number of tablets dispensed-number of tablets returned)/(number of days in dispensing period*number of tablets in dose) for dispensing periods available at time of data cut.
Subjects who do not return the expected number of tablets will have their compliance to study therapy over estimated respectively.

Table 3.2.2.1
Maraviroc Summary of Clinical Safety
Concomitant Drug Treatments
Phase 3 Treatment Experienced CCR5 Tropic Studies

	maraviroc QD	maraviroc BID	Placebo
Number of Subjects	414	426	209
Number (%) of Subjects With Any Concomitant Drug Treatment	404 (97.6)	410 (96.2)	201 (96.2)
ACEBUTOLOL	1	0	0
ACETORPHAN	1	1	0
ACETYLCARNITINE	0	3	0
ACETYLCYSTEINE	11	12	5
ACETYLSALICYLATE LYSINE	0	1	0
ACETYLSALICYLIC ACID	44	51	25
ACICLOVIR	75	77	36
ACIPIMOX	0	0	1
ACITRETIN	0	1	0
ACTIFED	1	0	0
ADAPALENE	1	0	0
ADEFOVIR DIPIVOXIL	1	0	0
ADENOSINE TRIPHOSPHATE	0	0	1
AKRITOIN	1	0	0
ALBENDAZOLE	1	0	0
ALBUMIN HUMAN	2	0	0
ALCLOMETASONE DIPROPIONATE	1	0	0
ALCOMYXINE	1	0	0
ALENDRONATE SODIUM	5	4	2
ALENDRONIC ACID	3	1	0
naproxen sodium* COLD & SINUS	0	1	0

Excludes antiretrovirals and optimized background therapy.

* ：新薬承認情報提供時に置換えた。

	maraviroc QD	maraviroc BID	Placebo
ALFUZOSIN	1	0	0
ALGIDOL	1	0	0
ALGINIC ACID	0	0	1
ALIMEMAZINE	1	0	0
ALIZAPRIDE	0	0	1
ALKA-SELTZER	0	0	1
ALKA-SELTZER PLUS	1	0	0
ALKALOL	1	0	0
ALL OTHER NON-THERAPEUTIC PRODUCTS	0	3	0
ALL OTHER THERAPEUTIC PRODUCTS	2	3	0
ALLEGRA-D	4	7	3
ALLERGOSPASMIN	1	0	0
ALLOPURINOL	3	7	4
ALOE BARBADENSIS	1	1	0
ALPHA-D-GALACTOSIDASE	0	1	0
ALPRAZOLAM	17	25	12
ALPROSTADIL	1	1	0
ALUMINIUM ACETATE	1	0	0
ALUMINIUM HYDROXIDE/DIPHENHYDRAMINE/MAGNESIUM HYDROXIDE/LIDOCAINE	1	1	0
ALUMINIUM MAGNESIUM SILICATE	0	0	1
AMCINONIDE	0	2	0
AMIKACIN	1	0	0
AMILORIDE HYDROCHLORIDE	0	0	1

Excludes antiretrovirals and optimized background therapy.

	maraviroc QD	maraviroc BID	Placebo
AMILORIDE W/HYDROCHLOROTHIAZIDE	0	1	0
AMINO ACIDS	1	3	0
AMINO ACIDS/MINERALS/VITAMINS	0	0	1
AMIODARONE	0	1	0
AMIODARONE HYDROCHLORIDE	1	0	0
AMITRIPTYLINE	13	11	5
AMITRIPTYLINE HYDROCHLORIDE	5	3	6
AMLODIPINE	1	3	3
AMLODIPINE BESILATE	9	10	2
AMMONIUM LACTATE	3	2	1
AMOSAN	0	1	0
AMOXI-CLAVULANICO	2	2	0
AMOXICILINA + CLAVULANICO	1	0	0
AMOXICILLIN	14	10	4
AMOXICILLIN W/CLAVULANATE POTASSIUM	0	2	0
AMPHOTERICIN B	8	4	4
AMPHOTERICIN B/DIPHENHYDRAMINE/HYDROCORTISONE/TETRACYCLINE	1	1	1
AMPHOTERICINE B, LIPOSOME	1	0	0
AMPICILLIN	1	2	1
ANABOLIC STEROIDS	0	1	0
ANAESTHETICS, GENERAL	1	1	0
ANDROGENS	0	1	1
ANDROSKAT	1	0	0

Excludes antiretrovirals and optimized background therapy.

	maraviroc QD	maraviroc BID	Placebo
ANDROSTENEDIONE	0	1	0
ANETHOLE TRITHIONE	0	0	1
ANTIBIOTICS	1	0	1
ANTIHAEMORRHOIDALS FOR TOPICAL USE	1	0	0
ANTIMIGRAINE PREPARATIONS	1	0	0
ANTIOXIDANTS	0	1	0
ANUSOL	0	3	0
ANUSOL-HC	1	0	0
AQUEOUS CREAM	0	2	0
ARGININE	2	0	0
ARGININE/BETA-HYDROXY-BETA-METHYLBUTYRATE/GLUTAMINE	0	0	3
ARIPIPRAZOLE	0	2	0
ARTHROTEC	0	1	2
ARTISIAL	0	0	1
ASASANTIN	1	0	1
ASCORBIC ACID	18	21	13
ASTENOLIT	1	0	0
ATENOLOL	14	12	8
ATOMOXETINE HYDROCHLORIDE	1	3	0
ATORVASTATIN	29	37	11
ATORVASTATIN CALCIUM	0	2	3
ATOVAQUONE	16	17	8
AUGMENTINE	1	0	0

Excludes antiretrovirals and optimized background therapy.

	maraviroc QD	maraviroc BID	Placebo
AURALGAN	0	0	1
AXOTAL (OLD FORM)	1	1	1
AZELASTINE	1	2	1
AZELASTINE HYDROCHLORIDE	1	2	1
AZITHROMYCIN	94	90	48
AZITHROMYCIN DIHYDRATE	0	1	0
B-KOMPLEX "LECIVA"	4	3	3
BACITRACIN	0	2	0
BACLOFEN	3	2	0
sulfamethoxazole/trimethoprim*	157	173	79
BAMIFYLLINE	0	1	0
BAMIPINE LACTATE	0	1	0
BECLOMETASONE	0	1	0
BECLOMETASONE DIPROPIONATE	3	0	2
BECOSYM FORTE	5	3	1
BEMINAL WITH C FORTIS	1	0	0
BENADRYL COLD AND FLU TABLETS	2	1	0
BENAZEPRIL	3	0	0
BENAZEPRIL HYDROCHLORIDE	0	0	1
BENFLUOREX	0	1	0
BENZAMYCIN	0	1	0
BENZATROPINE MESILATE	2	0	0
BENZOCAINE	0	1	0

Excludes antiretrovirals and optimized background therapy.

* ：新薬承認情報提供時に置換えた。

	maraviroc QD	maraviroc BID	Placebo
BENZONATATE	1	2	1
BENZOXONIUM CHLORIDE	0	1	0
BENZOYL PEROXIDE	1	2	0
BENZYLPENICILLIN	0	1	0
BETACAROTENE	1	2	1
BETAINE CITRATE	0	1	0
BETAMETHASONE	3	2	2
BETAMETHASONE DIPROPIONATE	2	2	1
BETAMETHASONE VALERATE	3	0	0
BEZAFIBRATE	1	1	0
BIFONAZOLE	1	0	0
BIMATOPROST	2	0	0
BISACODYL	2	2	2
BISMUTH SUBSALICYLATE	2	0	1
BISOPROLOL	1	2	1
BISOPROLOL FUMARATE	1	4	0
BLOPRESS PLUS	0	1	0
BOI-K ASPARTICO	1	0	0
BOOST	0	2	0
BORAGE OIL	0	1	0
BOSENTAN	2	0	0
BRIMONIDINE TARTRATE/TIMOLOL MALEATE	1	0	1
BROMAZEPAM	3	3	2

Excludes antiretrovirals and optimized background therapy.

	maraviroc QD	maraviroc BID	Placebo
BROMHEXINE HYDROCHLORIDE	0	0	1
BROMPHENIRAMINE MALEATE/DEXTROMETHORPHAN HYDROBROMIDE/GUAIFENESIN	1	0	0
BRONCHOSEDAL	1	0	0
BUDESONIDE	5	6	4
BUPIVACAINE	0	1	0
BUPIVACAINE HYDROCHLORIDE	1	0	0
BUPROPION	8	5	4
BUPROPION HYDROCHLORIDE	24	17	5
BUSCOPAN COMP.	1	0	0
BUSPIRONE	1	1	0
BUSPIRONE HYDROCHLORIDE	2	0	1
BUTALBITAL	0	1	0
CALAMINE LOTION	1	0	0
CALCITONIN, SALMON	1	0	0
CALCITRIOL	0	1	0
CALCIUM	14	10	7
CALCIUM ASCORBATE	0	0	1
CALCIUM CARBONATE	11	2	1
CALCIUM CITRATE	2	1	0
CALCIUM D3 "STADA"	0	1	0
CALCIUM FOLINATE	6	1	2
CALCIUM W/MAGNESIUM	2	1	1
CALCIUM WITH VITAMIN D	1	0	0

Excludes antiretrovirals and optimized background therapy.

	maraviroc QD	maraviroc BID	Placebo
CALCIUM, COMBINATIONS WITH OTHER DRUGS	1	0	0
CALCIUM/MINERALS NOS	1	0	0
CANDESARTAN	0	2	0
CANDESARTAN CILEXETIL	0	2	0
CANDIDA ALBICANS SKIN TEST ANTIGEN	0	1	0
CANESTEN-HC	1	2	0
CANNABIS	1	1	0
CAPSAICIN	1	0	0
CAPTOPRIL	2	1	0
CARBAMAZEPINE	1	3	1
CARBOCISTEINE	1	1	0
CARBOMER	0	1	0
CARISOPRODOL	2	4	1
CARNITINE	2	0	1
CARVEDILOL	0	3	0
CASPOFUNGIN	4	2	1
CASPOFUNGIN ACETATE	1	0	0
CEFACLOR	0	1	1
CEFALEXIN	6	6	5
CEFALEXIN MONOHYDRATE	10	13	0
CEFAZOLIN	0	2	0
CEFDINIR	0	1	0
CEFDITOREN	1	0	0

Excludes antiretrovirals and optimized background therapy.

	maraviroc QD	maraviroc BID	Placebo
CEFEPIME	1	3	0
CEFEPIME HYDROCHLORIDE	1	0	0
CEFIXIME	2	0	0
CEFOTAXIME	2	0	0
CEFOTETAN	0	1	0
CEFPODOXIME	0	1	0
CEFTAZIDIME	1	0	0
CEFTRIAXONE	1	3	2
CEFTRIAXONE SODIUM	3	4	0
CEFUROXIME	4	4	2
CEFUROXIME AXETIL	2	3	3
CELECOXIB	2	4	2
CELESTAMINE	0	1	0
CELESTONA BIFAS	1	0	0
CELIPROLOL	0	1	0
CENTRUM	4	6	4
CENTRUM SILVER	0	1	0
CETIRIZINE	7	7	4
CETIRIZINE HYDROCHLORIDE	13	22	5
CETIRIZINE/PSEUDOEPHEDRINE	3	0	1
CEVIMELINE HYDROCHLORIDE	0	2	0
CHARCOAL, ACTIVATED	0	1	0
CHERACOL /USA/	2	0	1

Excludes antiretrovirals and optimized background therapy.

	maraviroc QD	maraviroc BID	Placebo
CHERATUSSIN COUGH SYRUP	2	1	0
CHLORAL HYDRATE	0	1	0
CHLORAMPHENICOL	3	0	1
CHLORHEXIDINE	0	0	1
CHLORHEXIDINE GLUCONATE	1	0	0
CHLOROPHYLLIN SODIUM COPPER COMPLEX	1	0	0
CHLOROQUINE	1	0	0
CHLORPHENAMINE	1	2	0
CHLORPHENIRAMINE MAL/IBUPROFEN/PSEUDOEPHEDRINE HCL	1	0	0
CHLORPROMAZINE	1	0	0
CHLORPROMAZINE HYDROCHLORIDE	0	0	3
CHLORTALIDONE	1	1	0
CHOLESTEROL- AND TRIGLYCERIDE REDUCERS	0	1	0
CHOLINE MAGNESIUM TRISALICYLATE	1	0	0
CHONDROITIN/GLUCOSAMINE	3	1	0
CHONDROITIN/GLUCOSAMINE/METHYLSULFONYLMETHANE	0	1	0
CHORIONIC GONADOTROPHIN	1	1	0
CHROMIUM	0	1	0
CHROMIUM PICOLINATE	0	1	1
CICLESONIDE	1	0	0
CICLOPIROX OLAMINE	3	5	0
CICLOSPORIN	1	0	0
CIDERMEX	1	0	0

Excludes antiretrovirals and optimized background therapy.

	maraviroc QD	maraviroc BID	Placebo
CIDOFOVIR	0	2	1
CILAZAPRIL	1	1	0
CILEST	0	1	0
CIMETIDINE	1	1	0
CINCHOCAINE	2	0	0
CINCHOCAINE HCL/ESCULOSIDE/HYDROCORTISONE ACETATE/NEOMYCIN SULFATE	0	1	0
CINNAMON	0	0	1
CIPRO HC	0	1	0
CIPROFLOXACIN	24	21	12
CIPROFLOXACIN HYDROCHLORIDE	0	0	1
CIPROFLOXACIN/DEXAMETHASONE	0	1	0
CIRRUS	0	1	0
CISPLATIN	0	0	1
CITALOPRAM	6	5	4
CITALOPRAM HYDROBROMIDE	8	4	5
CITRACAL + D	1	0	0
CLARINASE	0	1	0
CLARITHROMYCIN	5	11	9
CLAVULIN	10	12	9
CLEMASTINE FUMARATE	0	1	0
CLENIL COMPOSITUM SPRAY	0	1	0
CLINDAMYCIN	9	9	7
CLINDAMYCIN HYDROCHLORIDE	2	1	0

Excludes antiretrovirals and optimized background therapy.

	maraviroc QD	maraviroc BID	Placebo
CLINDAMYCIN PHOSPHATE	1	2	0
CLOBETASOL PROPIONATE	1	1	1
CLOBETASONE BUTYRATE	0	1	1
CLOBUTINOL	1	0	0
CLOBUTINOL HYDROCHLORIDE	0	0	1
CLONAZEPAM	19	19	8
CLONIDINE	4	0	1
CLONIDINE HYDROCHLORIDE	0	1	0
CLOPERASTINE	0	1	0
CLOPIDOGREL	4	1	0
CLOPIDOGREL SULFATE	6	1	1
CLORAZEPATE DIPOTASSIUM	1	0	1
CLOTRASON	0	1	0
CLOTRIMAZOLE	14	12	5
CLOXACILLIN	1	0	0
CO-ADVIL	1	2	0
CO-DIOVAN	1	0	0
COAL TAR	1	0	0
COCAINE	0	1	0
COD-LIVER OIL	1	0	0
CODAFEN	0	1	0
CODEINE	2	2	0
CODEINE PHOSPHATE	0	3	0

Excludes antiretrovirals and optimized background therapy.

	maraviroc QD	maraviroc BID	Placebo
CODICLEAR	1	2	0
CODRAL COLD & FLU	1	0	1
COLCHICINE	1	5	0
COLESEVELAM HYDROCHLORIDE	0	1	0
COLESTYRAMINE	1	0	1
COLONLYTELY	0	0	1
COLOSTRUM	0	1	0
COLOXYL WITH SENNA	0	1	0
COLYTE "REED"	0	1	0
COMBINATIONS OF VITAMINS	1	0	0
COMBIVENT	0	1	2
COMTREX	1	0	0
COPPER	1	0	0
CORTICOSTEROID NOS	2	0	0
CORTICOSTEROIDS	0	0	1
CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS	0	0	1
CORTISONE	1	4	1
CORTISONE ACETATE	2	2	1
COSOPT	3	1	0
COTYLENOL	2	2	1
COUGH AND COLD PREPARATIONS	2	0	0
COUGH SYRUP	1	0	0
CREATINE	1	1	0

Excludes antiretrovirals and optimized background therapy.

	maraviroc QD	maraviroc BID	Placebo
CROMOGLICATE SODIUM	0	1	1
CROTAMITON	0	0	1
CYANOCOBALAMIN	18	18	10
CYCLO 3 /FRA/	0	1	0
CYCLOBENZAPRINE	1	4	2
CYCLOBENZAPRINE HYDROCHLORIDE	6	2	1
CYCLOPHOSPHAMIDE	0	1	0
CYCLOPHOSPHAMIDE/DOXORUBICIN/PREDNISONE/VINCRISTINE	0	0	1
CYNARA SCOLYMUS	0	1	0
CYPROHEPTADINE	2	1	0
CYPROHEPTADINE HYDROCHLORIDE	0	1	0
DAPSONE	37	36	21
DAPTOMYCIN	1	0	0
DARBEPOETIN ALFA	2	2	0
DAVITAMON 10	0	1	0
DAY & NIGHT COLD & FLU TABLETS	0	1	0
DERINOX	1	0	0
DESIPRAMINE	1	0	0
DESLORATADINE	8	4	2
DESONIDE	0	3	0
DESOXIMETASONE	0	1	0
DEXA-RHINOSPRAY N	1	0	0
DEXAMETHASONE	3	6	1

Excludes antiretrovirals and optimized background therapy.

	maraviroc QD	maraviroc BID	Placebo
DEXAMFETAMINE	0	0	2
DEXAMYTREX	1	0	0
DEXCHLORPHENIRAMINE	1	1	0
DEXERYL "PIERRE FABRE"	0	1	0
DEXPANTHENOL	0	1	0
DEXPANTHENOL/RETINOL PALMITATE/UREA	0	1	0
DEXTROMETHORPHAN	0	1	2
DEXTROMETHORPHAN HYDROBROMIDE	0	2	0
DEXTROPROPOXYPHENE	0	1	0
DEXTROPROPOXYPHENE HYDROCHLORIDE	0	2	1
DEXTROPROPOXYPHENE NAPSILATE	1	0	0
DEXTROSE AND SODIUM CHLORIDE INJECTION	0	3	0
DIAGNOSTIC AGENTS	1	0	0
DIAZEPAM	15	11	9
DICLOFENAC	8	5	1
DICLOFENAC POTASSIUM	0	1	1
DICLOFENAC SODIUM	3	5	4
DICLOXACILLIN SODIUM MONOHYDRATE	0	0	2
DICYCLOVERINE	1	0	0
DICYCLOVERINE HYDROCHLORIDE	1	0	0
DIGESTIVES, INCL ENZYMES	1	0	0
DIGOXIN	1	1	1
DIHYDROCODEINE	1	1	0

Excludes antiretrovirals and optimized background therapy.

	maraviroc QD	maraviroc BID	Placebo
DIHYDROXYALUMINUM SODIUM CARBONATE	1	0	0
DIIODOHYDROXYQUINOLINE	0	0	1
DILTIAZEM	0	3	0
DILTIAZEM HYDROCHLORIDE	3	1	1
DIMENHYDRINATE	1	1	0
DIMETAPP	0	1	0
DIMETICONE	0	1	0
DIMETICONE, ACTIVATED	2	3	1
DIMETINDENE MALEATE	2	0	1
DIOSMIN	0	1	0
DIPHENHYDRAMINE	6	5	2
DIPHENHYDRAMINE HYDROCHLORIDE	14	17	4
DIPHENOXYLATE	3	0	1
DIPHENOXYLATE W/ATROPINE SULFATE	1	0	0
DIPHTHERIA AND TETANUS TOXOIDS	0	1	0
DISPRAY NO 1	0	1	0
DOCUSATE	1	2	0
DOCUSATE SODIUM	2	6	2
DOLASETRON	0	0	1
DOLASETRON MESILATE	0	1	1
DOLOPROCT ZAEPFCHEN	0	1	0
DOMEBORO	0	0	2
DOMPERIDONE	3	3	3

Excludes antiretrovirals and optimized background therapy.

	maraviroc QD	maraviroc BID	Placebo
DONEPEZIL HYDROCHLORIDE	0	2	0
DONNATAL	0	0	1
DONTISOLON	1	0	0
DOPAMINE	2	0	0
DORCOL	0	2	0
DOSULEPIN	0	0	1
DOXAZOSIN	1	2	2
DOXAZOSIN MESILATE	1	1	0
DOXEPIN	3	4	0
DOXEPIN HYDROCHLORIDE	1	1	0
DOXORUBICIN	0	1	0
DOXORUBICIN HYDROCHLORIDE	0	1	1
DOXYCYCLINE	15	19	8
DOXYCYCLINE HYCLATE	0	1	0
DOXYCYCLINE HYDROCHLORIDE	0	1	1
DOXYLAMINE	0	1	0
DOXYLAMINE SUCCINATE	1	0	0
DOZOL	1	0	0
DRIXORAL	0	1	0
DRONABINOL	13	18	11
DROTAVERINE	0	0	1
DROTAVERINE HYDROCHLORIDE	0	0	1
DRUG, UNSPECIFIED	1	0	0

Excludes antiretrovirals and optimized background therapy.

Table 3.2.2.1
Maraviroc Summary of Clinical Safety
Concomitant Drug Treatments
Phase 3 Treatment Experienced CCR5 Tropic Studies

	maraviroc QD	maraviroc BID	Placebo
DUACT	0	1	0
DULOXETINE HYDROCHLORIDE	5	4	3
DUOVENT	0	0	1
DUTASTERIDE	0	4	0
DYAZIDE	2	3	3
DYNAMAG	2	0	0
E45	1	0	0
ECHINACEA	1	0	1
ECONAZOLE	1	0	0
ECONAZOLE NITRATE	1	0	0
EDUCTYL	0	1	0
EMEDASTINE FUMARATE	0	1	0
EMOLLIENTS AND PROTECTIVES	4	1	0
ENALAPRIL	6	2	2
ENALAPRIL MALEATE	1	3	2
ENDAL	1	3	0
ENOXAPARIN	1	1	1
ENSURE	9	0	2
ENSURE PLUS	2	1	1
ENTEX	1	1	0
EPHEDRINE	0	1	0
EPINEPHRINE	2	0	0
EPIRIZOLE	0	1	0

Excludes antiretrovirals and optimized background therapy.

	maraviroc QD	maraviroc BID	Placebo
EPOETIN ALFA	1	2	3
EPROSARTAN MESILATE/HYDROCHLOROTHIAZIDE	1	1	0
EPTACOG ALFA	1	0	0
ERDOSTEINE	0	1	0
ERGOCALCIFEROL	4	2	1
ERTAPENEM	1	0	0
ERYTHROMYCIN	4	2	2
ERYTHROPOIETIN	12	8	3
ERYTHROPOIETIN HUMAN	0	1	0
ESCHERICHIA COLI	0	1	0
ESCITALOPRAM	11	16	7
ESOMEPRAZOLE	14	15	8
ESOMEPRAZOLE MAGNESIUM	1	1	0
ESTAZOLAM	0	1	0
ESTRADIOL	3	1	0
ESTRADIOL VALERATE	0	2	0
ESTRIOL	1	0	0
ESTROGENS	0	1	0
ESTROGENS CONJUGATED	3	1	0
ESTROPIPATE	0	1	0
ESZOPICLONE	5	8	3
ETACRYNIC ACID	1	0	0
ETHAMBUTOL	4	5	4

Excludes antiretrovirals and optimized background therapy.

	maraviroc QD	maraviroc BID	Placebo
ETHAMBUTOL DIHYDROCHLORIDE	1	2	1
ETHINYLESTRADIOL/NORELGESTROMIN	0	1	0
ETODOLAC	0	0	1
ETORICOXIB	0	1	1
EUCERIN CREME	0	1	1
EUGYNON	0	1	0
EULATIN N N	0	1	0
EUNOVA	1	0	0
EVENING PRIMROSE OIL	0	0	1
EXTENDRYL	0	1	0
EZETIMIBE	7	6	2
EZETIMIBE/SIMVASTATIN	1	2	0
FACTOR VIII (ANTIHAEMOPHILIC FACTOR)	0	1	0
FAKTU	0	0	1
FAMCICLOVIR	8	8	5
FAMOTIDINE	4	7	5
FANSIDAR	1	0	1
FAT/CARBOHYDRATES/PROTEINS/MINERALS/VITAMINS,	1	0	0
FELODIPINE	0	1	0
FENOFIBRATE	28	41	13
FENOTEROL HYDROBROMIDE	1	0	0
FENSPIRIDE	1	0	0
FENTANYL	6	11	2

Excludes antiretrovirals and optimized background therapy.

	maraviroc QD	maraviroc BID	Placebo
FENTANYL CITRATE	0	1	0
FERRO "SANOL" /OLD FORM/	1	0	0
FERRO-FOLSAN	0	1	1
FERROGLYCINE SULFATE COMPLEX	0	0	1
FERROUS FUMARATE	2	1	0
FERROUS GLUCONATE	0	2	0
FERROUS GLYCINE SULFATE	1	0	0
FERROUS SULFATE	5	10	4
FERROUS SULFATE EXSICCATED	1	0	0
FEXOFENADINE	4	6	0
FEXOFENADINE HYDROCHLORIDE	10	9	4
FIBRE, DIETARY	1	0	0
FILGRASTIM	12	8	8
FINASTERIDE	2	2	5
FIORINAL-C 1/4	0	1	0
FISH OIL	18	18	4
FLECAINIDE ACETATE	0	1	0
FLEET ENEMA	1	0	0
FLOXIN OTIC	0	0	1
FLUCLOXACILLIN	2	2	1
FLUCLOXACILLIN SODIUM	1	0	0
FLUCONAZOLE	87	85	44
FLUCYTOSINE	0	1	0

Excludes antiretrovirals and optimized background therapy.

	maraviroc QD	maraviroc BID	Placebo
FLUDROCORTISONE	0	2	1
FLUDROCORTISONE ACETATE	3	2	0
FLUNISOLIDE	2	6	2
FLUOCINOLONE ACETONIDE	2	0	0
FLUOCINONIDE	2	3	1
FLUOROURACIL	2	4	1
FLUOXETINE	6	6	1
FLUOXETINE HYDROCHLORIDE	6	10	3
FLUPENTIXOL	1	0	0
FLUPHENAZINE DECANOATE	1	0	0
FLURAZEPAM	1	1	0
FLUTICASONE	6	3	3
FLUTICASONE PROPIONATE	19	18	7
FLUVASTATIN	2	2	0
FLUVASTATIN SODIUM	0	1	0
FLUVOXAMINE MALEATE	1	1	0
FOLIC ACID	10	11	4
FOLINIC ACID	1	2	2
FORMOTEROL FUMARATE	0	0	1
FORMULA 44 COUGH SYRUP	1	0	0
FOSCARNET	0	3	0
FOSCARNET SODIUM	1	0	2
FOSFOMYCIN	0	1	0

Excludes antiretrovirals and optimized background therapy.

	maraviroc QD	maraviroc BID	Placebo
FOSINOPRIL	2	4	0
FOSINOPRIL SODIUM	2	1	0
FRENADOL	0	1	0
FRESUBIN	1	0	0
FROSST 282	0	0	1
FUCICORT	0	1	0
FUMAGILLIN	1	0	0
FUROSEMIDE	7	7	3
FUSAFUNGINE	0	1	0
FUSIDATE SODIUM	4	4	0
FUSIDIC ACID	2	1	1
GABAPENTIN	28	37	22
GADOPENTETATE DIMEGLUMINE	0	1	0
GALENIC /CHLORPHENAMINE/PARACETAMOL/PSEUDOEPH	0	1	0
GALENIC /CODEINE/PROMETHAZINE/	1	0	0
GALENIC /FLUTICASONE/SALMETEROL/	1	0	0
GALENIC /GUAIFENESIN/HYDROCODONE/	1	0	0
GALENIC /PARACETAMOL/CODEINE/	0	2	1
GAMMA-AMINOBUTYRIC ACID	1	0	0
GANCICLOVIR	1	1	0
GARLIC	0	2	1
GATIFLOXACIN	5	2	3
GAVISCON	1	1	1

Excludes antiretrovirals and optimized background therapy.

	maraviroc QD	maraviroc BID	Placebo
GELATIN	0	1	0
GELOMYRTOL FORTE	1	0	0
GEMFIBROZIL	14	16	7
GEMIFLOXACIN	0	1	0
GENERAL NUTRIENTS	3	1	5
GENERAL NUTRIENTS/HERBAL NOS/MINERALS NOS/VITAMINS NOS	1	0	1
GENERAL NUTRIENTS/HERBAL NOS/VITAMINS NOS	0	1	0
GENERAL NUTRIENTS/MINERALS/VITAMINS	0	0	1
GENERAL NUTRIENTS/VITAMINS NOS	2	1	0
GENTAMICIN	1	1	0
GENTAMICIN SULFATE	0	1	0
GENTAMICIN SULFATE/INDOMETACIN	1	0	0
GINGER	1	0	0
GINKGO BILOBA	0	1	0
GINSENG	0	2	1
GIVALEX	0	1	0
GLIBENCLAMIDE	7	4	4
GLISOMET	0	2	0
GLICLAZIDE	0	1	0
GLIMEPIRIDE	1	2	1
GLIMEPIRIDE/ROSIGLITAZONE MALEATE	1	0	0
GLIPIZIDE	6	3	2
GLUCOSAMINE	3	2	2

Excludes antiretrovirals and optimized background therapy.

	maraviroc QD	maraviroc BID	Placebo
GLUCOSAMINE WITH MSM	0	1	0
GLUCOSE	0	1	0
GLYCERYL TRINITRATE	3	2	0
GLYCOPYRRONIUM BROMIDE	0	1	0
GONOCILLIN	2	2	1
GRANISETRON	0	0	1
GRANULOCYTE COLONY STIMULATING FACTOR	2	2	2
GRIPPOSTAD	1	0	0
GRIPPOSTAD C	1	0	0
GRISEOFULVIN	1	0	0
GUAIFENESIN	9	15	5
GUAIFENESIN W/DEXTROMETHORPHAN	0	1	1
GYNOFLOR	1	0	0
HALL'S MENTHO-LYPTUS	0	1	0
HALOPERIDOL	1	2	0
HARPAGOPHYTUM PROCUMBENS	0	1	0
HEMCORT H.C.	0	1	0
HEPARIN	0	2	2
HEPARIN-FRACTION, SODIUM SALT	1	3	1
HEPARINOID	2	0	1
HEPATITIS A VACCINE	2	1	1
HEPATITIS B VACCINE	2	2	1
HERBAL PREPARATION	1	3	1

Excludes antiretrovirals and optimized background therapy.

	maraviroc QD	maraviroc BID	Placebo
HEXACHLOROPHENE	1	0	0
HEXALYSE	0	1	0
HEXAMIDINE ISETIONATE	0	1	0
HOMATROPINE/HYDROCODONE	0	1	0
HOMEOPATIC PREPARATION	0	1	0
HOT COLDREX	0	1	0
HUMULIN 70/30	1	0	0
HYALURONATE SODIUM	0	0	1
HYALURONIC ACID	0	1	0
HYDRALAZINE	0	1	0
HYDROCHLOROTHIAZIDE	9	18	7
HYDROCODONE	8	13	7
HYDROCODONE BITARTRATE	1	1	0
HYDROCORTISONE	10	12	9
HYDROCORTISONE ACETATE	1	1	2
HYDROCORTISONE SODIUM SUCCINATE	0	1	0
HYDROCORTISONE VALERATE	1	0	0
HYDROCORTISONE-NEOMYCIN-POLYMYXIN B	0	2	0
HYDROMORPHONE	1	2	1
HYDROMORPHONE HYDROCHLORIDE	1	0	1
HYDROQUINONE	1	0	0
HYDROXOCOBALAMIN	1	0	0
HYDROXYCHLOROQUINE	0	1	0

Excludes antiretrovirals and optimized background therapy.

	maraviroc QD	maraviroc BID	Placebo
HYDROXYZINE	5	3	3
HYDROXYZINE EMBONATE	1	0	0
HYDROXYZINE HYDROCHLORIDE	5	6	4
HYOSCINE BUTYLBROMIDE	2	1	1
HYPROMELLOSE	0	3	1
HYZAAR	0	1	1
I.V. SOLUTIONS	0	2	1
IBANDRONATE SODIUM	0	1	0
IBUPROFEN	62	73	26
ICHTHAMMOL	1	0	0
IMIPRAMINE	0	1	0
IMIPRAMINE HYDROCHLORIDE	0	1	0
IMIQUIMOD	8	10	3
IMMUNOGLOBULIN HUMAN NORMAL	0	1	0
IMMUNOGLOBULINS	1	2	0
INDAPAMIDE	0	1	0
INDOMETACIN	1	0	1
INFLANEFRAN	0	1	0
INFLUENZA VACCINE	18	21	6
INFLUENZA VIRUS VACCINE POLYVALENT	19	12	2
INOSITOL	0	1	0
INSULIN	5	4	4
INSULIN ASPART	2	4	4

Excludes antiretrovirals and optimized background therapy.

	maraviroc QD	maraviroc BID	Placebo
INSULIN GLARGINE	5	4	2
INSULIN HUMAN	1	1	0
INSULIN HUMAN INJECTION, ISOPHANE	1	0	2
INSULIN INJECTION, ISOPHANE	0	2	1
INSULIN ISOPHANE, HUMAN BIOSYNTHETIC	0	0	1
INSULIN LISPRO	2	0	0
INSULIN NOVOLIN 70/30	0	2	0
IODINE	0	1	0
IOTROXATE MEGLUMINE	0	0	1
IOVERSOL	0	1	0
IPRATROPIUM	0	1	1
IPRATROPIUM BROMIDE	3	2	1
IRBESARTAN	4	1	0
IRON	2	3	3
ISONIAZID	0	0	1
ISOSORBIDE	0	1	0
ISOSORBIDE DINITRATE	3	1	0
ISOSORBIDE MONONITRATE	1	0	0
ISOTRETINOIN	0	0	1
ISPAGHULA HUSK	1	0	0
ITRACONAZOLE	9	7	6
IVERMECTIN	0	1	0
KALINOR-BRAUSETABLETTEN	0	1	0

Excludes antiretrovirals and optimized background therapy.

	maraviroc QD	maraviroc BID	Placebo
KAOPECTATE	1	0	0
KARVEA HCT	4	2	0
KARVOL "BOOTS"	0	1	0
KETOCONAZOLE	10	18	6
KETOPROFEN	1	3	1
KETOROLAC	0	2	1
KETOROLAC TROMETHAMINE	2	2	1
KETOTIFEN FUMARATE	0	1	0
LABETALOL	1	0	0
LACRI-LUBE	0	1	0
LACTIC ACID	1	0	0
LACTOBACILLUS ACIDOPHILUS	6	2	3
LACTULOSE	2	4	1
LAMOTRIGINE	3	1	2
LANREOTIDE	1	0	0
LANSOPRAZOLE	17	15	8
LANSOPRAZOLE/NAPROXEN	1	0	0
LATANOPROST	2	0	1
LAXATIVES	1	0	0
LECITHIN	2	1	0
LEKOVIT CA	2	0	0
LEMSIP	1	0	0
LENOGRASTIM	0	1	0

Excludes antiretrovirals and optimized background therapy.

	maraviroc QD	maraviroc BID	Placebo
LERCANIDIPINE	0	2	0
LEUPRORELIN	0	1	0
LEVETIRACETAM	0	2	0
LEVOCARNITINE	12	3	3
LEVOCETIRIZINE	1	2	0
LEVOCETIRIZINE DIHYDROCHLORIDE	0	1	0
LEVODROPROPIZINE	0	1	0
LEVOFLOXACIN	27	20	15
LEVOGLUTAMIDE	4	2	1
LEVOSALBUTAMOL	1	0	1
LEVOTHYROXINE	4	6	0
LEVOTHYROXINE SODIUM	11	11	4
LIDOCAINE	2	5	1
LIDOCAINE HYDROCHLORIDE	3	2	0
LINEZOLID	1	0	0
LINSEED OIL	3	3	0
LIOTHYRONINE	1	0	0
LISINOPRIL	20	17	9
LISTERINE /USA/	1	0	0
LITHIUM	1	1	1
LITHIUM CARBONATE	3	1	0
LOMOTIL	29	24	17
LOPERAMIDE	31	22	16

Excludes antiretrovirals and optimized background therapy.

	maraviroc QD	maraviroc BID	Placebo
LOPERAMIDE HYDROCHLORIDE	31	39	27
LORATADINE	16	21	3
LORAZEPAM	28	36	15
LORMETAZEPAM	2	0	2
LOSARTAN	3	2	0
LOSARTAN POTASSIUM	3	2	2
LOTREL	1	3	0
LOTRISONE	5	2	1
LOVASTATIN	1	0	1
LOXAPINE	2	1	0
LYSINE	2	1	0
LYSPAFEN	1	1	0
MAALOX	3	1	0
MACROGOL	0	2	1
MAGALDRATE	0	1	0
MAGNESIUM	3	5	0
MAGNESIUM CHLORIDE ANHYDROUS	0	0	1
MAGNESIUM HYDROXIDE	0	2	0
MAGNESIUM OXIDE	3	0	1
MAGNESIUM SULFATE	1	1	1
MAGNESIUM W/POTASSIUM	0	0	1
MAPROTILINE	0	0	1
MARCAIN-ADRENALIN	0	0	1

Excludes antiretrovirals and optimized background therapy.

	maraviroc QD	maraviroc BID	Placebo
MATHOINE	1	0	0
MAXEPA	1	0	0
MAXIDEX	0	0	1
MECLOZINE	0	4	0
MECLOZINE HYDROCHLORIDE	1	1	0
MEDINITE	9	9	0
MEDIVITAN N INJECTION	1	0	0
MEDROXYPROGESTERONE	1	0	0
MEDROXYPROGESTERONE ACETATE	1	0	0
MEFLOQUINE	2	0	0
MEGESTROL	1	0	1
MEGESTROL ACETATE	7	5	6
MELALEUCA ALTERNIFOLIA OIL	0	2	0
MELATONIN	1	4	3
MELOXICAM	3	7	3
MEMANTINE HYDROCHLORIDE	0	1	0
MEPREDNISONE	0	1	0
MEROPENEM	0	1	1
MESALAZINE	0	0	2
MESCOLOR	0	0	1
METAMIZOLE	3	2	1
METAMIZOLE SODIUM	5	1	0
METAMUCIL "PROCTER & GAMBLE"	1	0	1

Excludes antiretrovirals and optimized background therapy.

	maraviroc QD	maraviroc BID	Placebo
METAXALONE	1	3	0
METEOSPASMYL	0	0	1
METFORMIN	12	8	6
METFORMIN HYDROCHLORIDE	4	5	4
METFORMIN HYDROCHLORIDE/ROSIGLITAZONE	2	0	1
METHADONE	4	1	5
METHADONE HYDROCHLORIDE	0	0	1
METHAMPHETAMINE	0	1	0
METHIONINE	1	0	0
METHOCARBAMOL	0	3	0
METHYLCELLULOSE	1	0	0
METHYLPHENIDATE	2	5	0
METHYLPHENIDATE HYDROCHLORIDE	3	3	1
METHYLPREDNISOLONE	6	3	3
METHYLPREDNISOLONE ACEPONATE	0	1	0
METHYLPREDNISOLONE ACETATE	1	1	0
METHYLPREDNISOLONE SODIUM SUCCINATE	1	1	1
METHYLSULFONYLMETHANE	2	0	0
METIPRANOLOL HYDROCHLORIDE	1	0	0
METOCLOPRAMIDE	17	14	9
METOCLOPRAMIDE HYDROCHLORIDE	1	1	4
METOLAZONE	1	0	0
METOPROLOL	13	5	2

Excludes antiretrovirals and optimized background therapy.

	maraviroc QD	maraviroc BID	Placebo
METOPROLOL SUCCINATE	2	13	1
METOPROLOL TARTRATE	4	3	0
METRONIDAZOLE	14	15	11
MEXILETINE	1	0	0
MIANSERIN	0	1	0
MICONAZOLE	1	0	0
MICONAZOLE NITRATE	1	0	1
MICROLAX	0	1	0
MIDAZOLAM	2	6	0
MIDAZOLAM HYDROCHLORIDE	1	0	0
MIDRID	1	0	0
MINERALS NOS	2	1	0
MINOCYCLINE	4	6	0
MINOXIDIL	1	0	0
MIRTAZAPINE	10	15	9
MITOMYCIN	0	0	1
MIVACURIUM	0	1	0
MOCLOBEMIDE	1	0	0
MODAFINIL	2	1	0
MOMETASONE	1	1	4
MOMETASONE FUROATE	7	8	6
MONTELUKAST	0	1	1
MONTELUKAST SODIUM	7	7	2

Excludes antiretrovirals and optimized background therapy.

	maraviroc QD	maraviroc BID	Placebo
MORPHINE	4	11	3
MORPHINE HYDROCHLORIDE	0	1	0
MORPHINE SULFATE	5	8	5
MOXIFLOXACIN	3	9	1
MOXIFLOXACIN HYDROCHLORIDE	6	6	4
MULTIPLE VITAMINS	0	2	1
MULTIVITAMIN AND MINERAL SUPPLEMENT	3	0	0
MULTIVITAMINS	14	17	5
MULTIVITAMINS W/MINERALS	0	1	0
MULTIVITAMINS WITH MINERALS	0	3	1
MULTIVITAMINS, PLAIN	45	54	27
MUPIROCIN	3	3	5
MUPIROCIN CALCIUM	0	0	1
MYCOLOG	2	0	0
MYLANTA	0	0	3
MYRTOL	2	0	0
NABUMETONE	3	1	1
NADOLOL	0	0	1
NADROPARIN	0	1	0
NADROPARIN CALCIUM	0	1	0
NAFTIFINE HYDROCHLORIDE	1	0	1
NALTREXONE	0	0	1
NANDROLONE	5	7	3

Excludes antiretrovirals and optimized background therapy.

	maraviroc QD	maraviroc BID	Placebo
NANDROLONE DECANOATE	5	7	6
NAPHAZOLINE HYDROCHLORIDE	0	1	0
NAPROXEN	9	11	5
NAPROXEN SODIUM	3	6	4
NARATRIPTAN HYDROCHLORIDE	0	1	0
NARINE REPETABS	4	4	1
NASAL PREPARATIONS	1	0	0
NATEGLINIDE	0	1	0
NEBIVOLOL	0	1	0
NEFAZODONE HYDROCHLORIDE	0	1	0
NEMDYN	1	0	0
NEUROTRAT S FORTE	1	0	0
NICOTINAMIDE	0	1	0
NICOTINE	10	3	4
NICOTINIC ACID	15	8	1
NIFEDIPINE	3	2	2
NIFUROXAZIDE	1	1	0
NIMESULIDE	1	1	0
NITAZOXANIDE	1	0	0
NITE-TIME COLD MEDICINE	1	0	1
NITRAZEPAM	0	0	1
NITROFURANTOIN	0	1	0
NITROGEN, LIQUID	1	1	0

Excludes antiretrovirals and optimized background therapy.

	maraviroc QD	maraviroc BID	Placebo
NIZATIDINE	0	1	0
NO-FLU F	0	1	0
NOREPINEPHRINE BITARTRATE	0	0	1
NORFLOXACIN	3	1	0
NORTRIPTYLINE	1	2	1
NORTRIPTYLINE HYDROCHLORIDE	4	0	0
NOSCAPINE RESIN	1	0	0
NOVOLIN 20/80	1	1	0
NULYTELY	1	0	1
NYSTADERM COMP	1	0	0
NYSTADERMAL	0	1	0
NYSTATIN	14	5	3
OBETROL	0	0	1
OCADRIK	0	1	0
OCTOCAINE WITH EPINEPHRINE	0	0	1
OCTREOTIDE	1	1	0
OCTREOTIDE ACETATE	0	0	1
OFLOXACIN	2	2	0
OLANZAPINE	2	5	6
OLIVE LEAVES EXTRACT	0	0	1
OLMESARTAN MEDOXOMIL	2	3	0
OLOPATADINE	0	0	1
OLOPATADINE HYDROCHLORIDE	0	1	0

Excludes antiretrovirals and optimized background therapy.

	maraviroc QD	maraviroc BID	Placebo
OMEGA	0	0	1
OMEGA-3 MARINE TRIGLYCERIDES	1	2	0
OMEGA-3 TRIGLYCERIDES	5	4	0
OMEPRAZOLE	24	29	12
OMNIBIONTA	0	0	1
ONCE-A-DAY	0	0	1
ONDANSETRON	4	5	3
ONDANSETRON HYDROCHLORIDE	4	2	2
ONE-A-DAY	0	1	0
OPIPRAMOL	0	1	0
OPIUM ALKALOIDS AND DERIVATIVES	1	0	0
OPIUM TINCTURE	6	1	4
ORLISTAT	1	0	0
ORPHENADRINE	1	0	0
ORPHENADRINE CITRATE	1	0	0
OS-CAL	1	0	0
OSMOSAL	1	0	0
OTHER ANTIDIARRHOEALS	0	1	0
OTHER DERMATOLOGICAL PREPARATIONS	1	0	1
OTHER EMOLLIENTS AND PROTECTIVES	0	1	1
OTIPAX	0	1	0
OTOLOGICALS	0	1	0
OTOSPORIN	2	0	0

Excludes antiretrovirals and optimized background therapy.

	maraviroc QD	maraviroc BID	Placebo
OXANDROLONE	12	17	11
OXAZEPAM	3	2	1
OXCARBAZEPINE	1	2	0
OXICONAZOLE	0	1	0
OXYBUTYNIN	2	2	1
OXYBUTYNIN HYDROCHLORIDE	2	1	0
OXYCOCET	6	12	7
OXYCODONE	9	8	4
OXYCODONE HYDROCHLORIDE	5	9	3
OXYGEN	0	1	0
OXYMETAZOLINE	0	1	0
OXYMETAZOLINE HYDROCHLORIDE	2	1	0
OXYMETHOLONE	1	0	1
PANADEINE CO	6	10	7
PANCREATIN	2	3	1
PANCRELIPASE	3	4	2
PANTOPRAZOLE	9	8	6
PANTOPRAZOLE SODIUM	5	5	4
PARA-SELTZER	0	1	1
PARACETAMOL	58	43	16
PARAFFIN	1	0	0
PARAMOL-118	2	1	0
PAREGORIC	0	1	2

Excludes antiretrovirals and optimized background therapy.

	maraviroc QD	maraviroc BID	Placebo
PAROMOMYCIN	1	1	0
PAROMOMYCIN SULFATE	0	1	0
PAROXETINE	7	3	0
PAROXETINE HYDROCHLORIDE	6	7	4
PEGFILGRASTIM	1	2	0
PEGINTERFERON ALFA-2A	1	1	0
PEMIROLAST POTASSIUM	0	1	0
PENICILLIN NOS	2	3	0
PENTAMIDINE	12	8	4
PENTAMIDINE DIMESILATE	1	0	0
PENTAMIDINE ISETHIONATE	2	1	1
PENTOXIFYLLINE	0	0	3
PEP ACID	1	0	0
oxycodone/aspirin*	1	1	0
PERGOLIDE	1	0	0
PERI-COLACE	0	1	1
PERINDOPRIL	1	1	0
PERINDOPRIL ERBUMINE	0	1	0
PERMETHRIN	2	1	0
PETHIDINE	1	0	1
PETHIDINE HYDROCHLORIDE	0	3	0
PHENAZOPYRIDINE	0	0	1
PHENAZOPYRIDINE HYDROCHLORIDE	1	0	0

Excludes antiretrovirals and optimized background therapy.

* ：新薬承認情報提供時に置換えた。

	maraviroc QD	maraviroc BID	Placebo
PHENERGAN WITH CODEINE	2	1	0
PHENOL	1	0	0
PHENOXYMETHYLPENICILLIN	2	0	0
PHENOXYMETHYLPENICILLIN POTASSIUM	0	0	1
PHENYLEPHRINE	1	0	0
PHENYLEPHRINE HYDROCHLORIDE	1	1	1
PHENYTOIN	1	1	1
PHENYTOIN SODIUM	1	4	2
PHLOROGLUCINOL	0	0	1
PHOSPHATE-SANDOZ	1	0	0
PHOSPHATIDYL CHOLINE	0	1	0
PHOSPHORUS	1	0	0
PHYTOMENADIONE	1	0	0
PICO-SALAX	0	2	0
PILOCARPINE HYDROCHLORIDE	1	0	0
PIMECROLIMUS	1	2	0
PINIMENTHOL	0	1	0
PIOGLITAZONE	6	5	2
PIP/TAZO	2	1	2
PIPERACILLIN/TAZOBACTAM	0	1	0
PIRBUTEROL	0	1	0
PIRBUTEROL ACETATE	1	0	0
PIRETANIDE	0	1	0

Excludes antiretrovirals and optimized background therapy.

	maraviroc QD	maraviroc BID	Placebo
PIRITRAMIDE	0	1	0
PIROMIDIC ACID	0	0	2
PIROXICAM	0	1	0
PITUITARY AND HYPOTHALAMIC HORMONES	0	3	0
PLASMA PROTEIN FRACTION (HUMAN)	0	0	1
PNEUMOCOCCAL VACCINE	8	5	3
PODOPHYLLOTOXIN	3	2	0
POLIOMYELITIS VACCINE INACTIVATED	0	0	1
POLY-L-LACTIC ACID	1	6	2
POLYCARBOPHIL CALCIUM	0	1	0
POLYCITRA-K "WILLEN"	0	1	0
POLYHEXANIDE	0	1	0
POLYLACTIC ACID	3	3	0
POLYVIDONE	0	1	0
POSACONAZOLE	0	1	0
POTASSIUM	3	5	3
POTASSIUM CANRENOATE	1	0	0
POTASSIUM CHLORIDE	10	14	8
POTASSIUM PHOSPHATE	1	1	0
POVIDONE-IODINE	2	1	0
PRAMIPEXOLE	1	0	0
PRASTERONE	3	5	0
PRAVASTATIN	10	7	1

Excludes antiretrovirals and optimized background therapy.

	maraviroc QD	maraviroc BID	Placebo
PRAVASTATIN SODIUM	8	9	3
PRAZEPAM	0	1	1
PRED-G	0	1	0
PREDNAZOLINE	0	1	0
PREDNICARBATE	0	1	0
PREDNISOLONE	1	2	2
PREDNISOLONE ACETATE	0	1	1
PREDNISONE	9	13	4
PREGABALIN	6	8	3
PRENATAL VITAMINS	1	4	0
PRIMAQUINE	0	1	0
PRIMAQUINE PHOSPHATE	1	0	0
PRIMAXIN	1	2	1
PRIMIDONE	1	1	0
PRIMOX PLUS	1	0	0
PRINZIDE	2	2	0
PRIORIN	0	1	0
PRISTINAMYCIN	1	2	0
PROBENECID	0	0	1
PROCAINE	1	0	0
PROCHLORPERAZINE	6	2	3
PROCHLORPERAZINE EDISYLATE	6	4	5
PROCHLORPERAZINE MALEATE	1	2	0

Excludes antiretrovirals and optimized background therapy.

	maraviroc QD	maraviroc BID	Placebo
PROCTOFOAM HC	1	0	0
PROCTOSEDYL OINTMENT "ROCHE"	0	0	1
PROGUANIL	1	0	0
PROMETHAZINE	9	9	3
PROPACET	4	4	2
PROPANOL	0	1	0
PROPOFOL	0	3	0
PROPOLIS/UNDECYLENIC ACID/ZINC OXIDE	0	0	1
PROPRANOLOL	0	2	2
PROPRANOLOL HYDROCHLORIDE	0	4	0
PROPYLENE GLYCOL	0	1	0
PROTEIN SUPPLEMENTS	3	2	0
PSEUDOEPHEDRINE	5	2	3
PSEUDOEPHEDRINE HYDROCHLORIDE	7	10	4
PSYLLIUM	0	1	2
PSYLLIUM HYDROPHILIC MUCILLOID	6	7	2
PYRAZINAMIDE	0	0	1
PYRIDOXINE	1	0	1
PYRIDOXINE HYDROCHLORIDE	1	2	2
PYRIMETHAMINE	4	2	5
QUETIAPINE	1	2	0
QUETIAPINE FUMARATE	4	6	1
QUINAPRIL	1	0	0

Excludes antiretrovirals and optimized background therapy.

	maraviroc QD	maraviroc BID	Placebo
QUINAPRIL HYDROCHLORIDE	0	2	0
QUININE	0	1	0
QUININE SULFATE	1	2	0
RABEPRAZOLE	0	1	0
RABEPRAZOLE SODIUM	6	7	2
RAMELTEON	0	1	0
RAMIPRIL	6	6	4
RANITIDINE	9	11	5
RANITIDINE HYDROCHLORIDE	7	3	2
RED BLOOD CELLS	1	0	1
RED BLOOD CELLS, CONCENTRATED	1	1	0
REPAGLINIDE	0	2	0
RESPAIRE-SR-120	5	1	0
RETINOL	1	3	1
RHINARIS	0	0	1
RHINOFLUIMUCIL	0	1	0
RHODOGIL	0	0	1
RIBAVIRIN	1	0	0
RIBOFLAVIN	1	1	1
RIFABUTIN	1	4	1
RIFAMPICIN	1	0	1
RIFAXIMIN	2	0	0
RINGER-LACTATE SOLUTION "FRESENIUS"	1	2	0

Excludes antiretrovirals and optimized background therapy.

	maraviroc QD	maraviroc BID	Placebo
RISEDRONATE SODIUM	3	2	0
RISPERIDONE	3	3	0
RITUXIMAB	0	1	1
RIZATRIPTAN	2	0	0
RIZATRIPTAN BENZOATE	1	0	0
ROBAXISAL COMPUESTO	0	1	0
ROBITUSSIN A-C /OLD FORM/	1	1	0
ROBITUSSIN-DAC	0	1	0
ROBITUSSIN-DM	4	0	1
ROCURONIUM BROMIDE	1	0	0
ROPINIROLE HYDROCHLORIDE	2	0	0
ROSIGLITAZONE	1	1	0
ROSIGLITAZONE MALEATE	5	8	3
ROSUVASTATIN	9	5	3
ROXITHROMYCIN	1	3	1
SACCHAROMYCES BOULARDII	0	0	1
SALBUTAMOL	37	27	22
SALBUTAMOL SULFATE	3	2	0
SALICYLIC ACID	0	2	0
SALMETEROL XINAFOATE	2	1	1
SALMON OIL	1	1	0
SELEGILINE	1	0	1
SELENIDE SODIUM	0	1	0

Excludes antiretrovirals and optimized background therapy.

	maraviroc QD	maraviroc BID	Placebo
SELENIUM	1	5	1
SELENIUM SULFIDE	1	0	0
SENNA	3	2	0
SENNA FRUIT	2	0	0
SERENOA REPENS	2	3	2
SERETIDE MITE	7	6	4
SERTRALINE	1	5	5
SERTRALINE HYDROCHLORIDE	7	12	4
SHARK-LIVER OIL	0	0	1
SIDROS	1	0	0
SILDENAFIL	8	9	5
SILDENAFIL CITRATE	19	19	8
SILYMARIN	1	5	1
SIMECO	0	0	1
SIMVASTATIN	2	0	2
SINEMET	0	0	1
SM-33 ADULT FORMULA LIQUID	0	1	0
SODIUM BICARBONATE	5	1	3
SODIUM CHLORIDE	4	10	1
SODIUM FLUORIDE	1	0	0
SODIUM POLYSTYRENE SULFONATE	0	1	0
SOFRASOLONE O.R.L.	2	0	0
SOLIDAGO VIRGAUREA HERB	0	1	0

Excludes antiretrovirals and optimized background therapy.

	maraviroc QD	maraviroc BID	Placebo
SOLIFENACIN SUCCINATE	1	0	0
SOLUTIONS FOR PARENTERAL NUTRITION	3	0	0
SOMATOSTATIN	1	0	0
SOMATROPIN	9	9	4
SOY ISOFLAVONES	1	0	0
SPIRONOLACTONE	0	4	0
SPIRULINA	0	2	0
STERIMAR	1	0	0
STEROFUNDIN	1	0	0
SUCRALFATE	0	0	3
SULFACET-R	0	1	0
SULFACETAMIDE SODIUM	0	2	0
SULFADIAZINE	0	1	1
SULFADIAZINE SILVER	1	0	0
SULFAMETHOXAZOLE	1	3	2
SULFASALAZINE	1	2	0
SULINDAC	0	0	1
SUMATRIPTAN	1	3	1
SUMATRIPTAN SUCCINATE	5	2	2
SUPER VITAMIN B COMPLEX	0	1	0
SUPRADYN	1	0	0
SUSTANON	1	1	0
SYMBICORT TURBUHALER "DRACO"	0	1	1

Excludes antiretrovirals and optimized background therapy.

	maraviroc QD	maraviroc BID	Placebo
TACROLIMUS	1	0	1
TADALAFIL	13	15	8
TAMOXIFEN	0	1	0
TAMOXIFEN CITRATE	0	1	0
TAMSULOSIN	3	5	0
TAMSULOSIN HYDROCHLORIDE	8	7	3
TANNACOMP	1	0	0
TARAXACUM	0	1	0
TEGASEROD	1	0	0
TELITHROMYCIN	3	3	0
TELMISARTAN	0	1	0
TEMAZEPAM	16	20	8
TEMOCILLIN	1	0	0
TENOXICAM	0	0	1
TERAZOSIN	2	0	1
TERBINAFINE	7	1	0
TERBINAFINE HYDROCHLORIDE	5	4	2
TERBUTALINE	0	1	0
TERBUTALINE SULFATE	1	0	1
TERCONAZOLE	0	1	0
TESTOSTERONE	59	68	33
TESTOSTERONE CIPIONATE	12	8	8
TESTOSTERONE ENANTATE	2	3	1

Excludes antiretrovirals and optimized background therapy.

	maraviroc QD	maraviroc BID	Placebo
TESTOSTERONE PROPIONATE	1	0	1
TESTOSTERONE UNDECANOATE	3	2	0
TETANUS ANTITOXIN	1	0	0
TETANUS TOXOID	3	1	0
TETRACYCLINE	2	2	0
TETRAZEPAM	0	2	1
TETRYZOLINE HYDROCHLORIDE	1	1	0
THALIDOMIDE	0	1	1
THERAFLU	2	1	0
THERAGRAN	0	1	0
THIAMINE	0	1	0
THIAMINE HYDROCHLORIDE	0	0	2
THIOCODIN	0	1	0
THIOCOLCHICOSIDE	2	1	0
THIOCTIC ACID	5	3	3
THOMAPYRIN N	1	2	1
THROAT PREPARATIONS	0	1	0
THYROID	1	0	0
TIAGABINE HYDROCHLORIDE	0	1	1
TICLOPIDINE	1	0	0
TILACTASE	0	2	0
TIMOLOL	0	0	1
TINIDAZOLE	0	1	0

Excludes antiretrovirals and optimized background therapy.

	maraviroc QD	maraviroc BID	Placebo
TIOTROPIUM	0	1	0
TIOTROPIUM BROMIDE	1	1	1
TITANOREINE	1	0	0
TIZANIDINE	0	0	1
TOBRADEX	2	0	1
TOCOPHEROL	9	12	7
TOCOPHERYL ACETATE	1	0	0
TOLAZAMIDE	0	0	1
TOLNAFTATE	0	1	0
TOLTERODINE L-TARTRATE	0	0	1
TOPIRAMATE	2	2	1
TORASEMIDE	0	1	0
TPN	1	0	0
TRAMADOL	4	5	3
TRAMADOL HYDROCHLORIDE	3	4	4
TRAMADOL/ACETAMINOPHEN	1	0	0
TRANDOLAPRIL	1	1	0
TRANSPULMIN "ASTA MEDICA"	1	0	0
TRAPIDIL	0	1	0
TRAVAD PHOSPHATE ENEMA	1	0	0
TRAZODONE	19	20	9
TRAZODONE HYDROCHLORIDE	2	0	1
TRETINOIN	0	7	0

Excludes antiretrovirals and optimized background therapy.

	maraviroc QD	maraviroc BID	Placebo
TRIAMCINOLONE	5	12	5
TRIAMCINOLONE ACETONIDE	5	7	4
TRIAZOLAM	3	1	0
TRIFLURIDINE	0	1	0
TRIHEXYPHENIDYL	0	1	0
TRIHEXYPHENIDYL HYDROCHLORIDE	0	1	0
TRILAC	0	2	0
TRIMETAZIDINE	1	0	0
TRIMETHOBENZAMIDE	1	0	0
TRIMETHOBENZAMIDE HYDROCHLORIDE	1	0	0
TRIMETHOPRIM	1	1	0
TRIMIPRAMINE	2	0	0
TRIOBE	0	4	0
TRIOFAN	0	1	0
TROPATEPINE HYDROCHLORIDE	0	1	0
TROPICAMIDE	1	0	0
TROPISETRON	0	1	1
TROSPIUM CHLORIDE	1	2	0
TUBERCULIN PPD	0	1	0
TUSSEX COUGH	1	0	0
TUSSIN DM	0	1	1
TUSSIONEX PENNKINETIC	0	1	1
TYLENOL PM	0	8	0

Excludes antiretrovirals and optimized background therapy.

	maraviroc QD	maraviroc BID	Placebo
TYLENOL SINUS MEDICATION	3	0	0
TYPHOID VACCINE	1	0	1
UBIDECARENONE	10	5	2
ULOBETASOL PROPIONATE	0	0	1
ULTRACAIN D-S	1	0	0
ULTRACET	1	2	0
UMCKALOABO	0	0	1
UNACID	1	0	0
URALYT URATO	0	0	1
UREA	1	1	0
UREMOL HC	0	1	0
URSODEOXYCHOLIC ACID	0	1	0
VACCINIUM MACROCARPON	1	1	0
VALACICLOVIR	24	21	17
VALACICLOVIR HYDROCHLORIDE	25	36	13
VALDECOXIB	0	0	1
VALGANCICLOVIR	8	5	3
VALGANCICLOVIR HYDROCHLORIDE	7	9	3
VALPROATE BISMUTH	0	1	0
VALPROATE SEMISODIUM	2	3	1
VALPROATE SODIUM	1	2	0
VALPROIC ACID	4	1	1
VALSARTAN	4	3	0

Excludes antiretrovirals and optimized background therapy.

	maraviroc QD	maraviroc BID	Placebo
VANCOMYCIN	3	2	2
VANCOMYCIN HYDROCHLORIDE	1	0	0
VARDENAFIL	1	1	1
VARDENAFIL HYDROCHLORIDE	2	13	5
VELITEN	1	0	0
VENLAFAXINE	5	6	2
VENLAFAXINE HYDROCHLORIDE	11	18	6
VERAPAMIL	1	0	0
VERAPAMIL HYDROCHLORIDE	0	1	2
VICKS FORMULA 44 COUGH MIXTURE	0	1	0
VICKS FORMULA 44M	1	0	0
acetaminophen/hydrocodone bitartrate*	22	33	10
VICOPROFEN	1	1	1
VINCENTS TABLETS	0	1	0
VINCRISTINE	0	1	0
VIT B1,IN COMBINATION WITH VITAMIN B6 AND B12	0	0	1
VITACAL	3	1	0
VITAMIN B	2	3	4
VITAMIN B-COMPLEX	4	3	1
VITAMIN B-COMPLEX WITH VITAMIN C	0	1	0
VITAMINES-B-LABAZ	0	1	0
VITAMINS	0	2	1
VITAMINS WITH MINERALS	1	0	0

Excludes antiretrovirals and optimized background therapy.

* ：新薬承認情報提供時に置換えた。

	maraviroc QD	maraviroc BID	Placebo
VITAMINS, OTHER COMBINATIONS	1	0	0
VITIS VINIFERA EXTRACT	1	0	0
VORICONAZOLE	7	6	2
VOSOL HC	0	0	1
WALGREENS NON-DROWSY DAYTIME	0	1	0
WARFARIN	3	4	1
WARFARIN SODIUM	4	5	1
XIPAMIDE	0	1	0
XYLOMETAZOLINE HYDROCHLORIDE	1	0	0
YELLOW PHENOLPHTHALEIN	1	0	0
YOHIMBINE HYDROCHLORIDE	0	1	0
ZALEPLON	3	3	1
ZINC	2	4	0
ZINC OROTATE	0	0	1
ZIPRASIDONE	1	0	0
ZIPRASIDONE HYDROCHLORIDE	1	1	0
ZOLMITRIPTAN	0	0	1
ZOLPIDEM	10	13	7
ZOLPIDEM TARTRATE	25	26	13
ZOPICLONE	5	6	3
ZUCLOPENTHIXOL DECANOATE	1	0	0

Excludes antiretrovirals and optimized background therapy.

Table 3.2.2.2
Maraviroc Summary of Clinical Safety
Concomitant Optimized Background Therapy Treatments
Phase 3 Treatment Experienced CCR5 Tropic Studies

	maraviroc QD	maraviroc BID	Placebo
Number of Subjects	414	426	209
Number (%) of Subjects With Any Concomitant Drug Treatment	414 (100.0)	426 (100.0)	209 (100.0)
ABACAVIR	122	116	68
AMPRENAVIR	91	105	66
ATAZANAVIR	80	69	39
DELAVIRDINE	11	8	6
DIDANOSINE	87	83	57
EFAVIRENZ	29	29	13
EMTRICITABINE	146	173	88
ENFUVIRTIDE	168	182	91
INDINAVIR	13	15	4
LAMIVUDINE	190	182	80
LOPINAVIR	123	153	61
NELFINAVIR	3	4	1
NEVIRAPINE	17	22	6
RITONAVIR	3	0	0
RITONAVIR LOW-DOSE	357	369	182
SAQUINAVIR	56	47	25
STAVUDINE	49	42	21
T-1249	3	0	0
TENOFOVIR	339	355	176
TIPRANAVIR	66	63	29
TMC-114	0	0	1
ZIDOVUDINE	91	85	35

Low-dose Ritonavir is doses of 200mg BID and below.
Amprenavir and Fosamprenavir have been combined and reported as Amprenavir.
Salt forms have been reported under the name of the active drug substance to which they correspond.
Fixed dose combinations have been slpit into individual components.

Table 3.2.2.3
Maraviroc Summary of Clinical Safety
Optimized Background Therapy Combinations
Phase 3 Treatment Experienced CCR5 Tropic Studies

Treatment Combination	maraviroc QD		maraviroc BID		Placebo	
Number (%) of Subjects	414		426		209	
NRTI only	6	(1.4)	5	(1.1)	5	(2.3)
NRTI+T20	17	(4.1)	9	(2.1)	4	(1.9)
NRTI+PI	203	(49.0)	196	(46.0)	95	(45.4)
NRTI+PI+T20	132	(31.8)	158	(37.0)	80	(38.2)
NNRTI+NRTI	8	(1.9)	15	(3.5)	4	(1.9)
NNRTI+NRTI+T20	5	(1.2)	5	(1.1)	1	(0.4)
NNRTI+NRTI+PI	26	(6.2)	28	(6.5)	13	(6.2)
NNRTI+NRTI+PI+T20	13	(3.1)	8	(1.8)	6	(2.8)
NRTI+PI+Other Treatment*	3	(0.7)	0		1	(0.4)
Other	1	(0.2)	2	(0.4)	0	

* Other Treatment is either TMC-114 or T-1249.
Other is drug combinations not in the list above.

Table 3.2.2.4
Maraviroc Summary of Clinical Safety
Optimized Background Therapy Combinations
Phase 2b Treatment Experienced non-CCR5 Tropic Studies

Treatment Combination	maraviroc QD		maraviroc BID		Placebo	
Number (%) of Subjects	63		61		62	
NRTI+T20	3	(4.7)	2	(3.2)	1	(1.6)
NRTI+PI	17	(26.9)	15	(24.5)	18	(29.0)
NRTI+PI+T20	30	(47.6)	29	(47.5)	28	(45.1)
NNRTI+NRTI	2	(3.1)	2	(3.2)	1	(1.6)
NNRTI+NRTI+T20	1	(1.5)	2	(3.2)	0	
NNRTI+NRTI+PI	6	(9.5)	9	(14.7)	8	(12.9)
NNRTI+NRTI+PI+T20	4	(6.3)	2	(3.2)	5	(8.0)
Other	0		0		1	(1.6)

Other is combinations not shown in the list above.

Table 3.2.3.1
Maraviroc Summary of Clinical Safety
Concomitant Non Drug Treatments
Phase 3 Treatment Experienced CCR5 Tropic Studies

	maraviroc QD		maraviroc BID		Placebo	
Number of Subjects	414		426		209	
Number (%) of Subjects With At Least One Concomitant Nondrug Treatment:	98	(23.7)	101	(23.7)	51	(24.4)
GASTROINTESTINAL DISORDERS	1	(0.2)	0		0	
Oesophageal dilatation	1		0		0	
INFECTIONS AND INFESTATIONS	3	(0.7)	0		0	
Catheter sepsis	1		0		0	
Molluscum contagiosum	1		0		0	
Sinusitis fungal	1		0		0	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	0		1	(0.2)	0	
Joint sprain	0		1		0	
INVESTIGATIONS	49	(11.8)	58	(13.6)	32	(15.3)
Abdomen scan	1		0		0	
Abdominal X-ray	1		2		0	
Angiogram	0		0		1	
Arteriogram coronary	1		0		0	
Aspiration bone marrow	1		0		0	
Biopsy	0		1		2	
Biopsy anus	0		0		1	
Biopsy liver	0		2		0	
Biopsy lung	0		1		1	
Biopsy lymph gland	1		0		0	
Biopsy prostate	1		0		0	
Biopsy skin	1		3		1	
Blood culture	1		0		0	

	maraviroc QD	maraviroc BID	Placebo
Blood electrolytes	0	0	1
Blood gases	0	0	1
Blood pressure ambulatory	1	0	0
Blood triglycerides	0	1	0
Bone densitometry	1	1	0
Bone scan	0	1	1
Bronchoalveolar lavage	1	0	0
Bronchoscopy	1	1	0
Cardiac stress test	0	1	1
Catheterisation cardiac	0	0	1
Chest X-ray	14	16	9
Cholangiogram	1	0	1
Colonoscopy	3	4	1
Colposcopy	0	0	1
Computerised tomogram	4	8	3
Computerised tomogram abdomen	7	7	2
Computerised tomogram head	2	2	2
Computerised tomogram kidney	0	1	0
Computerised tomogram thorax	6	2	2
Culture	0	1	1
Culture throat	0	0	1
Culture urine	1	0	0
Cystoscopy	0	1	0
Cytology	0	1	0

	maraviroc QD	maraviroc BID	Placebo
Ear, nose and throat examination	0	1	0
Echocardiogram	2	3	1
Electrocardiogram	2	4	4
Electrocardiogram ambulatory	0	1	0
Electroencephalogram	1	1	0
Electroneurography	0	0	1
Endoscopy	1	0	0
Endoscopy upper gastrointestinal tract	1	6	2
Haematology test	0	0	1
Liver function test	0	0	1
Lumbar puncture	1	2	1
Mammogram	0	1	1
Nasoendoscopy	1	0	0
Nuclear magnetic resonance imaging	4	6	3
Nuclear magnetic resonance imaging abdominal	0	1	0
Nuclear magnetic resonance imaging brain	3	3	1
Oesophagogastroduodenoscopy	4	1	0
Parasite stool test positive	0	0	1
Proctoscopy	2	2	0
Pulmonary function test	2	0	0
Renal function test	0	0	1
Renal scan	0	1	0
Scan brain	2	2	0
Scan myocardial perfusion	0	1	0

	maraviroc QD	maraviroc BID	Placebo
Sigmoidoscopy	0	1	0
Skull X-ray	0	1	0
Smear cervix	0	2	0
Smear test	0	1	0
Spinal X-ray	2	3	2
Spirometry	0	1	0
Sputum culture	0	0	1
Sputum test	1	0	0
Tuberculin test	1	2	1
Tuberculin test negative	0	1	0
Ultrasound Doppler	1	0	1
Ultrasound abdomen	8	7	6
Ultrasound kidney	0	0	1
Ultrasound liver	1	0	0
Ultrasound pelvis	0	1	1
Ultrasound scan	3	3	1
Ultrasound skull	0	0	1
Urinary system X-ray	1	0	0
Vascular imaging	1	0	0
X-ray	0	1	0
X-ray limb	1	0	2
X-ray of pelvis and hip	0	1	1
METABOLISM AND NUTRITION DISORDERS	0	1 (0.2)	0
Hyperlipidaemia	0	1	0

	maraviroc QD		maraviroc BID		Placebo	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	0		0		1	(0.5)
Back pain	0		0		1	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	0		0		1	(0.5)
Skin papilloma	0		0		1	
NERVOUS SYSTEM DISORDERS	1	(0.2)	0		0	
Headache	1		0		0	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	1	(0.2)	0		0	
Productive cough	1		0		0	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	1	(0.2)	0		0	
Lipodystrophy acquired	1		0		0	
SOCIAL CIRCUMSTANCES	1	(0.2)	2	(0.5)	0	
Respite care	1		0		0	
Walking aid user	0		2		0	
SURGICAL AND MEDICAL PROCEDURES	63	(15.2)	61	(14.3)	26	(12.4)
Abscess drainage	2		0		3	
Acupuncture	1		1		3	
Angioplasty	0		1		0	
Artificial crown procedure	0		1		0	
Bladder catheterisation	0		1		0	
Breast cosmetic surgery	0		1		0	
Bunion operation	0		1		0	
Cardioversion	0		1		0	
Carpal tunnel decompression	0		1		0	
Cataract operation	0		0		1	

	maraviroc QD	maraviroc BID	Placebo
Catheter placement	1	0	0
Catheter removal	1	0	0
Central venous catheterisation	3	0	0
Chemotherapy	1	0	0
Chiropractic	3	2	0
Cholecystectomy	1	1	0
Cold compress therapy	2	0	0
Compression stockings application	1	0	0
Continuous positive airway pressure	0	0	1
Corneal transplant	1	0	0
Coronary arterial stent insertion	1	0	0
Cryotherapy	6	8	2
Dental treatment	0	1	0
Dermabrasion	0	0	1
Detached retina repair	0	1	0
Ear irrigation	0	2	0
Endodontic procedure	1	1	0
Epidural blood patch	0	1	0
Ethmoid sinus surgery	1	0	0
Facial operation	1	0	0
Gastrostomy tube insertion	0	0	1
Gingival operation	0	1	0
Haemodialysis	1	0	0
Haemorrhoid operation	1	1	0

	maraviroc QD	maraviroc BID	Placebo
Heat therapy	1	1	1
Hepatitis B immunisation	1	0	0
Hip arthroplasty	2	0	1
Incisional drainage	1	0	0
Influenza immunisation	0	0	1
Inguinal hernia repair	0	1	0
Injection	1	0	0
Intervertebral disc operation	0	1	0
Intra-nasal antrostomy	1	0	0
Intubation	1	0	0
Joint stabilisation	1	0	0
Laryngeal polypectomy	0	1	0
Limb operation	1	1	0
Lip lesion excision	0	1	0
Lipectomy	0	1	0
Lipoma excision	0	1	0
Liposuction	2	0	0
Lithotripsy	1	1	0
Malignant tumour excision	0	1	0
Massage	3	0	2
Medical device removal	0	1	0
Medical diet	1	0	0
Nail operation	0	1	0
Nutritional support	2	2	0

Maraviroc Summary of Clinical Safety
Concomitant Non Drug Treatments
Phase 3 Treatment Experienced CCR5 Tropic Studies

	maraviroc QD	maraviroc BID	Placebo
Office visit	5	5	2
Oxygen supplementation	1	0	1
Packed red blood cell transfusion	3	1	0
Penile operation	1	0	0
Phlebotomy	0	1	0
Photodynamic therapy	0	1	0
Physiotherapy	2	1	2
Plasmapheresis	0	1	0
Plastic surgery to the face	0	1	0
Polypectomy	0	1	0
Psychotherapy	0	0	1
Radiotherapy	1	0	2
Removal of foreign body	0	1	0
Removal of internal fixation	0	1	0
Resection of rectum	0	1	0
Resuscitation	0	1	0
Sinus operation	1	1	0
Skin lesion excision	0	2	0
Skin neoplasm excision	1	0	1
Speech rehabilitation	1	0	0
Sphenoid sinus operation	1	0	0
Spinal fusion surgery	0	1	0
Spinal operation	0	1	0
Splint application	0	1	0

Maraviroc Summary of Clinical Safety
Concomitant Non Drug Treatments
Phase 3 Treatment Experienced CCR5 Tropic Studies

	maraviroc QD	maraviroc BID	Placebo
Stent placement	1	0	0
Suture insertion	1	0	0
Therapeutic procedure	2	0	0
Toe amputation	1	0	0
Tooth extraction	4	2	0
UV light therapy	0	0	1
Ureteral stent insertion	0	1	0
Uterine dilation and curettage	0	0	1
Vascular cauterisation	0	1	0
Wart excision	3	2	0
Whole blood transfusion	2	4	2
Wound treatment	1	1	0

Table 3.3.1.1
Maraviroc Summary of Clinical Safety
Demographic Characteristics
Phase 2b/3 Studies All Maraviroc Therapy

	maraviroc					
	MALE		FEMALE		TOTAL	
Number (%) of Subjects	1052		160		1212	
Age (years):						
<16	0		0		0	
16-44	526	(50.0)	115	(71.9)	641	(52.9)
45-64	514	(48.9)	41	(25.6)	555	(45.8)
65 and over	12	(1.1)	4	(2.5)	16	(1.3)
Mean	45.0		40.5		44.4	
SD	8.2		10.6		8.7	
Range	16-75		16-75		16-75	
Race:						
WHITE	887	(84.3)	94	(58.8)	981	(80.9)
BLACK	136	(12.9)	54	(33.8)	190	(15.7)
ASIAN	10	(1.0)	5	(3.1)	15	(1.2)
OTHER	19	(1.8)	6	(3.8)	25	(2.1)
UNSPECIFIED	0		1	(0.6)	1	(0.1)

Height and weight may be collected post baseline.
For protocol 1026 only the QD arm is included. For 1027 and 1028 both blinded and open label treatment are included.

Table 3.3.1.2
Maraviroc Summary of Clinical Safety
Demographic Characteristics
Phase 3 Treatment Experienced CCR5 Tropic Studies

	maraviroc QD						maraviroc BID					
	MALE		FEMALE		TOTAL		MALE		FEMALE		TOTAL	
Number (%) of Subjects	363		51		414		382		44		426	
Age (years):												
<16	0		0		0		0		0		0	
16-44	172	(47.4)	31	(60.8)	203	(49.0)	168	(44.0)	28	(63.6)	196	(46.0)
45-64	184	(50.7)	17	(33.3)	201	(48.6)	210	(55.0)	15	(34.1)	225	(52.8)
>=65	7	(1.9)	3	(5.9)	10	(2.4)	4	(1.0)	1	(2.3)	5	(1.2)
Mean	45.8		44.7		45.6		46.7		43.3		46.3	
SD	7.9		10.6		8.2		7.5		9.2		7.7	
Range	17-75		30-75		17-75		21-69		25-73		21-73	
Race:												
WHITE	303	(83.5)	33	(64.7)	336	(81.2)	332	(86.9)	31	(70.5)	363	(85.2)
BLACK	53	(14.6)	17	(33.3)	70	(16.9)	40	(10.5)	11	(25.0)	51	(12.0)
ASIAN	3	(0.8)	0		3	(0.7)	4	(1.0)	1	(2.3)	5	(1.2)
OTHER	4	(1.1)	0		4	(1.0)	6	(1.6)	1	(2.3)	7	(1.6)
UNSPECIFIED	0		1	(2.0)	1	(0.2)	0		0		0	

Table 3.3.1.2
Maraviroc Summary of Clinical Safety
Demographic Characteristics
Phase 3 Treatment Experienced CCR5 Tropic Studies

	Placebo					
	MALE		FEMALE		TOTAL	
Number (%) of Subjects	185		24		209	
Age (years):						
<16	0		0		0	
16-44	82	(44.3)	17	(70.8)	99	(47.4)
45-64	100	(54.1)	7	(29.2)	107	(51.2)
>=65	3	(1.6)	0		3	(1.4)
Mean	46.2		41.8		45.7	
SD	7.8		7.6		7.9	
Range	29-72		29-57		29-72	
Race:						
WHITE	165	(89.2)	13	(54.2)	178	(85.2)
BLACK	16	(8.6)	10	(41.7)	26	(12.4)
ASIAN	1	(0.5)	0		1	(0.5)
OTHER	3	(1.6)	1	(4.2)	4	(1.9)
UNSPECIFIED	0		0		0	

Maraviroc Summary of Clinical Safety
Primary Diagnosis and Durations
Phase 3 Treatment Experienced CCR5 Tropic Studies

Number of Subjects		maraviroc QD 414	maraviroc BID 426	Placebo 209
Primary Diagnosis MedDRA (v9.0) Preferred term				
HIV infection				
	Number of Subjects	414	426	209
	Duration Since First Diagnosis (yrs)			
	Mean	14.2	13.9	14.3
	Range	1.0-27.8	2.3-26.1	3.4-25.1
	Unspecified (N)	0	0	0

Duration (years) from first diagnosis to Day 1 of study

Table 3.3.2.2
Maraviroc Summary of Clinical Safety
Medical History
Phase 3 Treatment Experienced CCR5 Tropic Studies

	maraviroc QD			maraviroc BID			Placebo		
Number of Subjects	414			426			209		
	Past	Present	Unknown	Past	Present	Unknown	Past	Present	Unknown
Number (%) of Subjects With At Least One Disease/Syndrome	375 (90.6)	375 (90.6)	18 (4.3)	397 (93.2)	390 (91.5)	18 (4.2)	194 (92.8)	193 (92.3)	10 (4.8)
Blood and lymphatic system disorders	47	49	0	57	50	0	23	25	0
Agranulocytosis	0	1	0	0	0	0	0	0	0
Anaemia	23	21	0	25	17	0	12	4	0
Anaemia haemolytic autoimmune	0	0	0	1	0	0	0	0	0
Coagulopathy	0	2	0	0	0	0	0	0	0
Eosinophilia	1	0	0	0	1	0	0	0	0
Hypergammaglobulinaemia	0	1	0	0	0	0	0	0	0
Hypochromic anaemia	0	1	0	0	0	0	0	0	0
Idiopathic thrombocytopenic purpura	0	0	0	2	1	0	1	1	0
Iron deficiency anaemia	0	2	0	1	1	0	1	1	0
Leukopenia	4	2	0	2	2	0	0	0	0
Lymph node pain	0	0	0	1	0	0	0	0	0
Lymphadenitis	0	0	0	1	0	0	0	0	0
Lymphadenopathy	7	16	0	11	16	0	7	9	0
Macrocytosis	0	1	0	0	0	0	0	0	0
Microcytic anaemia	0	1	0	0	0	0	0	0	0
Mononucleosis syndrome	1	0	0	0	0	0	0	0	0
Neutropenia	7	9	0	5	8	0	4	9	0
Pancytopenia	2	3	0	4	2	0	0	1	0
Polycythaemia	1	0	0	1	0	0	0	0	0
Splenic vein thrombosis	1	0	0	0	0	0	0	0	0
Splenomegaly	0	0	0	3	2	0	1	1	0
Thrombocytopenia	10	7	0	9	5	0	1	3	0
Thrombotic microangiopathy	0	1	0	0	0	0	0	0	0
Thrombotic thrombocytopenic purpura	0	0	0	1	0	0	0	0	0
Cardiac disorders	32	11	0	27	21	0	8	7	0
Acute myocardial infarction	1	0	0	0	0	0	2	0	0

Subjects are counted only once for each specific disease/syndrome in the table body.
MedDRA (v9.0) coding dictionary applied.

	maraviroc QD			maraviroc BID			Placebo		
Number of Subjects	414			426			209		
	Past	Present	Unknown	Past	Present	Unknown	Past	Present	Unknown
Angina pectoris	3	0	0	2	0	0	0	0	0
Aortic valve disease	0	0	0	0	1	0	0	1	0
Aortic valve incompetence	0	0	0	1	0	0	0	0	0
Aortic valve sclerosis	0	0	0	1	0	0	0	0	0
Arteriosclerosis coronary artery	0	0	0	0	0	0	1	0	0
Atrial fibrillation	1	0	0	0	1	0	0	0	0
Atrial flutter	0	1	0	0	0	0	0	1	0
Atrial tachycardia	0	0	0	1	0	0	0	0	0
Atrioventricular block	0	1	0	0	0	0	0	0	0
Atrioventricular block first degree	0	0	0	0	1	0	0	1	0
Bundle branch block left	0	0	0	0	1	0	0	0	0
Cardiac disorder	0	2	0	0	0	0	0	0	0
Cardiac failure	0	0	0	0	1	0	0	0	0
Cardiac failure congestive	0	1	0	2	3	0	0	0	0
Cardiomyopathy	2	1	0	1	4	0	0	0	0
Coronary artery disease	5	1	0	2	6	0	1	2	0
Diastolic dysfunction	0	0	0	0	0	0	0	1	0
Mitral valve prolapse	0	1	0	0	2	0	0	0	0
Myocardial infarction	14	0	0	15	0	0	1	0	0
Myocardial ischaemia	1	0	0	0	0	0	0	0	0
Myocarditis	0	0	0	1	0	0	1	0	0
Nodal arrhythmia	1	0	0	0	0	0	0	0	0
Palpitations	1	2	0	0	0	0	0	1	0
Pericardial effusion	1	0	0	0	0	0	0	0	0
Pericarditis	2	0	0	1	0	0	0	0	0
Pulmonary valve stenosis	0	0	0	1	0	0	0	0	0
Right ventricular failure	0	0	0	1	0	0	0	0	0
Supraventricular extrasystoles	0	0	0	0	1	0	0	0	0

Subjects are counted only once for each specific disease/syndrome in the table body.
MedDRA (v9.0) coding dictionary applied.

	maraviroc QD			maraviroc BID			Placebo		
Number of Subjects	414			426			209		
	Past	Present	Unknown	Past	Present	Unknown	Past	Present	Unknown
Tachyarrhythmia	1	0	0	0	0	0	0	0	0
Tachycardia	2	2	0	1	0	0	2	1	0
Tricuspid valve incompetence	0	0	0	1	0	0	0	0	0
Ventricular dysfunction	1	0	0	0	0	0	0	1	0
Ventricular extrasystoles	0	0	0	1	1	0	0	0	0
Wolff-Parkinson-White syndrome	1	0	0	0	2	0	0	0	0
Congenital, familial and genetic disorders	3	11	0	6	10	0	0	6	0
Cleft palate	1	0	0	0	0	0	0	0	0
Cleft uvula	0	0	0	0	0	0	0	1	0
Congenital aortic valve incompetence	0	0	0	0	1	0	0	0	0
Congenital generalised lipodystrophy	0	1	0	0	0	0	0	0	0
Congenital genital malformation female	0	0	0	0	1	0	0	0	0
Congenital oral malformation	0	0	0	1	0	0	0	0	0
Congenital visual acuity reduced	0	1	0	0	0	0	0	0	0
Corneal dystrophy	0	0	0	0	0	0	0	1	0
Deafness congenital	0	1	0	0	0	0	0	0	0
Factor VIII deficiency	0	0	0	0	1	0	0	0	0
Fanconi syndrome	0	1	0	2	1	0	0	0	0
Gilbert's syndrome	0	1	0	0	0	0	0	0	0
Glucose-6-phosphate dehydrogenase deficiency	0	1	0	0	1	0	0	1	0
Hydrocele	1	0	0	3	0	0	0	0	0
Ichthyosis	0	1	0	0	0	0	0	0	0
Kidney malformation	0	0	0	0	1	0	0	0	0
Mixed hyperlipidaemia	0	1	0	0	0	0	0	0	0
Porphyria non-acute	0	0	0	0	1	0	0	0	0
Sickle cell anaemia	1	0	0	0	0	0	0	0	0
Sickle cell trait	0	0	0	0	0	0	0	1	0
Solitary kidney	0	1	0	0	0	0	0	0	0

Subjects are counted only once for each specific disease/syndrome in the table body.
MedDRA (v9.0) coding dictionary applied.

	maraviroc QD			maraviroc BID			Placebo		
Number of Subjects	414			426			209		
	Past	Present	Unknown	Past	Present	Unknown	Past	Present	Unknown
Spondylolisthesis	0	0	0	0	1	0	0	1	0
Thalassaemia	0	1	0	0	0	0	0	0	0
Thalassaemia beta	0	1	0	0	2	0	0	1	0
Ear and labyrinth disorders	7	11	0	10	17	0	5	9	0
Deafness	1	2	0	0	0	0	0	1	0
Deafness bilateral	0	2	0	0	2	0	0	0	0
Deafness neurosensory	0	1	0	1	2	0	1	0	0
Deafness unilateral	0	0	0	0	3	0	0	0	0
Ear discomfort	0	0	0	1	0	0	0	0	0
Ear disorder	0	0	0	0	1	0	0	0	0
Ear pain	1	0	0	2	0	0	0	0	0
Eustachian tube obstruction	0	0	0	1	0	0	0	0	0
Hypoacusis	0	4	0	1	2	0	0	4	0
Otorrhoea	0	0	0	0	0	0	0	1	0
Presbyacusis	0	0	0	0	0	0	0	1	0
Tinnitus	3	3	0	1	3	0	0	3	0
Tympanic membrane perforation	2	0	0	0	3	0	2	0	0
Tympanic membrane scarring	0	0	0	0	1	0	0	0	0
Vertigo	1	0	0	3	4	0	1	0	0
Vertigo positional	0	0	0	0	1	0	0	0	0
Vestibular neuronitis	0	0	0	0	0	0	1	0	0
Endocrine disorders	12	56	0	12	62	0	4	25	0
Adrenal cortical insufficiency	0	0	0	0	1	0	0	0	0
Adrenal insufficiency	1	1	0	0	2	0	0	0	0
Adrenal mass	1	0	0	0	0	0	0	0	0
Adrenocortical insufficiency chronic	0	0	0	0	2	0	0	0	0
Androgen deficiency	0	1	0	1	1	0	0	1	0
Basedow's disease	1	2	0	0	0	0	0	0	0

Subjects are counted only once for each specific disease/syndrome in the table body.
MedDRA (v9.0) coding dictionary applied.

	maraviroc QD			maraviroc BID			Placebo		
Number of Subjects	414			426			209		
	Past	Present	Unknown	Past	Present	Unknown	Past	Present	Unknown
Cushing's syndrome	0	0	0	1	0	0	0	0	0
Growth hormone deficiency	0	1	0	0	1	0	0	0	0
Hyperadrenalism	1	0	0	0	0	0	0	0	0
Hyperandrogenism	0	0	0	0	1	0	0	0	0
Hyperparathyroidism	0	0	0	1	0	0	0	0	0
Hyperthyroidism	0	0	0	0	2	0	1	0	0
Hypoaldosteronism	0	0	0	0	1	0	0	0	0
Hypogonadism	7	45	0	7	39	0	2	24	0
Hypogonadism male	0	1	0	0	0	0	0	0	0
Hypothyroidism	0	8	0	2	14	0	1	0	0
Primary hypogonadism	0	0	0	0	1	0	0	0	0
Testicular failure	0	1	0	1	2	0	0	1	0
Thyroid disorder	1	0	0	0	0	0	0	0	0
Eye disorders	23	27	0	21	25	0	6	10	0
Amblyopia	0	0	0	0	1	0	0	0	0
Astigmatism	0	0	0	0	0	0	1	0	0
Blindness	0	1	0	0	2	0	0	2	0
Blindness unilateral	0	2	0	0	2	0	0	1	0
Cataract	3	3	0	1	0	0	0	0	0
Chorioretinitis	0	0	0	0	1	0	0	0	0
Conjunctivitis	9	1	0	5	1	0	1	0	0
Conjunctivitis allergic	0	1	0	0	0	0	0	0	0
Corneal scar	0	0	0	0	1	0	0	0	0
Dry eye	0	2	0	0	3	0	0	0	0
Episcleritis	0	0	0	1	0	0	0	0	0
Exophthalmos	1	0	0	0	0	0	0	0	0
Eye disorder	0	1	0	0	0	0	0	0	0
Eye haemorrhage	0	0	0	1	0	0	0	0	0

Subjects are counted only once for each specific disease/syndrome in the table body.
MedDRA (v9.0) coding dictionary applied.

	maraviroc QD			maraviroc BID			Placebo		
Number of Subjects	414			426			209		
	Past	Present	Unknown	Past	Present	Unknown	Past	Present	Unknown
Eye pruritus	0	1	0	0	1	0	0	0	0
Eyelid ptosis	0	1	0	0	0	0	0	0	0
Glaucoma	0	4	0	0	1	0	0	1	0
Hypermetropia	0	0	0	0	0	0	1	0	0
Iridocyclitis	2	0	0	0	0	0	0	0	0
Keratitis	0	0	0	0	0	0	1	0	0
Lagophthalmos	0	0	0	0	1	0	0	0	0
Macular degeneration	0	0	0	0	1	0	0	0	0
Myopia	0	1	0	0	2	0	0	4	0
Necrotising retinitis	0	2	0	1	0	0	0	0	0
Ocular vascular disorder	0	0	0	1	0	0	0	0	0
Optic nerve disorder	0	0	0	1	0	0	0	0	0
Presbyopia	0	0	0	0	0	0	0	1	0
Pseudophakia	0	0	0	1	0	0	0	0	0
Pterygium	1	0	0	0	0	0	0	0	0
Punctate keratitis	0	0	0	0	0	0	1	0	0
Refraction disorder	1	0	0	0	0	0	0	0	0
Retinal degeneration	0	0	0	0	1	0	0	0	0
Retinal detachment	0	0	0	0	0	0	1	0	0
Retinal haemorrhage	1	0	0	1	0	0	0	0	0
Retinal oedema	0	0	0	1	0	0	0	0	0
Retinal tear	0	0	0	1	0	0	0	0	0
Retinal vein occlusion	0	0	0	1	0	0	0	0	0
Retinal vein thrombosis	1	0	0	0	0	0	0	0	0
Retinitis	0	0	0	1	0	0	0	1	0
Retinopathy	1	1	0	0	0	0	0	0	0
Strabismus	0	0	0	1	1	0	0	1	0
Ulcerative keratitis	1	0	0	0	0	0	0	0	0

Subjects are counted only once for each specific disease/syndrome in the table body.
MedDRA (v9.0) coding dictionary applied.

	maraviroc QD			maraviroc BID			Placebo		
Number of Subjects	414			426			209		
	Past	Present	Unknown	Past	Present	Unknown	Past	Present	Unknown
Uveitis	0	0	0	1	0	0	1	0	0
Vision blurred	3	4	0	3	5	0	0	0	0
Visual acuity reduced	0	1	0	0	1	0	0	0	0
Visual disturbance	0	1	0	3	2	0	0	0	0
Vitreous floaters	2	0	0	0	1	0	0	0	0
Gastrointestinal disorders	130	138	0	125	171	0	56	74	0
Abdominal discomfort	0	1	0	1	0	0	0	0	0
Abdominal distension	3	2	0	5	2	0	1	3	0
Abdominal hernia	2	0	0	0	1	0	0	3	0
Abdominal pain	1	5	0	6	1	0	1	3	0
Abdominal pain lower	0	1	0	0	1	0	0	1	0
Abdominal pain upper	2	0	0	1	1	0	0	0	0
Abdominal tenderness	0	0	0	1	0	0	0	0	0
Acquired oesophageal web	0	1	0	0	0	0	0	0	0
Anal fissure	4	1	0	2	4	0	0	0	0
Anal fistula	5	1	0	1	2	0	2	0	0
Anal polyp	0	0	0	1	0	0	1	0	0
Anal ulcer	1	0	0	0	2	0	0	0	0
Anogenital dysplasia	2	4	0	0	3	0	0	0	0
Anorectal disorder	1	0	0	1	0	0	0	0	0
Aphthous stomatitis	5	3	0	3	4	0	3	1	0
Appendicitis perforated	1	0	0	0	0	0	0	0	0
Aptyalism	0	0	0	0	1	0	0	0	0
Ascites	0	0	0	0	0	0	0	1	0
Breath odour	0	1	0	0	0	0	0	0	0
Cheilitis	3	2	0	3	0	0	2	0	0
Coeliac disease	0	0	0	0	0	0	1	0	0
Colitis	0	1	0	5	0	0	3	1	0

Subjects are counted only once for each specific disease/syndrome in the table body.
MedDRA (v9.0) coding dictionary applied.

Table 3.3.2.2
Maraviroc Summary of Clinical Safety
Medical History
Phase 3 Treatment Experienced CCR5 Tropic Studies

	maraviroc QD			maraviroc BID			Placebo		
Number of Subjects	414			426			209		
	Past	Present	Unknown	Past	Present	Unknown	Past	Present	Unknown
Colitis ulcerative	0	0	0	1	0	0	2	0	0
Colonic polyp	5	0	0	1	0	0	0	0	0
Constipation	4	9	0	5	9	0	2	2	0
Crohn's disease	0	2	0	2	0	0	1	0	0
Defaecation urgency	0	1	0	0	0	0	0	0	0
Diarrhoea	34	69	0	29	75	0	12	37	0
Diarrhoea haemorrhagic	0	0	0	1	0	0	0	0	0
Diverticulum	0	0	0	1	0	0	0	0	0
Diverticulum intestinal	0	1	0	1	0	0	0	0	0
Dry mouth	1	3	0	1	4	0	0	2	0
Duodenal ulcer	1	0	0	0	0	0	0	0	0
Duodenitis	3	0	0	1	1	0	0	0	0
Duodenogastric reflux	0	1	0	0	0	0	0	0	0
Dyspepsia	1	6	0	6	6	0	0	4	0
Dysphagia	3	4	0	4	0	0	1	0	0
Enteritis	0	0	0	2	2	0	1	0	0
Enterocolitis	1	0	0	0	0	0	0	0	0
Erosive oesophagitis	1	0	0	0	0	0	0	0	0
Eructation	0	0	0	0	1	0	0	0	0
Faecal incontinence	1	1	0	0	0	0	0	0	0
Femoral hernia	2	0	0	0	0	0	0	0	0
Flatulence	0	3	0	3	3	0	0	0	0
Frequent bowel movements	0	0	0	0	1	0	0	0	0
Gastric disorder	0	0	0	0	1	0	1	0	0
Gastric mucosal lesion	1	0	0	0	0	0	0	0	0
Gastric ulcer	2	3	0	2	0	0	1	0	0
Gastritis	6	2	0	7	5	0	2	3	0
Gastritis erosive	0	0	0	1	0	0	0	0	0

Subjects are counted only once for each specific disease/syndrome in the table body.
MedDRA (v9.0) coding dictionary applied.

	maraviroc QD			maraviroc BID			Placebo		
Number of Subjects	414			426			209		
	Past	Present	Unknown	Past	Present	Unknown	Past	Present	Unknown
Gastrointestinal disorder	1	0	0	2	0	0	0	0	0
Gastrointestinal haemorrhage	1	1	0	2	0	0	1	0	0
Gastrointestinal ulcer haemorrhage	0	0	0	1	0	0	0	0	0
Gastrooesophageal reflux disease	10	38	0	9	51	0	3	22	0
Gingival bleeding	1	0	0	0	0	0	0	0	0
Gingival disorder	0	1	0	0	0	0	0	0	0
Gingival recession	0	0	0	1	1	0	0	0	0
Gingivitis	6	1	0	3	4	0	1	0	0
Haematemesis	0	0	0	0	0	0	1	0	0
Haematochezia	1	0	0	1	0	0	1	0	0
Haemorrhoidal haemorrhage	0	1	0	0	0	0	0	0	0
Haemorrhoids	8	7	0	18	9	0	4	4	0
Hiatus hernia	1	2	0	2	3	0	2	2	0
Hyperchlorhydria	0	0	0	0	1	0	0	1	0
Hypoaesthesia oral	1	0	0	0	0	0	0	0	0
Impaired gastric emptying	0	0	0	1	1	0	0	0	0
Inguinal hernia	5	0	0	6	0	0	2	1	0
Intestinal obstruction	2	0	0	0	0	0	0	0	0
Irritable bowel syndrome	1	5	0	1	1	0	2	1	0
Leukoplakia oral	1	0	0	1	2	0	1	0	0
Lip disorder	0	0	0	1	0	0	0	0	0
Lip ulceration	1	0	0	0	0	0	0	0	0
Lower gastrointestinal haemorrhage	2	0	0	0	0	0	1	0	0
Malabsorption	1	1	0	0	3	0	1	0	0
Mallory-Weiss syndrome	1	0	0	0	0	0	0	0	0
Mouth cyst	0	0	0	1	0	0	0	0	0
Mouth ulceration	1	1	0	4	0	0	2	1	0
Nausea	6	18	0	11	19	0	3	11	0

Subjects are counted only once for each specific disease/syndrome in the table body.
MedDRA (v9.0) coding dictionary applied.

	maraviroc QD			maraviroc BID			Placebo		
Number of Subjects	414			426			209		
	Past	Present	Unknown	Past	Present	Unknown	Past	Present	Unknown
Odynophagia	1	0	0	1	0	0	0	0	0
Oesophageal achalasia	0	0	0	0	0	0	0	1	0
Oesophageal dilatation	0	0	0	0	0	0	0	1	0
Oesophageal haemorrhage	0	0	0	1	0	0	0	0	0
Oesophageal stenosis	0	0	0	1	2	0	0	0	0
Oesophageal ulcer	2	0	0	1	0	0	2	0	0
Oesophagitis	1	1	0	1	1	0	1	1	0
Oesophagitis ulcerative	0	0	0	1	0	0	0	0	0
Oral soft tissue disorder	0	0	0	1	0	0	0	0	0
Pancreatic insufficiency	0	1	0	0	0	0	0	0	0
Pancreatic pseudocyst	0	0	0	1	0	0	0	0	0
Pancreatitis	24	0	0	17	0	0	10	1	0
Pancreatitis acute	3	0	0	0	0	0	0	0	0
Pancreatitis chronic	1	0	0	2	0	0	0	0	0
Pancreatitis necrotising	1	0	0	1	0	0	0	0	0
Pancreatitis relapsing	0	0	0	1	0	0	0	0	0
Paraesthesia oral	1	0	0	0	0	0	0	0	0
Parotid duct cyst	0	0	0	1	0	0	0	0	0
Parotid gland enlargement	0	0	0	0	2	0	0	0	0
Peptic ulcer	0	0	0	4	1	0	5	0	0
Periodontal disease	0	1	0	1	0	0	0	0	0
Periodontitis	0	1	0	0	0	0	0	1	0
Peritonitis	3	0	0	1	0	0	0	0	0
Pharyngoesophageal diverticulum	1	0	0	0	0	0	0	0	0
Pneumatosis intestinalis	0	0	0	1	0	0	0	0	0
Proctalgia	0	0	0	0	2	0	0	1	0
Proctitis	3	0	0	2	0	0	0	0	0
Proctocolitis	0	0	0	1	0	0	0	0	0

Subjects are counted only once for each specific disease/syndrome in the table body.
MedDRA (v9.0) coding dictionary applied.

	maraviroc QD			maraviroc BID			Placebo		
Number of Subjects	414			426			209		
	Past	Present	Unknown	Past	Present	Unknown	Past	Present	Unknown
Pruritus ani	1	0	0	0	0	0	0	0	0
Pseudopolyposis	0	0	0	0	1	0	0	0	0
Rectal discharge	0	0	0	0	1	0	0	0	0
Rectal fissure	0	0	0	4	0	0	0	0	0
Rectal haemorrhage	2	1	0	2	3	0	1	1	0
Rectal ulcer	0	0	0	1	0	0	1	0	0
Reflux gastritis	0	0	0	1	1	0	0	0	0
Reflux oesophagitis	1	2	0	2	2	0	1	2	0
Saliva altered	0	1	0	0	0	0	0	0	0
Salivary gland disorder	0	0	0	1	0	0	0	0	0
Salivary gland mass	0	1	0	0	0	0	0	0	0
Small intestinal obstruction	0	0	0	1	0	0	0	0	0
Stomach discomfort	0	2	0	0	1	0	0	0	0
Stomatitis	1	0	0	3	0	0	0	0	0
Swollen tongue	0	0	0	1	0	0	0	0	0
Tooth disorder	0	1	0	0	0	0	0	0	0
Tooth loss	0	1	0	0	0	0	0	0	0
Toothache	0	1	0	0	0	0	0	0	0
Umbilical hernia	2	1	0	3	3	0	1	0	0
Varices oesophageal	1	0	0	0	0	0	1	0	0
Vomiting	1	3	0	9	6	0	1	4	0
General disorders and administration site conditions	39	70	0	32	75	0	12	47	0
Adverse drug reaction	1	0	0	1	0	0	0	0	0
Asthenia	5	3	0	2	4	0	0	6	0
Atrophy	0	3	0	0	2	0	0	1	0
Axillary pain	0	1	0	0	0	0	0	0	0
Chest discomfort	1	0	0	1	1	0	0	0	0
Chest pain	2	3	0	3	1	0	0	1	0

Subjects are counted only once for each specific disease/syndrome in the table body.
MedDRA (v9.0) coding dictionary applied.

	maraviroc QD			maraviroc BID			Placebo		
Number of Subjects	414			426			209		
	Past	Present	Unknown	Past	Present	Unknown	Past	Present	Unknown
Chills	0	1	0	1	1	0	0	1	0
Chronic fatigue syndrome	0	0	0	1	2	0	0	0	0
Cyst	1	0	0	3	1	0	0	0	0
Difficulty in walking	1	0	0	0	0	0	0	0	0
Drug intolerance	2	1	0	1	1	0	1	1	0
Dysplasia	0	1	0	0	0	0	0	0	0
Facial pain	0	0	0	1	0	0	0	0	0
Fat tissue increased	2	0	0	0	3	0	0	1	0
Fatigue	12	51	0	11	50	0	5	33	0
Feeling hot	0	0	0	1	0	0	0	0	0
Gait disturbance	0	0	0	0	1	0	0	0	0
Hernia	1	0	0	0	0	0	0	0	0
Ill-defined disorder	0	0	0	0	1	0	0	0	0
Infusion related reaction	1	0	0	0	0	0	0	0	0
Injection site nodule	0	0	0	0	1	0	0	2	0
Injection site pruritus	0	0	0	0	1	0	0	0	0
Injection site reaction	1	4	0	1	4	0	0	3	0
Injection site scar	0	0	0	0	0	0	0	1	0
Malaise	1	2	0	0	0	0	2	0	0
Mass	0	0	0	0	1	0	0	1	0
Metaplasia	1	0	0	0	0	0	0	0	0
Nodule	0	1	0	0	1	0	0	0	0
Non-cardiac chest pain	0	0	0	1	0	0	0	0	0
Oedema	0	0	0	0	0	0	1	0	0
Oedema peripheral	2	3	0	1	0	0	0	2	0
Pain	2	3	0	2	4	0	0	1	0
Polyp	0	0	0	1	0	0	0	1	0
Pseudocyst	0	0	0	0	0	0	1	0	0

Subjects are counted only once for each specific disease/syndrome in the table body.
MedDRA (v9.0) coding dictionary applied.

	maraviroc QD			maraviroc BID			Placebo		
Number of Subjects	414			426			209		
	Past	Present	Unknown	Past	Present	Unknown	Past	Present	Unknown
Pyrexia	8	2	0	6	1	0	2	2	0
Thirst	0	0	0	1	0	0	0	0	0
Ulcer	0	0	0	2	0	0	1	0	0
Xerosis	0	0	0	0	1	0	0	0	0
Hepatobiliary disorders	31	9	0	24	14	0	12	12	0
Biliary colic	1	0	0	0	0	0	0	0	0
Biliary dilatation	1	0	0	0	0	0	0	0	0
Cholangitis	2	0	0	1	0	0	0	0	0
Cholecystitis	4	0	0	1	0	0	0	0	0
Cholecystitis chronic	0	1	0	0	0	0	0	0	0
Cholelithiasis	6	3	0	3	1	0	1	2	0
Cholestasis	0	0	0	0	1	0	1	0	0
Chronic hepatitis	0	0	0	1	1	0	0	0	0
Cytolytic hepatitis	0	0	0	1	0	0	1	0	0
Gallbladder disorder	1	0	0	1	0	0	0	0	0
Gallbladder polyp	1	0	0	0	1	0	0	0	0
Hepatic cirrhosis	1	0	0	0	0	0	0	1	0
Hepatic cyst	0	1	0	1	0	0	0	0	0
Hepatic failure	0	0	0	0	0	0	1	0	0
Hepatic fibrosis	0	0	0	1	0	0	0	1	0
Hepatic function abnormal	1	0	0	0	0	0	0	0	0
Hepatic lesion	0	0	0	0	0	0	1	0	0
Hepatic steatosis	2	1	0	2	5	0	3	4	0
Hepatitis	10	1	0	7	1	0	1	0	0
Hepatitis toxic	2	0	0	1	0	0	1	0	0
Hepatomegaly	3	1	0	1	1	0	1	3	0
Hepatosplenomegaly	1	0	0	1	0	0	0	0	0
Hepatotoxicity	0	0	0	1	0	0	1	0	0

Subjects are counted only once for each specific disease/syndrome in the table body.
MedDRA (v9.0) coding dictionary applied.

Table 3.3.2.2
Maraviroc Summary of Clinical Safety
Medical History
Phase 3 Treatment Experienced CCR5 Tropic Studies

	maraviroc QD			maraviroc BID			Placebo		
Number of Subjects	414			426			209		
	Past	Present	Unknown	Past	Present	Unknown	Past	Present	Unknown
Hyperbilirubinaemia	1	1	0	2	2	0	1	1	0
Jaundice	2	0	0	1	0	0	1	0	0
Liver disorder	1	0	0	0	4	0	0	0	0
Immune system disorders	17	86	0	28	80	0	5	43	0
Allergy to animal	0	2	0	1	0	0	0	1	0
Allergy to arthropod bite	0	1	0	1	0	0	0	0	0
Allergy to arthropod sting	1	1	0	0	0	0	0	0	0
Allergy to vaccine	0	1	0	0	0	0	0	0	0
Autoimmune disorder	0	0	0	0	1	0	0	0	0
Decreased immune responsiveness	1	0	0	0	0	0	0	0	0
Drug hypersensitivity	11	57	0	17	40	0	3	29	0
Food allergy	0	2	0	1	0	0	0	0	0
House dust allergy	0	0	0	0	1	0	0	0	0
Hypersensitivity	0	0	0	0	2	0	1	1	0
Hypogammaglobulinaemia	0	0	0	0	0	0	0	1	0
Immune system disorder	0	1	0	0	0	0	0	0	0
Immunodeficiency	0	0	0	0	1	0	0	0	0
Iodine allergy	0	1	0	0	1	0	0	0	0
Latex allergy	0	0	0	0	1	0	0	0	0
Multiple allergies	1	2	0	1	3	0	0	1	0
Sarcoidosis	0	0	0	2	0	0	0	0	0
Seasonal allergy	3	36	0	6	37	0	1	17	0
Infections and infestations	339	188	17	355	195	17	173	97	9
AIDS dementia complex	3	3	0	2	3	2	2	0	0
AIDS encephalopathy	3	0	0	2	0	0	0	1	0
AIDS related complication	0	2	0	0	0	0	0	0	0
AIDS retinopathy	0	1	0	0	2	0	0	0	0
Abdominal abscess	1	0	0	0	0	0	0	0	0

Subjects are counted only once for each specific disease/syndrome in the table body.
MedDRA (v9.0) coding dictionary applied.

	maraviroc QD			maraviroc BID			Placebo		
Number of Subjects	414			426			209		
	Past	Present	Unknown	Past	Present	Unknown	Past	Present	Unknown
Abscess	1	0	0	0	0	0	0	0	0
Abscess jaw	1	0	0	0	0	0	0	0	0
Abscess limb	1	0	0	0	0	0	0	0	0
Acarodermatitis	3	0	0	2	0	0	1	1	0
Acquired immunodeficiency syndrome	1	4	0	0	3	0	0	2	0
Acute sinusitis	1	0	0	1	0	0	0	0	0
Amoebiasis	1	0	0	1	0	0	0	0	0
Anal abscess	1	0	0	0	0	0	0	0	0
Anal candidiasis	1	0	0	0	0	0	0	0	0
Anorectal infection	1	0	0	0	0	0	0	0	0
Appendicitis	4	0	0	6	0	0	0	0	0
Arthritis bacterial	0	0	0	1	0	0	0	0	0
Arthritis infective	0	0	0	0	0	0	2	0	0
Aspergillosis	0	0	0	1	0	0	0	0	0
Atypical mycobacterial lymphadenitis	1	0	0	0	0	0	0	0	0
Bacteraemia	1	0	0	0	0	0	0	0	0
Bacterial allergy	0	0	0	0	0	0	0	1	0
Bacterial infection	2	0	0	0	1	0	1	0	0
Balanitis candida	1	0	0	1	0	0	0	0	0
Bartonellosis	1	0	0	0	0	0	0	0	0
Blastocystis infection	3	0	0	3	0	0	2	0	0
Body tinea	1	1	0	1	0	0	0	0	0
Borrelia infection	0	0	0	1	0	0	0	0	0
Boutonneuse fever	0	0	0	0	0	0	1	0	0
Bronchiectasis	1	1	0	0	0	0	0	0	0
Bronchitis	19	4	0	27	2	0	8	0	0
Bronchitis acute	0	0	0	1	0	0	1	0	0
Bronchitis bacterial	0	0	0	1	0	0	0	0	0

Subjects are counted only once for each specific disease/syndrome in the table body.
MedDRA (v9.0) coding dictionary applied.

	maraviroc QD			maraviroc BID			Placebo		
Number of Subjects	414			426			209		
	Past	Present	Unknown	Past	Present	Unknown	Past	Present	Unknown
Bronchitis chronic	1	2	0	0	3	0	0	2	0
Bronchopneumonia	3	0	0	0	0	0	1	0	0
Bullous impetigo	0	0	0	0	1	0	0	0	0
Campylobacter gastroenteritis	0	0	0	1	0	0	0	0	0
Campylobacter infection	1	0	0	2	0	0	0	0	0
Candidiasis	104	13	3	107	13	4	53	6	2
Carbuncle	1	0	0	0	0	0	0	0	0
Cat scratch disease	0	0	0	1	0	0	0	0	0
Catheter sepsis	0	0	0	0	0	0	1	0	0
Catheter site infection	0	0	0	1	0	0	0	0	0
Cellulitis	12	0	0	7	0	0	4	1	0
Cellulitis pharyngeal	1	0	0	0	0	0	0	0	0
Cellulitis staphylococcal	0	1	0	0	0	0	0	0	0
Central line infection	1	0	0	0	0	0	0	0	0
Cerebral toxoplasmosis	1	0	0	0	0	0	0	0	0
Chlamydial infection	3	0	0	3	0	0	2	0	0
Chronic sinusitis	6	9	0	5	12	0	5	6	0
Clostridial infection	2	0	0	1	0	0	1	0	0
Clostridium difficile colitis	0	0	0	1	0	0	0	0	0
Coccidioidomycosis	0	1	2	1	1	5	0	0	1
Colitis pseudomembranous	0	0	0	1	0	0	0	0	0
Condyloma acuminatum	39	18	0	38	8	0	16	7	0
Conjunctivitis viral	0	1	0	0	0	0	0	0	0
Cryptococcosis	8	2	0	7	1	6	7	1	2
Cystitis	1	0	0	0	0	0	0	0	0
Cytomegalovirus chorioretinitis	4	1	0	2	0	0	1	0	0
Cytomegalovirus colitis	1	0	0	0	0	0	0	0	0
Cytomegalovirus infection	32	6	0	28	7	3	12	3	1

Subjects are counted only once for each specific disease/syndrome in the table body.
MedDRA (v9.0) coding dictionary applied.

	maraviroc QD			maraviroc BID			Placebo		
Number of Subjects	414			426			209		
	Past	Present	Unknown	Past	Present	Unknown	Past	Present	Unknown
Cytomegalovirus oesophagitis	0	0	0	1	0	0	0	0	0
Cytomegalovirus viraemia	1	0	0	0	0	0	0	0	0
Dental caries	0	1	0	0	0	0	0	0	0
Dermatophytosis	1	0	0	0	0	0	0	0	0
Diarrhoea infectious	2	0	0	0	0	0	1	0	0
Disseminated tuberculosis	16	3	0	10	2	4	7	2	3
Diverticulitis	1	0	0	3	1	0	1	0	0
Dysentery	0	0	0	1	0	0	0	0	0
Ear infection	1	1	0	1	0	0	1	1	0
Eczema infected	0	1	0	0	0	0	0	0	0
Empyema	1	0	0	0	0	0	0	0	0
Encephalitis viral	0	0	0	1	0	0	0	0	0
Endocarditis	1	0	0	1	0	0	0	0	0
Enterococcal bacteraemia	0	0	0	1	0	0	0	0	0
Enterocolitis AIDS	0	0	0	0	0	0	2	0	0
Epstein-Barr virus infection	0	0	0	0	1	0	0	0	0
Erysipelas	0	0	0	1	0	0	0	0	0
Escherichia infection	0	0	0	1	0	0	0	0	0
Escherichia sepsis	0	0	0	1	0	0	0	0	0
Escherichia urinary tract infection	0	1	0	0	0	0	0	0	0
Eye infection syphilitic	1	0	0	0	0	0	0	0	0
Eye infection toxoplasmal	1	0	0	0	0	0	0	0	0
Folliculitis	18	10	0	11	6	0	3	2	0
Fungaemia	0	0	0	1	0	0	0	0	0
Fungal infection	0	0	0	1	2	0	0	2	0
Fungal rash	0	0	0	0	1	0	0	0	0
Fungal skin infection	1	2	0	2	1	0	1	0	0
Furuncle	2	0	0	1	0	0	1	0	0

Subjects are counted only once for each specific disease/syndrome in the table body.
MedDRA (v9.0) coding dictionary applied.

	maraviroc QD			maraviroc BID			Placebo		
Number of Subjects	414			426			209		
	Past	Present	Unknown	Past	Present	Unknown	Past	Present	Unknown
Gastroenteritis	3	1	0	3	0	0	1	0	0
Gastroenteritis cryptosporidial	14	2	2	20	1	4	6	1	1
Gastroenteritis salmonella	1	0	0	0	0	0	0	0	0
Gastrointestinal candidiasis	0	0	0	1	0	0	0	0	0
Genital candidiasis	0	0	0	2	0	0	0	0	0
Genital infection fungal	0	0	0	0	1	0	0	0	0
Giardiasis	9	0	0	6	0	0	3	0	0
Gingival abscess	0	0	0	0	0	0	0	1	0
Gonorrhoea	9	0	0	18	0	0	7	0	0
Groin abscess	0	0	0	1	0	0	0	0	0
HIV infection	1	1	0	0	1	0	0	0	0
HIV peripheral neuropathy	0	1	0	1	0	0	0	0	0
HIV wasting syndrome	47	53	0	55	47	3	24	31	2
Helicobacter gastritis	2	0	0	2	0	0	1	0	0
Helicobacter infection	0	0	0	1	0	0	0	0	0
Hepatitis A	11	0	0	14	0	0	9	1	0
Hepatitis B	18	17	0	31	11	0	14	11	0
Hepatitis C	6	14	0	2	26	0	3	18	0
Hepatitis infectious	0	0	0	0	0	0	1	0	0
Hepatitis viral	1	0	0	0	0	0	0	0	0
Herpes ophthalmic	0	0	0	3	0	0	0	0	0
Herpes simplex	88	41	3	80	47	3	35	23	2
Herpes simplex ophthalmic	1	0	0	0	0	0	0	0	0
Herpes virus infection	4	7	0	6	8	0	1	2	0
Herpes zoster	81	6	0	79	2	0	37	1	0
Herpes zoster infection neurological	0	0	0	0	0	0	1	0	0
Herpes zoster multi-dermatomal	0	0	0	0	0	0	1	0	0
Herpes zoster ophthalmic	2	1	0	1	0	0	1	0	0

Subjects are counted only once for each specific disease/syndrome in the table body.
MedDRA (v9.0) coding dictionary applied.

	maraviroc QD			maraviroc BID			Placebo		
Number of Subjects	414			426			209		
	Past	Present	Unknown	Past	Present	Unknown	Past	Present	Unknown
Herpes zoster oticus	1	0	0	0	0	0	0	0	0
Herpetic stomatitis	1	0	0	0	0	0	1	0	0
Histoplasmosis	2	1	1	0	2	2	2	0	1
Histoplasmosis disseminated	1	0	0	0	0	0	0	0	0
Hordeolum	0	0	0	0	1	0	0	0	0
Impetigo	2	0	0	0	0	0	1	0	0
Infection parasitic	0	0	0	1	0	0	0	0	0
Infectious mononucleosis	4	0	0	4	0	0	0	0	0
Influenza	2	0	0	1	0	0	1	0	0
Isosporiasis	1	2	3	2	1	5	0	0	1
Keratitis herpetic	0	1	0	0	0	0	1	0	0
Laryngitis	3	0	0	0	0	0	0	0	0
Lobar pneumonia	2	0	0	0	0	0	0	0	0
Localised infection	1	0	0	0	0	0	1	0	0
Lower respiratory tract infection	0	0	0	0	0	0	1	0	0
Lower respiratory tract infection viral	0	0	0	0	0	0	1	0	0
Lung abscess	1	0	0	0	0	0	0	0	0
Lung infection	0	0	0	2	0	0	1	0	0
Lyme disease	1	0	0	0	0	0	0	0	0
Lymph node abscess	1	0	0	0	0	0	0	0	0
Lymph node tuberculosis	1	0	0	0	0	0	0	0	0
Lymphangitis	0	0	0	1	0	0	0	0	0
Malaria	4	0	0	2	0	0	3	0	0
Mastitis	1	0	0	0	0	0	0	0	0
Meningitis	1	0	0	4	0	0	2	0	0
Meningitis aseptic	0	0	0	2	0	0	2	0	0
Meningitis cryptococcal	0	1	0	0	1	0	1	0	0
Meningitis tuberculous	0	0	0	0	0	0	1	0	0

Subjects are counted only once for each specific disease/syndrome in the table body.
MedDRA (v9.0) coding dictionary applied.

Table 3.3.2.2
Maraviroc Summary of Clinical Safety
Medical History
Phase 3 Treatment Experienced CCR5 Tropic Studies

	maraviroc QD			maraviroc BID			Placebo		
Number of Subjects	414			426			209		
	Past	Present	Unknown	Past	Present	Unknown	Past	Present	Unknown
Meningitis viral	2	0	0	4	0	0	2	1	0
Microsporidia infection	2	0	0	1	0	0	1	0	0
Molluscum contagiosum	13	7	0	14	7	0	3	3	0
Mycobacterial infection	2	0	0	1	1	0	1	0	0
Mycobacterium avium complex infection	1	0	0	1	0	0	0	0	0
Mycotic aneurysm	0	0	0	0	0	0	1	0	0
Myringitis bullous	1	0	0	0	0	0	0	0	0
Nasopharyngitis	0	0	0	2	0	0	0	0	0
Necrotising ulcerative gingivostomatitis	0	1	0	0	0	0	0	0	0
Neisseria infection	1	0	0	0	0	0	0	0	0
Neurosyphilis	1	0	0	1	0	0	0	0	0
Nocardiosis	1	0	0	1	0	0	0	0	0
Oesophageal candidiasis	6	1	0	2	2	0	4	0	0
Onychomycosis	10	13	0	3	13	0	2	6	0
Oral candidiasis	56	19	0	43	13	0	29	5	0
Oral fungal infection	3	1	0	2	0	0	0	0	0
Oral hairy leukoplakia	26	5	0	18	3	0	10	2	0
Oral infection	0	0	0	0	1	0	0	0	0
Orchitis	1	0	0	1	0	0	0	0	0
Oropharyngeal candidiasis	2	0	0	5	1	0	1	0	0
Osteomyelitis	3	1	0	0	0	0	0	0	0
Osteomyelitis bacterial	0	0	0	0	0	0	0	1	0
Otitis externa	2	0	0	3	0	0	0	0	0
Otitis externa candida	0	0	0	0	1	0	0	0	0
Otitis externa fungal	1	0	0	0	0	0	0	0	0
Otitis media	3	0	0	4	0	0	0	0	0
Otitis media acute	0	0	0	1	0	0	0	0	0
Otitis media chronic	0	0	0	0	1	0	1	0	0

Subjects are counted only once for each specific disease/syndrome in the table body.
MedDRA (v9.0) coding dictionary applied.

	maraviroc QD			maraviroc BID			Placebo		
Number of Subjects	414			426			209		
	Past	Present	Unknown	Past	Present	Unknown	Past	Present	Unknown
Pancreatic abscess	0	0	0	0	0	0	1	0	0
Papilloma viral infection	6	3	0	1	3	0	2	0	0
Paronychia	2	0	0	4	0	0	2	0	0
Parotid abscess	0	0	0	0	0	0	1	0	0
Parotitis	4	0	0	1	0	0	0	0	0
Perianal abscess	0	0	0	3	0	0	3	0	0
Perianal fungal infection	0	0	0	0	1	0	0	0	0
Peritoneal abscess	1	0	0	0	0	0	0	0	0
Pertussis	0	0	0	1	0	0	0	0	0
Pharyngeal candidiasis	1	0	0	1	0	0	0	0	0
Pharyngitis	5	0	0	4	0	0	0	0	0
Pharyngitis streptococcal	1	0	0	2	0	0	0	0	0
Pilonidal cyst	0	0	0	1	0	0	0	0	0
Pleurisy viral	0	0	0	1	0	0	0	0	0
Pneumococcal bacteraemia	1	0	0	0	0	0	0	0	0
Pneumocystis jiroveci pneumonia	91	2	4	99	0	6	43	0	3
Pneumonia	34	0	0	21	0	0	14	1	0
Pneumonia bacterial	18	2	1	25	1	4	18	0	1
Pneumonia fungal	0	0	0	0	0	0	0	1	0
Pneumonia pneumococcal	1	0	0	1	0	0	1	0	0
Pneumonia primary atypical	0	0	0	1	0	0	0	0	0
Pneumonia streptococcal	1	0	0	1	0	0	0	0	0
Poliomyelitis	0	0	0	0	0	0	1	0	0
Primary syphilis	0	0	0	1	0	0	0	0	0
Proctitis herpes	0	1	0	1	0	0	0	0	0
Progressive multifocal leukoencephalopathy	0	4	1	2	2	4	1	0	0
Pseudomonal bacteraemia	1	0	0	0	0	0	0	0	0
Pseudomonas infection	3	0	0	0	1	0	0	0	0

Subjects are counted only once for each specific disease/syndrome in the table body.
MedDRA (v9.0) coding dictionary applied.

	maraviroc QD			maraviroc BID			Placebo		
Number of Subjects	414			426			209		
	Past	Present	Unknown	Past	Present	Unknown	Past	Present	Unknown
Pulmonary mycosis	0	0	0	1	0	0	0	0	0
Pulmonary tuberculosis	2	0	0	1	0	0	0	0	0
Pyelonephritis	1	0	0	3	0	0	0	0	0
Pyothorax	1	0	0	0	0	0	0	0	0
Rash pustular	0	1	0	0	0	0	0	0	0
Rectal abscess	3	0	0	0	0	0	0	0	0
Recurring skin boils	0	0	0	1	0	0	0	0	0
Reiter's syndrome	0	0	0	1	1	0	0	0	0
Respiratory tract infection viral	0	0	0	1	0	0	0	0	0
Rhinitis	0	2	0	0	3	0	1	3	0
Salmonella sepsis	3	1	1	1	1	5	0	0	0
Salmonellosis	0	0	0	0	0	0	1	0	0
Salpingitis	0	0	0	1	0	0	1	0	0
Scrotal abscess	1	0	0	0	0	0	0	0	0
Scrotal infection	0	1	0	0	0	0	0	0	0
Secondary syphilis	1	1	0	0	0	0	0	0	0
Sepsis	2	0	0	0	0	0	1	0	0
Shigella infection	2	0	0	0	0	0	0	0	0
Sialoadenitis	0	0	0	1	0	0	0	0	0
Sinusitis	19	8	0	31	11	0	7	6	0
Skin candida	0	0	0	1	0	0	0	0	0
Skin infection	0	1	0	3	0	0	0	0	0
Staphylococcal abscess	1	0	0	1	0	0	0	0	0
Staphylococcal bacteraemia	2	0	0	0	0	0	0	0	0
Staphylococcal infection	2	1	0	6	1	0	4	0	0
Staphylococcal sepsis	0	0	0	1	0	0	0	0	0
Streptococcal bacteraemia	0	0	0	0	0	0	1	0	0
Streptococcal infection	0	0	0	2	0	0	0	0	0

Subjects are counted only once for each specific disease/syndrome in the table body.
MedDRA (v9.0) coding dictionary applied.

	maraviroc QD			maraviroc BID			Placebo		
Number of Subjects	414			426			209		
	Past	Present	Unknown	Past	Present	Unknown	Past	Present	Unknown
Strongyloidiasis	0	0	0	1	0	0	0	0	0
Subcutaneous abscess	2	1	0	3	0	0	0	0	0
Sweat gland infection	1	1	0	1	0	0	0	0	0
Sweating fever	1	0	0	0	0	0	0	0	0
Syphilis	28	1	0	26	0	0	17	1	0
Taeniasis	0	0	0	0	1	0	0	0	0
Thrombophlebitis septic	1	0	0	0	0	0	0	0	0
Tinea barbae	1	0	0	0	1	0	0	0	0
Tinea capitis	1	0	0	0	0	0	0	0	0
Tinea cruris	3	0	0	1	1	0	0	0	0
Tinea infection	0	0	0	1	1	0	4	0	0
Tinea pedis	6	3	0	1	4	0	1	2	0
Tinea versicolour	4	0	0	2	0	0	0	1	0
Tonsillitis	1	0	0	0	0	0	0	0	0
Tooth abscess	1	0	0	0	0	0	2	0	0
Toxoplasmosis	13	2	0	10	1	5	7	0	0
Tracheobronchitis	0	0	0	1	0	0	0	0	0
Trichophyton infection	1	0	0	0	0	0	0	0	0
Tuberculosis	13	1	1	24	2	3	8	1	0
Upper respiratory tract infection	7	1	0	12	3	0	1	0	0
Upper respiratory tract infection bacterial	1	0	0	0	0	0	0	0	0
Urethritis	2	0	0	3	0	0	2	0	0
Urethritis chlamydial	0	0	0	0	0	0	1	0	0
Urethritis gonococcal	2	0	0	2	0	0	1	0	0
Urinary tract infection	4	1	0	7	0	0	7	0	0
Urosepsis	0	0	0	1	0	0	0	0	0
Vaginal candidiasis	6	1	0	0	1	0	0	0	0
Vaginal infection	0	0	0	0	0	0	2	0	0

Subjects are counted only once for each specific disease/syndrome in the table body.
MedDRA (v9.0) coding dictionary applied.

	maraviroc QD			maraviroc BID			Placebo		
Number of Subjects	414			426			209		
	Past	Present	Unknown	Past	Present	Unknown	Past	Present	Unknown
Vaginitis bacterial	0	0	0	1	0	0	0	0	0
Varicella	3	0	0	2	0	0	1	0	0
Viral diarrhoea	1	0	0	0	0	0	0	0	0
Viral hepatitis carrier	0	1	0	0	1	0	0	2	0
Viral infection	1	0	0	4	1	0	0	0	0
Viral oesophagitis	0	0	0	0	0	0	1	0	0
Viral pharyngitis	0	0	0	1	0	0	1	0	0
Viral upper respiratory tract infection	0	0	0	1	0	0	0	0	0
Visceral leishmaniasis	0	0	0	0	0	0	1	0	0
Vulvitis	0	1	0	0	0	0	0	0	0
Vulvovaginal mycotic infection	0	0	0	1	1	0	0	0	0
Vulvovaginitis trichomonal	1	0	0	1	0	0	0	0	0
Injury, poisoning and procedural complications	31	6	0	32	10	0	8	3	0
Ankle fracture	2	0	0	3	0	0	0	0	0
Arthropod bite	2	0	0	2	0	0	0	0	0
Burns third degree	0	0	0	1	0	0	0	0	0
Cervical vertebral fracture	0	0	0	0	0	0	1	0	0
Clavicle fracture	0	0	0	2	0	0	0	0	0
Compression fracture	0	0	0	1	0	0	0	0	0
Concussion	0	0	0	2	0	0	0	0	0
Contusion	1	0	0	0	0	0	0	0	0
Deafness occupational	0	0	0	0	1	0	0	0	0
Device failure	0	0	0	0	1	0	0	0	0
Drug toxicity	1	0	0	0	0	0	0	0	0
Ear injury	1	0	0	0	0	0	0	0	0
Epicondylitis	0	0	0	1	0	0	1	0	0
Excoriation	0	0	0	3	0	0	0	0	0
Facial bones fracture	3	0	0	0	0	0	0	0	0

Subjects are counted only once for each specific disease/syndrome in the table body.
MedDRA (v9.0) coding dictionary applied.

	maraviroc QD			maraviroc BID			Placebo		
Number of Subjects	414			426			209		
	Past	Present	Unknown	Past	Present	Unknown	Past	Present	Unknown
Fall	1	0	0	1	0	0	0	0	0
Femur fracture	1	0	0	2	0	0	0	0	0
Fibula fracture	0	0	0	1	0	0	0	0	0
Foot fracture	0	0	0	1	0	0	0	0	0
Frostbite	0	0	0	1	0	0	0	0	0
Gun shot wound	1	0	0	0	0	0	0	0	0
Hand fracture	1	0	0	0	0	0	1	0	0
Head injury	2	0	0	0	0	0	0	0	0
Hip fracture	0	0	0	1	0	0	0	0	0
Incisional hernia	0	1	0	0	0	0	0	0	0
Injury	0	0	0	2	0	0	0	0	0
Joint dislocation	1	0	0	0	0	0	0	0	0
Joint injury	1	0	0	3	1	0	0	0	0
Joint sprain	1	0	0	1	0	0	0	0	0
Ligament injury	0	0	0	0	0	0	1	0	0
Limb traumatic amputation	0	0	0	1	0	0	0	0	0
Lower limb fracture	2	0	0	1	0	0	0	1	0
Lung injury	1	0	0	0	0	0	0	0	0
Meniscus lesion	1	0	0	1	0	0	0	0	0
Multiple fractures	0	0	0	1	0	0	0	0	0
Muscle strain	1	0	0	0	1	0	0	0	0
Nerve injury	0	0	0	0	1	0	0	0	0
Patella fracture	1	0	0	1	0	0	0	0	0
Pelvic fracture	1	0	0	0	0	0	0	0	0
Post-traumatic pain	0	0	0	0	1	0	0	0	0
Postoperative adhesion	1	0	0	0	0	0	0	0	0
Procedural pain	0	0	0	0	1	0	0	0	0
Rib fracture	0	0	0	2	0	0	0	1	0

Subjects are counted only once for each specific disease/syndrome in the table body.
MedDRA (v9.0) coding dictionary applied.

	maraviroc QD			maraviroc BID			Placebo		
Number of Subjects	414			426			209		
	Past	Present	Unknown	Past	Present	Unknown	Past	Present	Unknown
Road traffic accident	4	1	0	2	1	0	0	0	0
Scratch	0	1	0	0	0	0	0	0	0
Silicosis	0	1	0	0	0	0	0	0	0
Skin laceration	0	0	0	2	0	0	0	0	0
Skull fracture	0	0	0	1	0	0	0	0	0
Spinal compression fracture	0	1	0	0	0	0	1	0	0
Spinal fracture	0	0	0	3	0	0	0	1	0
Splenic rupture	1	0	0	0	0	0	0	0	0
Thermal burn	0	0	0	0	0	0	1	0	0
Thoracic vertebral fracture	0	0	0	1	1	0	0	0	0
Tibia fracture	1	0	0	1	0	0	0	0	0
Tooth fracture	0	0	0	1	1	0	0	0	0
Traumatic haematoma	1	0	0	0	0	0	0	0	0
Treatment noncompliance	0	1	0	0	0	0	0	0	0
Ulna fracture	1	0	0	0	0	0	0	0	0
Upper limb fracture	2	0	0	2	0	0	0	0	0
Whiplash injury	0	0	0	0	0	0	1	0	0
Wound	1	0	0	0	0	0	0	0	0
Wrist fracture	1	0	0	2	0	0	1	0	0
Investigations	49	49	0	47	66	0	28	42	0
Alanine aminotransferase increased	0	1	0	0	1	0	0	0	0
Androgens decreased	0	3	0	0	4	0	0	3	0
Anti-HBs antibody positive	0	1	0	0	0	0	0	0	0
Arteriogram coronary abnormal	0	0	0	0	1	0	0	0	0
Arthroscopy	0	0	0	2	0	0	1	0	0
Aspartate aminotransferase increased	0	1	0	1	2	0	0	0	0
Aspiration pleural cavity	1	0	0	0	0	0	0	0	0
Bacteria sputum identified	0	0	0	0	0	0	1	0	0

Subjects are counted only once for each specific disease/syndrome in the table body.
MedDRA (v9.0) coding dictionary applied.

	maraviroc QD			maraviroc BID			Placebo		
Number of Subjects	414			426			209		
	Past	Present	Unknown	Past	Present	Unknown	Past	Present	Unknown
Bacteria stool identified	0	0	0	1	0	0	0	0	0
Bacteria tissue specimen identified	1	0	0	0	0	0	0	0	0
Bacterial culture positive	1	0	0	1	0	0	2	0	0
Biopsy	0	0	0	1	0	0	0	0	0
Biopsy bone marrow	0	0	0	1	0	0	0	0	0
Biopsy cervix	1	0	0	0	0	0	0	0	0
Biopsy colon	1	0	0	1	0	0	0	0	0
Biopsy liver	0	0	0	0	0	0	2	0	0
Biopsy lymph gland	1	0	0	1	0	0	1	0	0
Biopsy oesophagus	0	0	0	1	0	0	0	0	0
Biopsy skin	1	0	0	1	0	0	0	1	0
Biopsy thyroid gland	1	0	0	0	0	0	0	0	0
Blood albumin decreased	0	0	0	1	0	0	0	0	0
Blood alkaline phosphatase increased	0	0	0	0	1	0	0	0	0
Blood amylase increased	1	1	0	1	0	0	0	0	0
Blood bilirubin increased	1	0	0	0	0	0	0	0	0
Blood cholesterol increased	1	5	0	4	6	0	0	2	0
Blood creatine phosphokinase	0	0	0	0	1	0	0	0	0
Blood creatine phosphokinase increased	0	2	0	0	1	0	0	1	0
Blood creatinine increased	2	2	0	0	0	0	0	0	0
Blood glucose abnormal	0	0	0	0	0	0	0	1	0
Blood glucose increased	0	1	0	3	1	0	0	0	0
Blood insulin increased	0	0	0	1	0	0	0	0	0
Blood lactate dehydrogenase increased	0	0	0	0	1	0	0	0	0
Blood lactic acid increased	1	0	0	0	0	0	1	0	0
Blood phosphorus decreased	0	1	0	0	0	0	0	0	0
Blood pressure	0	0	0	0	0	0	1	0	0
Blood pressure increased	1	0	0	1	1	0	0	1	0

Subjects are counted only once for each specific disease/syndrome in the table body.
MedDRA (v9.0) coding dictionary applied.

	maraviroc QD			maraviroc BID			Placebo		
Number of Subjects	414			426			209		
	Past	Present	Unknown	Past	Present	Unknown	Past	Present	Unknown
Blood prolactin increased	0	0	0	0	1	0	0	0	0
Blood sodium decreased	0	1	0	0	0	0	0	0	0
Blood testosterone abnormal	0	0	0	0	0	0	0	1	0
Blood testosterone decreased	2	7	0	1	5	0	1	6	0
Blood triglycerides increased	1	4	0	2	8	0	1	4	0
Blood uric acid increased	1	1	0	0	0	0	0	1	0
Body mass index decreased	0	0	0	0	1	0	0	0	0
Bone density decreased	0	0	0	0	1	0	2	0	0
Bronchoscopy	0	0	0	1	0	0	0	0	0
CD4 lymphocytes	0	0	0	0	0	0	0	1	0
CD4 lymphocytes decreased	0	1	0	0	1	0	0	0	0
Cardiac murmur	1	4	0	1	3	0	3	7	0
Cardiac stress test normal	0	0	0	0	0	0	1	0	0
Cardiovascular evaluation	0	0	0	0	0	0	0	1	0
Carnitine decreased	1	1	0	0	0	0	0	0	0
Catheterisation cardiac	0	0	0	1	0	0	0	0	0
Chest X-ray normal	0	0	0	1	0	0	0	0	0
Colonoscopy	1	0	0	1	1	0	0	0	0
Colposcopy	1	0	0	0	0	0	0	0	0
Computerised tomogram	0	0	0	1	0	0	0	0	0
Computerised tomogram abdomen	0	0	0	1	0	0	0	0	0
Cystoscopy	1	0	0	0	0	0	0	0	0
Cytomegalovirus antibody positive	0	1	0	0	0	0	0	0	0
Cytomegalovirus antigen	1	0	0	0	0	0	0	0	0
Cytomegalovirus antigen positive	0	0	0	1	0	0	0	0	0
Cytomegalovirus test	0	1	0	0	0	0	0	0	0
Dental examination abnormal	1	0	0	0	1	0	0	0	0
Diagnostic procedure	0	1	0	1	0	0	0	0	0

Subjects are counted only once for each specific disease/syndrome in the table body.
MedDRA (v9.0) coding dictionary applied.

	maraviroc QD			maraviroc BID			Placebo		
Number of Subjects	414			426			209		
	Past	Present	Unknown	Past	Present	Unknown	Past	Present	Unknown
Electrocardiogram ambulatory	0	0	0	1	0	0	0	0	0
Electrocardiogram change	0	0	0	0	1	0	0	0	0
Emergency care examination	0	0	0	1	0	0	0	0	0
Endoscopic retrograde cholangiopancreatography	0	0	0	1	0	0	0	0	0
Endoscopy	1	0	0	0	0	0	0	0	0
Gamma-glutamyltransferase decreased	0	0	0	0	0	0	0	1	0
Gamma-glutamyltransferase increased	0	1	0	1	1	0	0	1	0
HIV test positive	0	0	0	0	2	0	0	0	0
Heart rate abnormal	0	0	0	0	1	0	0	0	0
Heart rate irregular	0	0	0	0	0	0	0	1	0
Helicobacter pylori identification test positive	0	0	0	0	1	0	0	0	0
Hepatic enzyme increased	0	0	0	2	0	0	0	3	0
Hepatitis A virus	2	0	0	0	0	0	0	0	0
Hepatitis B antibody positive	2	1	0	1	0	0	0	0	0
Hepatitis B antigen positive	0	0	0	0	1	0	0	0	0
Hepatitis B positive	1	1	0	0	0	0	0	0	0
Hepatitis B surface antigen positive	0	0	0	1	2	0	0	0	0
Hepatitis B virus	2	0	0	0	0	0	0	0	0
Hepatitis C antibody	0	0	0	0	1	0	0	0	0
Hepatitis C antibody positive	0	0	0	0	3	0	0	0	0
Hepatitis C positive	2	2	0	0	3	0	0	3	0
Hepatitis C virus	0	1	0	0	2	0	0	1	0
Hepatitis E antigen positive	0	0	0	0	1	0	0	0	0
Herpes simplex serology positive	0	0	0	0	0	0	0	1	0
Human papilloma virus test positive	1	0	0	2	1	0	1	0	0
Intraocular pressure increased	0	1	0	0	0	0	0	0	0
Lipase increased	1	0	0	1	0	0	0	0	0
Lipids increased	2	0	0	0	0	0	0	0	0

Subjects are counted only once for each specific disease/syndrome in the table body.
MedDRA (v9.0) coding dictionary applied.

	maraviroc QD			maraviroc BID			Placebo		
Number of Subjects	414			426			209		
	Past	Present	Unknown	Past	Present	Unknown	Past	Present	Unknown
Liver function test abnormal	3	4	0	3	7	0	2	2	0
Low density lipoprotein increased	1	0	0	0	0	0	0	0	0
Lymph node palpable	0	0	0	0	1	0	0	0	0
Lymphocyte count decreased	0	2	0	0	0	0	0	0	0
Oesophagogastroduodenoscopy	0	0	0	2	0	0	0	0	0
Platelet count decreased	0	0	0	1	0	0	1	1	0
Precancerous cells present	0	0	0	0	0	0	0	1	0
Prostate examination abnormal	0	1	0	1	1	0	1	0	0
Protein total decreased	0	0	0	1	0	0	0	0	0
Protein urine	1	0	0	0	0	0	0	0	0
QRS axis abnormal	1	0	0	0	0	0	0	0	0
Red blood cell count decreased	0	0	0	1	0	0	0	0	0
Smear cervix abnormal	3	1	0	2	0	0	0	0	0
Smear site unspecified abnormal	1	1	0	0	0	0	0	0	0
Spleen palpable	0	0	0	0	0	0	0	1	0
Syphilis test positive	0	1	0	0	0	0	0	0	0
Toxoplasma serology positive	0	0	0	1	0	0	0	0	0
Transaminases	0	0	0	0	0	0	1	0	0
Transaminases increased	2	2	0	1	3	0	1	0	0
Tuberculin test	0	0	0	1	0	0	0	0	0
Tuberculin test positive	4	0	0	2	0	0	1	0	0
Ultrasound abdomen	0	0	0	1	0	0	0	0	0
Ultrasound abdomen abnormal	0	0	0	1	0	0	0	0	0
Ultrasound abdomen normal	0	0	0	1	0	0	0	0	0
Virus culture	0	0	0	0	0	0	1	0	0
Virus culture positive	0	1	0	0	0	0	0	0	0
Weight decreased	3	9	0	8	11	0	5	5	0
Weight increased	0	0	0	0	1	0	0	0	0

Subjects are counted only once for each specific disease/syndrome in the table body.
MedDRA (v9.0) coding dictionary applied.

	maraviroc QD			maraviroc BID			Placebo		
Number of Subjects	414			426			209		
	Past	Present	Unknown	Past	Present	Unknown	Past	Present	Unknown
White blood cell count decreased	0	0	0	1	1	0	0	0	0
X-ray	0	0	0	1	0	0	0	0	0
Metabolism and nutrition disorders	53	146	0	51	153	0	22	81	0
Anorexia	3	4	0	2	5	0	3	3	0
Cachexia	5	11	0	7	7	0	4	5	0
Carnitine deficiency	0	0	0	1	0	0	0	0	0
Decreased appetite	0	6	0	2	6	0	0	3	0
Dehydration	0	2	0	1	0	0	0	1	0
Diabetes mellitus	3	19	0	2	19	0	0	8	0
Diabetes mellitus insulin-dependent	0	1	0	0	3	0	0	0	0
Diabetes mellitus non-insulin-dependent	1	19	0	1	16	0	0	14	0
Dyslipidaemia	6	12	0	1	6	0	1	2	0
Facial wasting	2	10	0	2	19	0	0	10	0
Fat redistribution	1	0	0	0	0	0	0	0	0
Glucose tolerance impaired	0	0	0	1	1	0	0	0	0
Gout	4	2	0	4	6	0	0	1	0
Hypercalcaemia	0	0	0	1	0	0	0	0	0
Hypercholesterolaemia	5	16	0	2	23	0	1	15	0
Hyperglycaemia	0	2	0	3	0	0	1	1	0
Hyperkalaemia	0	0	0	1	0	0	0	0	0
Hyperlactacidaemia	0	0	0	2	0	0	1	0	0
Hyperlipidaemia	18	54	0	12	66	0	3	30	0
Hyperproteinaemia	1	0	0	0	0	0	0	1	0
Hypertriglyceridaemia	2	17	0	6	22	0	3	9	0
Hyperuricaemia	1	1	0	0	4	0	0	1	0
Hypoalbuminaemia	1	0	0	0	0	0	0	0	0
Hypocalcaemia	0	0	0	1	0	0	0	0	0
Hypoglycaemia	0	1	0	2	0	0	0	0	0

Subjects are counted only once for each specific disease/syndrome in the table body.
MedDRA (v9.0) coding dictionary applied.

	maraviroc QD			maraviroc BID			Placebo		
Number of Subjects	414			426			209		
	Past	Present	Unknown	Past	Present	Unknown	Past	Present	Unknown
Hypokalaemia	0	2	0	2	1	0	0	0	0
Hypolipidaemia	0	0	0	0	1	0	0	0	0
Hyponatraemia	1	0	0	0	0	0	0	0	0
Hypophosphataemia	0	2	0	2	0	0	0	1	0
Hypovolaemia	0	0	0	1	0	0	0	0	0
Insulin resistance	0	0	0	0	1	0	0	1	0
Iron deficiency	0	1	0	0	0	0	1	0	0
Lactic acidosis	1	0	0	1	0	0	2	0	0
Lactose intolerance	1	1	0	0	3	0	0	1	0
Malnutrition	0	2	0	2	0	0	0	1	0
Metabolic acidosis	0	2	0	0	0	0	1	0	0
Mitochondrial toxicity	0	0	0	1	0	0	1	0	0
Multi-vitamin deficiency	0	1	0	0	0	0	0	0	0
Obesity	2	3	0	0	5	0	0	3	0
Vitamin B12 deficiency	2	4	0	0	2	0	1	3	0
Vitamin C deficiency	1	0	0	0	0	0	0	0	0
Musculoskeletal and connective tissue disorders	43	98	0	47	89	0	23	49	0
Ankylosing spondylitis	0	0	0	1	1	0	0	0	0
Arthralgia	3	20	0	9	14	0	3	9	0
Arthritis	1	5	0	2	7	0	2	6	0
Arthropathy	0	1	0	0	0	0	0	0	0
Articular calcification	1	0	0	0	0	0	0	0	0
Back pain	9	23	0	10	23	0	4	16	0
Bone disorder	0	1	0	0	0	0	0	0	0
Bone pain	0	0	0	1	0	0	0	2	0
Bunion	0	0	0	0	1	0	0	0	0
Bursitis	2	1	0	0	1	0	0	1	0
Buttock pain	1	0	0	0	0	0	0	0	0

Subjects are counted only once for each specific disease/syndrome in the table body.
MedDRA (v9.0) coding dictionary applied.

	maraviroc QD			maraviroc BID			Placebo		
Number of Subjects	414			426			209		
	Past	Present	Unknown	Past	Present	Unknown	Past	Present	Unknown
Cervical spinal stenosis	0	1	0	0	0	0	0	0	0
Chondrocalcinosis pyrophosphate	0	0	0	0	0	0	1	0	0
Chondromalacia	0	1	0	0	0	0	0	0	0
Connective tissue disorder	0	1	0	0	0	0	0	0	0
Costochondritis	1	0	0	1	1	0	0	0	0
Exostosis	1	0	0	0	0	0	0	0	0
Extraskeletal ossification	1	0	0	0	0	0	0	0	0
Fibromyalgia	0	2	0	0	2	0	0	0	0
Flank pain	1	1	0	1	0	0	0	0	0
Gouty arthritis	0	0	0	1	0	0	0	0	0
Haemophilic arthropathy	0	0	0	0	1	0	0	0	0
Inguinal mass	0	0	0	0	1	0	0	0	0
Intervertebral disc degeneration	1	1	0	1	0	0	0	1	0
Intervertebral disc disorder	0	2	0	0	0	0	0	1	0
Intervertebral disc protrusion	1	3	0	3	5	0	1	4	0
Joint contracture	0	0	0	1	0	0	0	0	0
Joint range of motion decreased	0	0	0	0	1	0	0	0	0
Joint stiffness	0	0	0	1	0	0	0	0	0
Joint swelling	0	0	0	0	0	0	1	0	0
Juvenile arthritis	1	0	0	0	0	0	0	0	0
Lumbar spinal stenosis	0	1	0	0	0	0	0	0	0
Metatarsalgia	1	1	0	0	0	0	0	0	0
Monarthritis	0	1	0	1	2	0	1	0	0
Muscle atrophy	0	0	0	0	1	0	0	0	0
Muscle spasms	5	5	0	1	5	0	2	3	0
Muscle tightness	0	0	0	1	0	0	0	0	0
Muscle twitching	0	1	0	0	0	0	0	0	0
Muscular weakness	0	3	0	1	1	0	0	0	0

Subjects are counted only once for each specific disease/syndrome in the table body.
MedDRA (v9.0) coding dictionary applied.

	maraviroc QD			maraviroc BID			Placebo		
Number of Subjects	414			426			209		
	Past	Present	Unknown	Past	Present	Unknown	Past	Present	Unknown
Musculoskeletal discomfort	0	0	0	0	1	0	0	0	0
Musculoskeletal pain	0	0	0	0	1	0	1	1	0
Musculoskeletal stiffness	0	0	0	0	2	0	0	0	0
Myalgia	7	6	0	5	9	0	6	3	0
Myopathy	0	1	0	4	1	0	0	0	0
Myopathy toxic	0	0	0	0	0	0	1	0	0
Myositis	0	0	0	1	0	0	1	1	0
Neck pain	0	3	0	1	4	0	0	1	0
Osteoarthritis	0	9	0	0	7	0	0	4	0
Osteochondrosis	0	0	0	0	0	0	0	1	0
Osteonecrosis	2	5	0	3	0	0	2	1	0
Osteopenia	0	8	0	0	8	0	1	1	0
Osteoporosis	0	7	0	0	3	0	0	2	0
Pain in extremity	4	3	0	1	8	0	0	4	0
Pathological fracture	1	0	0	0	0	0	0	0	0
Periarthritis	0	0	0	1	1	0	0	0	0
Pes cavus	0	1	0	0	0	0	0	0	0
Plantar fasciitis	0	3	0	2	1	0	0	1	0
Polyarthritis	0	0	0	0	1	0	0	0	0
Polymyalgia rheumatica	0	0	0	0	0	0	0	1	0
Psoriatic arthropathy	0	1	0	0	2	0	0	0	0
Rhabdomyolysis	1	0	0	0	0	0	0	0	0
Rheumatic fever	0	0	0	1	0	0	0	0	0
Rheumatoid arthritis	0	0	0	1	1	0	0	1	0
Rotator cuff syndrome	1	0	0	0	0	0	0	0	0
Sarcopenia	0	0	0	1	0	0	0	0	0
Scoliosis	1	4	0	0	3	0	0	0	0
Shoulder pain	1	6	0	1	4	0	0	0	0

Subjects are counted only once for each specific disease/syndrome in the table body.
MedDRA (v9.0) coding dictionary applied.

	maraviroc QD			maraviroc BID			Placebo		
Number of Subjects	414			426			209		
	Past	Present	Unknown	Past	Present	Unknown	Past	Present	Unknown
Sjogren's syndrome	0	1	0	0	1	0	0	0	0
Spinal column stenosis	0	0	0	0	0	0	0	2	0
Spinal deformity	0	0	0	0	1	0	1	0	0
Spinal osteoarthritis	0	5	0	1	5	0	0	1	0
Spondylitis	0	0	0	0	0	0	0	1	0
Temporomandibular joint syndrome	1	2	0	1	2	0	0	0	0
Tendonitis	6	1	0	3	1	0	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	75	27	2	90	33	4	39	20	1
Adenocarcinoma	0	0	0	1	0	0	0	0	0
Anal cancer	1	0	0	6	0	0	7	0	0
B-cell lymphoma	1	0	0	0	0	0	0	0	0
Basal cell carcinoma	12	3	0	11	2	0	5	2	0
Benign breast neoplasm	0	0	0	1	0	0	0	0	0
Benign colonic neoplasm	0	1	0	0	0	0	1	0	0
Benign oesophageal neoplasm	0	0	0	0	1	0	0	0	0
Benign salivary gland neoplasm	0	0	0	0	1	0	0	0	0
Benign small intestinal neoplasm	0	0	0	1	0	0	0	0	0
Bowen's disease	1	0	0	1	1	0	1	1	0
Breast adenoma	1	0	0	0	0	0	0	0	0
Breast cancer	1	0	0	1	0	0	0	0	0
Buccal cavity papilloma	0	1	0	2	2	0	0	2	0
Carcinoma in situ	1	1	0	0	0	0	0	0	0
Cervix cancer metastatic	2	0	1	3	0	0	0	1	0
Cervix carcinoma	1	0	0	2	0	0	0	0	0
Colon adenoma	0	0	0	0	0	0	1	0	0
Colon cancer	2	1	0	0	0	0	0	0	0
Gammopathy	0	1	0	1	0	0	0	0	0

Subjects are counted only once for each specific disease/syndrome in the table body.
MedDRA (v9.0) coding dictionary applied.

	maraviroc QD			maraviroc BID			Placebo		
Number of Subjects	414			426			209		
	Past	Present	Unknown	Past	Present	Unknown	Past	Present	Unknown
Haemangioma	0	0	0	0	0	0	1	0	0
Hodgkin's disease	2	0	0	3	0	0	0	0	0
Kaposi's sarcoma	18	5	1	28	8	4	9	3	1
Lipoma	1	0	0	4	3	0	0	1	0
Lipoma of breast	0	1	0	0	0	0	0	0	0
Lung neoplasm	0	1	0	0	1	0	2	1	0
Lung neoplasm malignant	0	0	0	0	0	0	1	0	0
Lymphoma	15	1	0	18	1	3	9	1	0
Malignant melanoma	0	0	0	2	0	0	0	0	0
Melanocytic naevus	0	2	0	1	0	0	0	0	0
Meningioma	1	0	0	0	0	0	0	0	0
Metastases to kidney	1	0	0	0	0	0	0	0	0
Metastases to liver	1	0	0	0	0	0	0	0	0
Metastases to lung	1	0	0	0	0	0	0	0	0
Neoplasm	1	0	0	0	0	0	0	1	0
Neoplasm malignant	0	0	0	0	0	0	0	1	0
Neoplasm prostate	0	0	0	1	0	0	0	0	0
Neuroma	1	0	0	0	0	0	0	0	0
Non-Hodgkin's lymphoma	2	0	0	0	0	0	0	0	0
Papillary thyroid cancer	1	0	0	0	0	0	0	0	0
Papilloma	0	1	0	0	0	0	0	0	0
Pituitary tumour	1	0	0	0	0	0	0	0	0
Pituitary tumour benign	0	0	0	1	0	0	0	0	0
Prostate cancer	0	0	0	1	0	0	0	0	0
Renal cell carcinoma stage unspecified	0	0	0	1	0	0	0	0	0
Salivary gland cancer	0	0	0	1	0	0	0	0	0
Sarcoma	1	0	0	1	0	0	0	0	0
Seborrhoeic keratosis	0	1	0	0	1	0	0	2	0

Subjects are counted only once for each specific disease/syndrome in the table body.
MedDRA (v9.0) coding dictionary applied.

	maraviroc QD			maraviroc BID			Placebo		
Number of Subjects	414			426			209		
	Past	Present	Unknown	Past	Present	Unknown	Past	Present	Unknown
Skin cancer	1	0	0	1	2	0	1	0	0
Skin papilloma	12	6	0	11	12	0	4	5	0
Squamous cell carcinoma	6	4	0	1	2	0	5	0	0
Squamous cell carcinoma of skin	1	0	0	0	1	0	1	0	0
Testicular neoplasm	1	0	0	1	0	0	0	0	0
Thyroid adenoma	1	0	0	1	0	0	0	0	0
Thyroid neoplasm	0	0	0	0	1	0	0	0	0
Uterine leiomyoma	2	1	0	0	1	0	1	0	0
Vulval cancer	1	0	0	0	0	0	0	0	0
Xanthoma	0	0	0	1	0	0	0	0	0
Nervous system disorders	76	147	0	95	141	0	36	75	0
Ageusia	0	0	0	1	0	0	0	0	0
Amnesia	2	0	0	2	0	0	0	3	0
Areflexia	0	2	0	0	1	0	0	2	0
Autonomic neuropathy	1	0	0	0	0	0	0	0	0
Balance disorder	1	0	0	0	1	0	0	0	0
Carotid artery stenosis	0	0	0	0	1	0	0	0	0
Carpal tunnel syndrome	2	1	0	4	4	0	0	1	0
Cerebral atrophy	0	0	0	0	0	0	0	1	0
Cerebral haematoma	0	0	0	1	0	0	0	0	0
Cerebral infarction	1	0	0	0	0	0	1	0	0
Cerebrovascular accident	2	0	0	3	0	0	0	0	0
Cerebrovascular disorder	0	0	0	0	0	0	1	0	0
Cervicobrachial syndrome	0	0	0	2	1	0	0	1	0
Cluster headache	0	0	0	1	0	0	0	0	0
Cognitive disorder	1	0	0	0	0	0	0	0	0
Complex partial seizures	1	0	0	0	0	0	0	0	0
Complicated migraine	0	1	0	0	0	0	0	0	0

Subjects are counted only once for each specific disease/syndrome in the table body.
MedDRA (v9.0) coding dictionary applied.

	maraviroc QD			maraviroc BID			Placebo		
Number of Subjects	414			426			209		
	Past	Present	Unknown	Past	Present	Unknown	Past	Present	Unknown
Convulsion	4	7	0	4	3	0	4	3	0
Cranial neuropathy	0	0	0	0	1	0	0	0	0
Dementia	0	0	0	0	2	0	0	0	0
Demyelinating polyneuropathy	0	0	0	0	1	0	0	0	0
Demyelination	0	0	0	0	1	0	0	0	0
Diabetic neuropathy	0	0	0	0	1	0	0	0	0
Disturbance in attention	0	0	0	1	1	0	0	0	0
Dizziness	7	3	0	6	6	0	2	1	0
Dysaesthesia	0	0	0	0	0	0	0	1	0
Dysgeusia	0	0	0	2	1	0	0	0	0
Dystonia	0	1	0	0	1	0	0	0	0
Encephalitis	0	0	0	0	0	0	1	0	0
Encephalomalacia	0	0	0	1	0	0	0	0	0
Encephalopathy	1	1	0	0	1	0	1	1	0
Epilepsy	0	3	0	4	2	0	1	1	0
Essential tremor	0	0	0	0	2	0	1	0	0
Facial palsy	5	0	0	7	2	0	1	0	0
Grand mal convulsion	0	1	0	1	0	0	0	0	0
Guillain-Barre syndrome	1	0	0	1	0	0	0	0	0
Headache	8	27	0	15	35	0	4	15	0
Hemiparesis	0	0	0	1	0	0	0	0	0
Hyperkinesia	0	0	0	1	0	0	0	0	0
Hypersomnia	1	0	0	0	0	0	0	0	0
Hypertonia	0	0	0	0	1	0	0	0	0
Hypoaesthesia	1	5	0	3	6	0	0	3	0
Hyporeflexia	1	1	0	0	2	0	0	1	0
Hypotonia	0	0	0	1	0	0	0	0	0
Intention tremor	0	0	0	0	1	0	0	0	0

Subjects are counted only once for each specific disease/syndrome in the table body.
MedDRA (v9.0) coding dictionary applied.

	maraviroc QD			maraviroc BID			Placebo		
Number of Subjects	414			426			209		
	Past	Present	Unknown	Past	Present	Unknown	Past	Present	Unknown
Lethargy	0	0	0	0	0	0	0	1	0
Leukoencephalopathy	0	0	0	1	0	0	0	0	0
Loss of consciousness	3	0	0	0	0	0	0	0	0
Lumbar radiculopathy	1	2	0	0	1	0	0	0	0
Mastication disorder	0	1	0	0	0	0	0	0	0
Memory impairment	2	1	0	2	1	0	0	0	0
Migraine	6	11	0	4	14	0	3	5	0
Migraine with aura	0	0	0	2	0	0	0	0	0
Muscle contractions involuntary	2	0	0	0	0	0	0	0	0
Myelopathy	2	0	0	0	0	0	0	0	0
Myoclonus	0	0	0	1	0	0	0	0	0
Narcolepsy	0	0	0	0	0	0	0	1	0
Nerve compression	0	0	0	0	0	0	0	1	0
Nerve root lesion	0	0	0	0	0	0	1	0	0
Nervous system disorder	0	0	0	1	1	0	0	0	0
Neuralgia	0	0	0	0	1	0	0	2	0
Neuritis	1	1	0	0	0	0	0	0	0
Neuropathy	11	18	0	11	19	0	2	11	0
Neuropathy peripheral	12	72	0	25	56	0	8	35	0
Optic neuritis	0	1	0	0	0	0	0	0	0
Paraesthesia	5	5	0	3	4	0	2	2	0
Paraplegia	0	1	0	0	0	0	0	0	0
Parkinson's disease	0	0	0	0	1	0	0	0	0
Partial seizures	0	1	0	0	0	0	0	0	0
Peripheral sensory neuropathy	0	0	0	0	1	0	0	0	0
Polyneuropathy	8	11	0	7	8	0	3	3	0
Poor quality sleep	0	0	0	0	1	0	0	0	0
Post herpetic neuralgia	1	3	0	3	0	0	2	0	0

Subjects are counted only once for each specific disease/syndrome in the table body.
MedDRA (v9.0) coding dictionary applied.

	maraviroc QD			maraviroc BID			Placebo		
Number of Subjects	414			426			209		
	Past	Present	Unknown	Past	Present	Unknown	Past	Present	Unknown
Radial nerve palsy	1	0	0	0	0	0	1	0	0
Radicular pain	0	0	0	0	1	0	0	0	0
Radiculopathy	1	1	0	3	1	0	0	1	0
Restless legs syndrome	0	5	0	1	0	0	0	0	0
Sciatica	1	3	0	1	3	0	1	3	0
Sensory disturbance	1	1	0	0	0	0	0	0	0
Sinus headache	0	0	0	0	1	0	0	1	0
Sleep phase rhythm disturbance	0	0	0	0	0	0	0	1	0
Somnolence	1	0	0	0	0	0	0	0	0
Speech disorder	0	0	0	0	1	0	0	0	0
Spinal vascular disorder	0	0	0	1	0	0	0	0	0
Status epilepticus	0	0	0	0	1	0	0	0	0
Subarachnoid haemorrhage	0	0	0	0	0	0	1	0	0
Syncope	4	0	0	2	1	0	1	0	0
Tension headache	0	2	0	1	0	0	1	0	0
Transient ischaemic attack	0	0	0	1	0	0	1	0	0
Tremor	1	0	0	0	1	0	0	1	0
Trigeminal neuralgia	0	1	0	0	0	0	0	0	0
Pregnancy, puerperium and perinatal conditions	1	0	0	3	0	0	0	0	0
Ectopic pregnancy	1	0	0	1	0	0	0	0	0
Perineal laceration	0	0	0	1	0	0	0	0	0
Pregnancy	0	0	0	1	0	0	0	0	0
Psychiatric disorders	60	152	0	66	157	0	33	93	0
Adjustment disorder	0	0	0	1	0	0	0	0	0
Affect lability	0	0	0	2	0	0	0	0	0
Aggression	0	1	0	0	0	0	0	1	0
Agitation	0	1	0	0	0	0	0	0	0
Alcoholism	8	1	0	9	3	0	7	0	0

Subjects are counted only once for each specific disease/syndrome in the table body.
MedDRA (v9.0) coding dictionary applied.

Table 3.3.2.2
Maraviroc Summary of Clinical Safety
Medical History
Phase 3 Treatment Experienced CCR5 Tropic Studies

	maraviroc QD			maraviroc BID			Placebo		
Number of Subjects	414			426			209		
	Past	Present	Unknown	Past	Present	Unknown	Past	Present	Unknown
Anxiety	9	37	0	8	42	0	3	25	0
Anxiety disorder	1	3	0	0	7	0	0	3	0
Attention deficit/hyperactivity disorder	0	3	0	0	2	0	1	1	0
Bipolar I disorder	0	0	0	0	0	0	0	1	0
Bipolar disorder	2	2	0	0	6	0	0	4	0
Confusional state	0	0	0	0	0	0	0	2	0
Conversion disorder	0	0	0	1	0	0	0	0	0
Delusion	0	1	0	0	0	0	0	0	0
Depressed mood	0	0	0	1	0	0	0	1	0
Depression	39	94	0	32	99	0	16	55	0
Drug dependence	2	0	0	2	0	0	1	0	0
Dysthymic disorder	0	0	0	2	1	0	0	0	0
Gender identity disorder	0	1	0	0	0	0	0	0	0
Generalised anxiety disorder	0	0	0	0	2	0	0	0	0
Hallucination	1	1	0	0	0	0	0	0	0
Initial insomnia	1	0	0	0	0	0	0	0	0
Insomnia	6	62	0	14	65	0	8	34	0
Libido decreased	1	5	0	0	4	0	1	2	0
Loss of libido	0	0	0	0	1	0	0	0	0
Major depression	0	1	0	2	2	0	1	2	0
Mania	1	0	0	0	1	0	0	0	0
Mental disorder	0	1	0	0	1	0	1	0	0
Mood altered	1	0	0	0	0	0	0	0	0
Nervousness	0	0	0	0	1	0	0	0	0
Nicotine dependence	0	0	0	0	1	0	0	0	0
Obsessive thoughts	0	0	0	0	1	0	0	0	0
Obsessive-compulsive disorder	1	0	0	0	1	0	0	0	0
Panic attack	0	5	0	0	2	0	0	0	0

Subjects are counted only once for each specific disease/syndrome in the table body.
MedDRA (v9.0) coding dictionary applied.

	maraviroc QD			maraviroc BID			Placebo		
Number of Subjects	414			426			209		
	Past	Present	Unknown	Past	Present	Unknown	Past	Present	Unknown
Panic disorder	0	1	0	0	1	0	0	1	0
Post-traumatic stress disorder	1	1	0	0	1	0	0	0	0
Psychosexual disorder	0	0	0	0	0	0	0	1	0
Psychotic disorder	2	3	0	3	0	0	1	0	0
Schizoaffective disorder	0	1	0	0	0	0	0	1	0
Schizophrenia	1	1	0	0	1	0	0	0	0
Sleep disorder	3	5	0	2	4	0	1	2	0
Social phobia	0	1	0	0	0	0	0	0	0
Stress	2	0	0	0	2	0	0	0	0
Suicidal ideation	2	0	0	1	0	0	0	0	0
Suicide attempt	3	0	0	0	0	0	0	0	0
Renal and urinary disorders	51	22	0	43	30	0	25	13	0
Atonic urinary bladder	0	1	0	0	0	0	0	0	0
Bladder disorder	0	0	0	0	2	0	0	0	0
Calculus bladder	1	0	0	1	0	0	0	0	0
Calculus ureteric	0	0	0	1	0	0	0	0	0
Calculus urethral	0	0	0	1	0	0	0	0	0
Calculus urinary	2	0	0	0	0	0	1	0	0
Chromaturia	0	0	0	1	0	0	0	0	0
Dysuria	2	1	0	3	1	0	1	1	0
Fanconi syndrome acquired	0	1	0	0	0	0	0	0	0
Focal glomerulosclerosis	0	0	0	1	0	0	0	0	0
Glomerulonephritis	1	0	0	0	1	0	0	0	0
Glycosuria	0	0	0	1	0	0	0	0	0
Haematuria	4	0	0	2	2	0	1	0	0
Hydronephrosis	0	0	0	1	0	0	0	0	0
Hypertonic bladder	0	0	0	1	0	0	0	0	0
Incontinence	0	0	0	0	1	0	0	0	0

Subjects are counted only once for each specific disease/syndrome in the table body.
MedDRA (v9.0) coding dictionary applied.

	maraviroc QD			maraviroc BID			Placebo		
Number of Subjects	414			426			209		
	Past	Present	Unknown	Past	Present	Unknown	Past	Present	Unknown
Microalbuminuria	0	1	0	0	0	0	0	0	0
Micturition urgency	0	0	0	0	0	0	0	1	0
Nephrocalcinosis	0	1	0	0	0	0	0	0	0
Nephrolithiasis	25	2	0	25	4	0	13	2	0
Neurogenic bladder	0	1	0	0	0	0	0	1	0
Nocturia	1	3	0	2	2	0	1	1	0
Pollakiuria	2	3	0	1	4	0	1	1	0
Polyuria	1	0	0	0	0	0	0	0	0
Proteinuria	1	1	0	0	2	0	2	1	0
Pyuria	0	0	0	1	0	0	0	0	0
Renal colic	5	0	0	0	0	0	2	0	0
Renal cyst	0	1	0	0	1	0	0	0	0
Renal failure	3	4	0	5	6	0	4	0	0
Renal failure acute	0	0	0	3	0	0	1	0	0
Renal failure chronic	0	2	0	1	4	0	1	0	0
Renal impairment	1	0	0	0	0	0	1	0	0
Renal tubular disorder	1	1	0	0	0	0	0	0	0
Renal tubular necrosis	1	0	0	0	0	0	0	0	0
Stress incontinence	0	0	0	0	0	0	0	1	0
Ureteric stenosis	0	0	0	1	0	0	0	0	0
Urinary bladder polyp	1	0	0	0	0	0	0	0	0
Urinary hesitation	0	0	0	0	1	0	1	1	0
Urinary incontinence	1	0	0	0	0	0	0	0	0
Urinary retention	0	0	0	1	2	0	0	2	0
Urinary tract disorder	1	0	0	0	0	0	0	0	0
Urinary tract obstruction	0	0	0	0	0	0	0	1	0
Urine flow decreased	0	0	0	0	1	0	0	0	0
Reproductive system and breast disorders	33	47	0	25	67	0	16	24	0

Subjects are counted only once for each specific disease/syndrome in the table body.
MedDRA (v9.0) coding dictionary applied.

	maraviroc QD			maraviroc BID			Placebo		
Number of Subjects	414			426			209		
	Past	Present	Unknown	Past	Present	Unknown	Past	Present	Unknown
Amenorrhoea	1	0	0	0	0	0	0	0	0
Balanitis	0	0	0	1	0	0	0	0	0
Bartholin's cyst	0	0	0	0	1	0	0	0	0
Benign prostatic hyperplasia	1	4	0	0	10	0	0	2	0
Breast discharge	0	0	0	0	0	0	0	1	0
Breast mass	0	1	0	0	1	0	1	0	0
Breast tenderness	0	0	0	0	0	0	0	1	0
Cervical dysplasia	4	2	0	2	3	0	0	0	0
Dysfunctional uterine bleeding	1	0	0	0	0	0	0	0	0
Dysmenorrhoea	1	1	0	0	0	0	0	0	0
Endometriosis	1	0	0	1	0	0	0	0	0
Epididymal cyst	1	0	0	0	1	0	0	0	0
Epididymitis	3	0	0	1	0	0	1	0	0
Erectile dysfunction	4	33	0	9	39	0	1	16	0
Female genital tract fistula	1	0	0	0	0	0	1	0	0
Fibrocystic breast disease	1	0	0	0	0	0	0	1	0
Genital lesion	1	0	0	0	0	0	0	0	0
Genital rash	0	1	0	0	0	0	0	0	0
Gynaecomastia	6	5	0	4	3	0	2	1	0
Hypertrophy breast	0	1	0	0	0	0	0	0	0
Menopausal symptoms	0	0	0	0	1	0	0	0	0
Menorrhagia	0	0	0	0	0	0	1	0	0
Organic erectile dysfunction	0	1	0	0	0	0	0	0	0
Ovarian cyst	1	0	0	1	0	0	0	0	0
Penile swelling	0	0	0	1	0	0	0	0	0
Peyronie's disease	0	0	0	0	2	0	0	0	0
Prostatism	0	0	0	0	0	0	0	1	0
Prostatitis	8	0	0	5	1	0	7	1	0

Subjects are counted only once for each specific disease/syndrome in the table body.
MedDRA (v9.0) coding dictionary applied.

	maraviroc QD			maraviroc BID			Placebo		
Number of Subjects	414			426			209		
	Past	Present	Unknown	Past	Present	Unknown	Past	Present	Unknown
Scrotal disorder	0	0	0	0	0	0	1	0	0
Scrotal mass	1	0	0	0	0	0	0	0	0
Sexual dysfunction	2	3	0	0	7	0	0	1	0
Testicular pain	1	0	0	0	0	0	0	0	0
Uterine disorder	0	0	0	1	0	0	0	0	0
Vaginal haemorrhage	1	0	0	0	0	0	1	0	0
Vulval leukoplakia	0	0	0	1	0	0	0	0	0
Vulval ulceration	0	0	0	0	0	0	1	0	0
Vulvar dysplasia	0	1	0	0	0	0	0	0	0
Vulvovaginal discomfort	0	1	0	0	0	0	0	0	0
Respiratory, thoracic and mediastinal disorders	38	89	0	36	66	0	16	51	0
Acute respiratory distress syndrome	1	0	0	0	0	0	0	0	0
Allergic bronchitis	0	1	0	0	0	0	0	0	0
Allergic sinusitis	0	6	0	0	2	0	0	0	0
Asthma	5	28	0	5	18	0	5	19	0
Bronchial disorder	0	0	0	0	0	0	0	1	0
Bronchial hyperactivity	0	3	0	1	3	0	0	3	0
Bronchospasm	0	1	0	1	0	0	0	0	0
Bullous lung disease	0	0	0	1	0	0	0	0	0
Chronic obstructive pulmonary disease	1	4	0	1	2	0	0	8	0
Cough	2	11	0	4	5	0	2	1	0
Diaphragmatic rupture	1	0	0	0	0	0	0	0	0
Dyspnoea	4	3	0	6	4	0	1	3	0
Dyspnoea exertional	0	2	0	0	3	0	1	1	0
Emphysema	0	0	0	0	1	0	0	0	0
Epistaxis	1	0	0	5	0	0	0	0	0
Haemoptysis	1	0	0	1	0	0	0	0	0
Hiccups	0	0	0	0	0	0	0	1	0

Subjects are counted only once for each specific disease/syndrome in the table body.
MedDRA (v9.0) coding dictionary applied.

	maraviroc QD			maraviroc BID			Placebo		
Number of Subjects	414			426			209		
	Past	Present	Unknown	Past	Present	Unknown	Past	Present	Unknown
Lung disorder	2	0	0	0	0	0	1	0	0
Lung infiltration	1	0	0	0	0	0	0	0	0
Mediastinal mass	1	0	0	0	0	0	0	0	0
Nasal congestion	0	4	0	2	1	0	0	0	0
Nasal polyps	1	1	0	0	0	0	0	2	0
Nasal septum deviation	1	2	0	1	2	0	0	1	0
Nasal ulcer	0	1	0	0	0	0	0	0	0
Pharyngeal mass	0	0	0	1	0	0	0	0	0
Pharyngeal pouch	1	0	0	0	0	0	0	0	0
Pharyngolaryngeal pain	2	2	0	2	0	0	0	0	0
Pleural effusion	2	0	0	0	0	0	0	0	0
Pleural fibrosis	0	0	0	0	0	0	0	1	0
Pleurisy	0	0	0	1	0	0	0	0	0
Pneumonitis	1	0	0	1	0	0	0	0	0
Pneumothorax	2	0	0	1	0	0	3	0	0
Postnasal drip	0	2	0	1	0	0	0	0	0
Productive cough	0	1	0	1	0	0	0	0	0
Pulmonary embolism	3	0	0	3	0	0	2	0	0
Pulmonary granuloma	0	0	0	0	0	0	0	1	0
Pulmonary hypertension	0	2	0	1	0	0	0	0	0
Pulmonary vascular disorder	1	0	0	0	0	0	0	0	0
Respiratory disorder	0	0	0	0	1	0	0	0	0
Respiratory distress	0	0	0	0	0	0	0	1	0
Respiratory failure	0	0	0	1	0	0	0	0	0
Respiratory tract congestion	0	0	0	1	1	0	0	0	0
Rhinitis allergic	8	23	0	5	26	0	1	12	0
Rhinitis perennial	0	0	0	0	0	0	0	1	0
Rhinitis seasonal	0	0	0	0	2	0	1	2	0

Subjects are counted only once for each specific disease/syndrome in the table body.
MedDRA (v9.0) coding dictionary applied.

	maraviroc QD			maraviroc BID			Placebo		
Number of Subjects	414			426			209		
	Past	Present	Unknown	Past	Present	Unknown	Past	Present	Unknown
Rhinorrhoea	0	1	0	0	0	0	0	0	0
Rhonchi	1	0	0	0	0	0	0	0	0
Sinus congestion	2	2	0	0	3	0	0	2	0
Sinus disorder	0	0	0	0	1	0	0	0	0
Sleep apnoea syndrome	1	6	0	0	7	0	1	4	0
Throat tightness	0	0	0	1	0	0	0	0	0
Tonsillar hypertrophy	0	0	0	0	1	0	0	0	0
Wheezing	0	1	0	1	0	0	0	0	0
Skin and subcutaneous tissue disorders	73	148	0	69	149	0	30	68	0
Acanthosis	1	0	0	0	0	0	0	0	0
Acne	3	2	0	4	6	0	0	3	0
Acne pustular	1	0	0	0	0	0	0	0	0
Actinic keratosis	1	3	0	1	2	0	0	2	0
Alopecia	1	4	0	1	2	0	0	1	0
Alopecia areata	0	1	0	0	0	0	0	0	0
Angioneurotic oedema	1	0	0	0	0	0	0	0	0
Dandruff	0	0	0	0	1	0	0	0	0
Decubitus ulcer	1	1	0	0	0	0	0	0	0
Dermal cyst	0	1	0	1	1	0	0	0	0
Dermatitis	3	9	0	8	4	0	3	4	0
Dermatitis allergic	2	0	0	1	0	0	1	0	0
Dermatitis atopic	1	1	0	3	1	0	0	1	0
Dermatitis contact	0	1	0	3	1	0	1	0	0
Dermatitis psoriasiform	0	0	0	1	0	0	0	0	0
Dermographism	0	1	0	0	0	0	0	0	0
Drug eruption	4	3	0	7	0	0	2	0	0
Dry skin	0	8	0	1	5	0	0	3	0
Dyshidrosis	1	0	0	1	1	0	0	0	0

Subjects are counted only once for each specific disease/syndrome in the table body.
MedDRA (v9.0) coding dictionary applied.

Table 3.3.2.2
Maraviroc Summary of Clinical Safety
Medical History
Phase 3 Treatment Experienced CCR5 Tropic Studies

	maraviroc QD			maraviroc BID			Placebo		
Number of Subjects	414			426			209		
	Past	Present	Unknown	Past	Present	Unknown	Past	Present	Unknown
Eczema	8	6	0	5	9	0	3	3	0
Eosinophilic pustular folliculitis	2	0	0	2	0	0	2	0	0
Erythema	0	0	0	0	0	0	1	2	0
Exfoliative rash	0	0	0	1	0	0	0	0	0
Fat atrophy	0	0	0	0	3	0	0	0	0
Guttate psoriasis	0	0	0	0	0	0	1	0	0
Heat rash	1	0	0	0	0	0	0	0	0
Hirsutism	0	1	0	0	0	0	0	0	0
Hyperhidrosis	0	1	0	0	4	0	0	1	0
Hyperkeratosis	2	0	0	0	3	0	0	0	0
Ingrowing nail	0	2	0	0	1	0	1	0	0
Intertrigo	0	0	0	1	0	0	0	0	0
Leukoplakia	2	0	0	2	2	0	1	0	0
Lipoatrophy	2	23	0	1	16	0	2	10	0
Lipodystrophy acquired	9	62	0	6	67	0	4	29	0
Lipohypertrophy	1	2	0	1	7	0	0	0	0
Male pattern baldness	0	0	0	1	0	0	0	1	0
Melanodermia	0	1	0	1	0	0	0	0	0
Nail dystrophy	1	1	0	0	0	0	0	0	0
Neurodermatitis	1	2	0	1	1	0	0	0	0
Night sweats	6	7	0	2	8	0	0	7	0
Onychoclasis	1	0	0	0	0	0	0	0	0
Palpable purpura	0	0	0	0	1	0	0	0	0
Photodermatosis	0	0	0	0	1	0	0	0	0
Photosensitivity reaction	0	0	0	0	1	0	0	0	0
Pityriasis	1	0	0	0	0	0	0	0	0
Pityriasis rosea	2	0	0	0	0	0	0	0	0
Prurigo	0	0	0	0	0	0	1	0	0

Subjects are counted only once for each specific disease/syndrome in the table body.
MedDRA (v9.0) coding dictionary applied.

	maraviroc QD			maraviroc BID			Placebo		
Number of Subjects	414			426			209		
	Past	Present	Unknown	Past	Present	Unknown	Past	Present	Unknown
Pruritus	0	7	0	4	7	0	1	2	0
Psoriasis	6	6	0	3	7	0	1	4	0
Purpura	1	0	0	1	0	0	1	0	0
Rash	9	6	0	10	5	0	3	2	0
Rash erythematous	0	1	0	1	0	0	0	0	0
Rash macular	0	1	0	0	0	0	0	0	0
Rash maculo-papular	2	1	0	0	1	0	0	0	0
Rash papular	0	1	0	0	1	0	1	0	0
Rash pruritic	1	0	0	1	1	0	0	0	0
Rosacea	1	4	0	2	6	0	0	3	0
Scar	0	1	0	0	0	0	0	0	0
Seborrhoea	1	1	0	2	1	0	1	0	0
Seborrhoeic dermatitis	15	15	0	11	12	0	3	4	0
Skin atrophy	0	1	0	0	0	0	0	0	0
Skin depigmentation	0	1	0	0	0	0	0	0	0
Skin discolouration	0	2	0	0	1	0	0	0	0
Skin disorder	1	0	0	0	0	0	0	0	0
Skin exfoliation	0	0	0	2	0	0	0	0	0
Skin fissures	0	0	0	1	0	0	0	0	0
Skin hyperpigmentation	0	1	0	0	0	0	1	1	0
Skin inflammation	0	0	0	0	0	0	0	1	0
Skin lesion	0	4	0	2	4	0	2	0	0
Skin nodule	0	0	0	1	0	0	0	0	0
Skin reaction	0	0	0	0	1	0	0	0	0
Skin ulcer	1	1	0	0	0	0	0	2	0
Stevens-Johnson syndrome	0	0	0	1	0	0	0	0	0
Urticaria	0	3	0	2	1	0	1	0	0
Urticaria thermal	0	0	0	1	1	0	0	0	0

Subjects are counted only once for each specific disease/syndrome in the table body.
MedDRA (v9.0) coding dictionary applied.

	maraviroc QD			maraviroc BID			Placebo		
Number of Subjects	414			426			209		
	Past	Present	Unknown	Past	Present	Unknown	Past	Present	Unknown
Xeroderma	1	0	0	2	1	0	0	0	0
Social circumstances	31	11	0	40	18	0	19	7	0
Alcohol use	3	1	0	1	1	0	0	0	0
Alcoholic	0	0	0	1	0	0	0	0	0
Breast prosthesis user	0	0	0	1	0	0	0	0	0
Contraindication to medical treatment	0	0	0	0	0	0	0	1	0
Corrective lens user	0	1	0	0	2	0	0	1	0
Denture wearer	0	1	0	0	0	0	0	0	0
Drug abuser	23	0	0	36	2	0	17	0	0
Edentulous	0	0	0	0	0	0	0	1	0
Ex-smoker	0	0	0	1	0	0	0	0	0
Exposure to communicable disease	0	1	0	0	0	0	1	0	0
High risk sexual behaviour	0	1	0	0	1	0	0	0	0
Learning disability	1	0	0	0	0	0	0	0	0
Menopause	0	1	0	0	1	0	0	0	0
Multigravida	0	0	0	2	0	0	0	0	0
Multiparous	0	0	0	1	0	0	0	0	0
Parity	0	0	0	1	0	0	0	0	0
Polysubstance abuse	1	0	0	1	0	0	2	0	0
Postmenopause	0	1	0	0	0	0	0	0	0
Smoker	1	2	0	1	5	0	0	2	0
Tobacco abuse	2	0	0	0	4	0	2	2	0
Tobacco user	0	1	0	0	3	0	0	0	0
Wheelchair user	0	1	0	0	0	0	0	0	0
Surgical and medical procedures	129	14	0	140	9	0	61	9	0
Abdominal hernia repair	1	0	0	1	0	0	0	0	0
Abdominal operation	1	0	0	0	0	0	1	0	0
Abscess drainage	1	0	0	0	0	0	2	0	0

Subjects are counted only once for each specific disease/syndrome in the table body.
MedDRA (v9.0) coding dictionary applied.

Table 3.3.2.2
Maraviroc Summary of Clinical Safety
Medical History
Phase 3 Treatment Experienced CCR5 Tropic Studies

	maraviroc QD			maraviroc BID			Placebo		
Number of Subjects	414			426			209		
	Past	Present	Unknown	Past	Present	Unknown	Past	Present	Unknown
Adenoidectomy	0	0	0	1	0	0	1	0	0
Adenotonsillectomy	0	0	0	1	0	0	0	0	0
Adhesiolysis	1	0	0	0	0	0	0	0	0
Allergenic desensitisation procedure	1	1	0	0	1	0	0	0	0
Angioplasty	1	0	0	4	0	0	0	0	0
Anorectal operation	0	0	0	4	0	0	0	0	0
Anticoagulant therapy	1	1	0	0	0	0	0	0	0
Antral lavage	0	0	0	1	0	0	0	0	0
Aortic bypass	0	0	0	1	0	0	0	0	0
Aortic valve replacement	1	0	0	1	0	0	0	0	0
Appendicectomy	21	0	0	19	0	0	7	0	0
Arm amputation	0	0	0	0	0	0	1	0	0
Arterial bypass operation	0	0	0	1	0	0	0	0	0
Arterial stent insertion	1	0	0	1	0	0	0	0	0
Arthroscopic surgery	2	0	0	0	0	0	0	0	0
Atherectomy	0	0	0	1	0	0	0	0	0
Benign breast lump removal	1	0	0	0	0	0	0	0	0
Benign tumour excision	1	0	0	0	0	0	0	0	0
Bile duct stent insertion	0	0	0	1	0	0	0	0	0
Bladder catheterisation	0	0	0	1	0	0	0	0	0
Bladder operation	0	0	0	1	0	0	1	0	0
Blepharoplasty	0	0	0	0	1	0	0	0	0
Bone debridement	0	0	0	0	0	0	1	0	0
Bone lesion excision	1	0	0	0	0	0	0	0	0
Bone operation	0	0	0	1	0	0	0	0	0
Brachytherapy	0	0	0	1	0	0	0	0	0
Brain tumour operation	1	0	0	0	0	0	0	0	0
Breast cosmetic surgery	1	0	0	2	0	0	1	0	0

Subjects are counted only once for each specific disease/syndrome in the table body.
MedDRA (v9.0) coding dictionary applied.

	maraviroc QD			maraviroc BID			Placebo		
Number of Subjects	414			426			209		
	Past	Present	Unknown	Past	Present	Unknown	Past	Present	Unknown
Breast cyst excision	0	0	0	1	0	0	0	0	0
Breast operation	0	0	0	2	0	0	0	0	0
Breast prosthesis removal	0	0	0	1	0	0	0	0	0
Bunion operation	0	0	0	1	0	0	0	0	0
Caecum operation	0	0	0	1	0	0	0	0	0
Caesarean section	4	0	0	3	0	0	0	0	0
Cardiac operation	1	0	0	0	0	0	0	0	0
Carpal tunnel decompression	0	0	0	2	0	0	0	0	0
Cartilage operation	0	0	0	0	0	0	1	0	0
Cataract operation	1	0	0	0	0	0	2	0	0
Catheter placement	2	0	0	0	0	0	0	0	0
Catheter removal	1	0	0	0	0	0	0	0	0
Central venous catheterisation	2	0	0	0	1	0	0	0	0
Cervical polypectomy	1	0	0	0	0	0	0	0	0
Cervix operation	0	0	0	1	0	0	0	0	0
Chemotherapy	1	0	0	1	0	0	0	0	0
Chemotherapy single agent local	0	0	0	0	1	0	0	0	0
Cholecystectomy	12	0	0	13	0	0	2	0	0
Cholecystostomy	1	0	0	0	0	0	0	0	0
Cholelithotomy	0	0	0	1	0	0	0	0	0
Circumcision	1	0	0	0	0	0	1	0	0
Cleft palate repair	0	0	0	0	0	0	1	0	0
Colectomy	1	0	0	1	0	0	0	0	0
Colostomy	0	0	0	0	1	0	0	1	0
Coronary angioplasty	2	0	0	3	1	0	0	0	0
Coronary arterial stent insertion	5	0	0	4	0	0	1	0	0
Coronary artery surgery	2	0	0	4	0	0	3	1	0
Cryotherapy	0	0	0	1	0	0	0	0	0

Subjects are counted only once for each specific disease/syndrome in the table body.
MedDRA (v9.0) coding dictionary applied.

	maraviroc QD			maraviroc BID			Placebo		
Number of Subjects	414			426			209		
	Past	Present	Unknown	Past	Present	Unknown	Past	Present	Unknown
Cyst removal	1	0	0	2	0	0	0	0	0
Cystopexy	0	0	0	1	0	0	0	0	0
Dental prosthesis placement	0	0	0	0	1	0	0	0	0
Dialysis	0	0	0	1	0	0	0	0	0
Diaphragmatic operation	1	0	0	0	0	0	0	0	0
Drug delivery device implantation	1	0	0	0	0	0	0	0	0
Drug withdrawal maintenance therapy	0	0	0	0	0	0	0	1	0
Ear tube insertion	0	1	0	0	0	0	1	0	0
Endodontic procedure	1	0	0	0	0	0	0	0	0
Enteral nutrition	0	0	0	0	0	0	0	1	0
Ethmoid sinus surgery	0	0	0	1	0	0	0	0	0
Eustachian tube operation	0	0	0	0	0	0	0	1	0
Explorative laparotomy	0	0	0	1	0	0	0	0	0
Eye laser surgery	1	0	0	0	0	0	1	0	0
Eye muscle tenotomy	0	0	0	1	0	0	0	0	0
Eye operation	2	0	0	2	0	0	0	0	0
Eyelid operation	1	0	0	0	0	0	0	0	0
Facial operation	0	0	0	1	0	0	0	0	0
Fistula repair	0	0	0	1	0	0	0	0	0
Foot operation	0	0	0	1	0	0	0	0	0
Fracture treatment	1	0	0	0	0	0	0	0	0
Fulguration	1	0	0	0	0	0	0	0	0
Gallbladder operation	0	0	0	1	0	0	0	0	0
Gastrectomy	0	0	0	0	0	0	1	0	0
Gastric bypass	0	0	0	1	0	0	0	0	0
Gastric operation	0	0	0	1	0	0	0	0	0
Gastrointestinal tube insertion	0	0	0	1	0	0	0	0	0
Gastrostomy tube insertion	0	0	0	0	0	0	0	1	0

Subjects are counted only once for each specific disease/syndrome in the table body.
MedDRA (v9.0) coding dictionary applied.

	maraviroc QD			maraviroc BID			Placebo		
Number of Subjects	414			426			209		
	Past	Present	Unknown	Past	Present	Unknown	Past	Present	Unknown
Haemorrhoid operation	4	0	0	3	0	0	2	0	0
Hair transplant	0	0	0	1	0	0	1	0	0
Hernia repair	6	0	0	7	0	0	2	1	0
Hip arthroplasty	7	1	0	3	0	0	3	0	0
Hormone replacement therapy	0	0	0	0	0	0	1	0	0
Hysterectomy	5	0	0	5	0	0	5	0	0
Incisional drainage	0	0	0	2	0	0	0	0	0
Inguinal hernia repair	5	0	0	9	0	0	5	0	0
Injection	3	0	0	0	0	0	0	0	0
Intervertebral disc operation	0	0	0	3	0	0	3	0	0
Intestinal resection	1	0	0	0	0	0	0	0	0
Intra-nasal antrostomy	0	0	0	1	0	0	0	0	0
Jaw operation	1	0	0	0	0	0	0	0	0
Joint surgery	1	0	0	0	0	0	0	0	0
Knee arthroplasty	0	0	0	1	0	0	0	0	0
Knee meniscectomy	1	0	0	1	0	0	0	0	0
Knee operation	1	0	0	1	0	0	2	0	0
Lacrimal duct procedure	0	0	0	1	0	0	0	0	0
Laparotomy	0	0	0	1	0	0	0	0	0
Laser therapy	1	0	0	1	0	0	0	0	0
Ligament operation	0	0	0	2	0	0	2	0	0
Limb operation	0	0	0	2	0	0	0	0	0
Lipectomy	1	0	0	0	0	0	1	0	0
Lipoma excision	1	0	0	1	0	0	0	0	0
Liposuction	1	1	0	1	0	0	0	0	0
Lithotripsy	0	0	0	0	0	0	0	1	0
Loop electrosurgical excision procedure	0	1	0	0	0	0	0	0	0
Lung cyst removal	0	0	0	0	0	0	1	0	0

Subjects are counted only once for each specific disease/syndrome in the table body.
MedDRA (v9.0) coding dictionary applied.

	maraviroc QD			maraviroc BID			Placebo		
Number of Subjects	414			426			209		
	Past	Present	Unknown	Past	Present	Unknown	Past	Present	Unknown
Lung lobectomy	0	0	0	0	0	0	1	0	0
Lymphadenectomy	2	0	0	2	0	0	1	0	0
Malignant tumour excision	3	0	0	0	0	0	1	0	0
Mass excision	1	0	0	0	0	0	0	0	0
Medical device implantation	1	0	0	0	0	0	0	0	0
Meniscus operation	0	0	0	2	0	0	0	0	0
Myomectomy	1	0	0	0	0	0	0	0	0
Myringotomy	1	0	0	0	0	0	0	1	0
Nasal septal operation	0	0	0	1	0	0	0	0	0
Nephrectomy	0	0	0	1	0	0	0	0	0
Oesophageal dilation procedure	0	0	0	1	0	0	0	0	0
Oophorectomy	1	0	0	1	0	0	0	0	0
Oral surgery	0	0	0	0	0	0	1	0	0
Orbit plastic repair	1	0	0	0	0	0	0	0	0
Orthopedic procedure	1	0	0	0	0	0	0	0	0
Osteosynthesis	0	0	0	1	0	0	0	0	0
Packed red blood cell transfusion	2	0	0	0	0	0	0	0	0
Pancreatic operation	0	0	0	1	0	0	0	0	0
Pancreatic pseudocyst drainage	0	0	0	1	0	0	0	0	0
Parenteral nutrition	0	0	0	0	0	0	0	1	0
Parotid cyst excision	0	0	0	1	0	0	0	0	0
Parotidectomy	1	0	0	0	0	0	1	0	0
Patent ductus arteriosus repair	0	0	0	0	0	0	1	0	0
Pelvic exenteration	0	0	0	1	0	0	0	0	0
Phlebectomy	0	0	0	1	0	0	1	0	0
Phlebotomy	0	0	0	1	0	0	0	0	0
Pilonidal sinus repair	2	0	0	0	0	0	0	0	0
Plastic surgery to the face	1	0	0	1	0	0	0	0	0

Subjects are counted only once for each specific disease/syndrome in the table body.
MedDRA (v9.0) coding dictionary applied.

	maraviroc QD			maraviroc BID			Placebo		
Number of Subjects	414			426			209		
	Past	Present	Unknown	Past	Present	Unknown	Past	Present	Unknown
Pneumonectomy	0	0	0	0	0	0	1	0	0
Polypectomy	1	0	0	0	0	0	0	0	0
Prophylaxis	0	1	0	1	0	0	0	0	0
Prostatectomy	1	0	0	0	0	0	0	0	0
Psychotherapy	0	0	0	1	0	0	0	0	0
Radiotherapy	0	0	0	2	0	0	1	0	0
Radiotherapy to skin	1	0	0	0	0	0	0	0	0
Rectal fistula repair	2	0	0	0	0	0	0	0	0
Rectal polypectomy	1	0	0	0	0	0	0	0	0
Removal of internal fixation	0	0	0	1	0	0	0	0	0
Renal stone removal	1	0	0	0	0	0	0	0	0
Repair of imperforate rectum	0	0	0	1	0	0	0	0	0
Rhinoplasty	4	0	0	1	0	0	0	0	0
Rotator cuff repair	0	0	0	1	0	0	0	0	0
Salivary gland operation	0	1	0	0	0	0	0	0	0
Salpingectomy	2	0	0	0	0	0	0	0	0
Sarcoma excision	0	0	0	1	0	0	0	0	0
Scar excision	1	0	0	0	0	0	0	0	0
Septoplasty	1	0	0	1	0	0	1	0	0
Severed digit reimplantation	0	0	0	1	0	0	0	0	0
Shoulder arthroplasty	1	0	0	0	0	0	0	0	0
Shoulder operation	1	0	0	1	0	0	0	0	0
Sinus operation	1	2	0	1	0	0	2	0	0
Skin cosmetic procedure	2	0	0	0	0	0	0	0	0
Skin graft	0	0	0	1	0	0	1	0	0
Skin lesion excision	1	0	0	1	0	0	0	0	0
Skin neoplasm excision	4	0	0	3	0	0	2	0	0
Skin operation	1	0	0	1	0	0	0	0	0

Subjects are counted only once for each specific disease/syndrome in the table body.
MedDRA (v9.0) coding dictionary applied.

Table 3.3.2.2
Maraviroc Summary of Clinical Safety
Medical History
Phase 3 Treatment Experienced CCR5 Tropic Studies

	maraviroc QD			maraviroc BID			Placebo		
Number of Subjects	414			426			209		
	Past	Present	Unknown	Past	Present	Unknown	Past	Present	Unknown
Small intestinal resection	1	0	0	0	0	0	0	0	0
Spinal fusion surgery	0	0	0	0	0	0	2	0	0
Spinal laminectomy	1	0	0	1	0	0	0	0	0
Spinal operation	0	0	0	1	0	0	0	0	0
Splenectomy	0	0	0	1	0	0	2	0	0
Stent placement	0	0	0	1	0	0	0	0	0
Stent removal	0	0	0	1	0	0	0	0	0
Sterilisation	0	0	0	1	0	0	1	0	0
Surgery	1	0	0	0	0	0	0	0	0
Temporomandibular joint surgery	1	0	0	0	0	0	0	0	0
Tendon repair	0	0	0	1	0	0	1	0	0
Tendon sheath lesion excision	0	0	0	1	0	0	0	0	0
Therapeutic procedure	1	0	0	0	0	0	0	0	0
Thoracic operation	0	0	0	0	0	0	1	0	0
Thoracotomy	1	0	0	0	0	0	0	0	0
Thyroid nodule removal	0	0	0	1	0	0	0	0	0
Thyroidectomy	4	0	0	0	0	0	1	0	0
Toe operation	0	0	0	1	0	0	0	0	0
Tonsillectomy	16	0	0	13	0	0	5	0	0
Tooth extraction	2	1	0	0	1	0	0	1	0
Tracheostomy	1	0	0	0	0	0	0	0	0
Transgender operation	0	0	0	1	0	0	0	0	0
Tubal ligation	3	1	0	4	0	0	0	1	0
Tumour excision	2	0	0	1	0	0	1	0	0
Turbinectomy	2	0	0	0	0	0	0	0	0
Umbilical hernia repair	3	0	0	5	0	0	0	0	0
Ureteric operation	0	0	0	1	0	0	0	0	0
Uvuloplasty	0	0	0	1	0	0	0	0	0

Subjects are counted only once for each specific disease/syndrome in the table body.
MedDRA (v9.0) coding dictionary applied.

	maraviroc QD			maraviroc BID			Placebo		
Number of Subjects	414			426			209		
	Past	Present	Unknown	Past	Present	Unknown	Past	Present	Unknown
Vaginal operation	0	0	0	1	0	0	0	0	0
Varicose vein operation	1	1	0	0	0	0	2	0	0
Vasectomy	0	0	0	1	0	0	0	0	0
Vulvectomy	2	0	0	0	0	0	0	0	0
Wart excision	4	1	0	6	1	0	4	0	0
Weight control	0	1	0	0	0	0	0	0	0
Whole blood transfusion	0	0	0	2	0	0	1	0	0
Wisdom teeth removal	1	0	0	0	0	0	0	0	0
Wound debridement	1	0	0	0	0	0	0	0	0
Wrist surgery	0	0	0	1	0	0	0	0	0
Vascular disorders	26	82	0	26	96	0	19	46	0
Aortic stenosis	0	1	0	0	0	0	0	0	0
Arterial disorder	0	1	0	0	2	0	0	1	0
Arterial thrombosis limb	0	0	0	1	0	0	1	0	0
Arteriosclerosis	0	1	0	0	0	0	0	0	0
Blood pressure fluctuation	0	0	0	0	1	0	0	0	0
Deep vein thrombosis	4	1	0	10	2	0	5	0	0
Hot flush	1	0	0	0	1	0	1	1	0
Hypertension	11	74	0	8	86	0	7	41	0
Hypotension	0	2	0	0	1	0	0	0	0
Iliac artery occlusion	0	0	0	0	1	0	0	0	0
Microangiopathy	1	0	0	0	0	0	0	0	0
Orthostatic hypotension	3	0	0	1	1	0	0	0	0
Pallor	0	0	0	1	0	0	0	0	0
Peripheral arterial occlusive disease	0	0	0	0	1	0	1	0	0
Peripheral vascular disorder	0	0	0	0	0	0	0	1	0
Phlebitis	2	0	0	0	0	0	1	0	0
Phlebitis superficial	1	0	0	0	0	0	0	0	0

Subjects are counted only once for each specific disease/syndrome in the table body.
MedDRA (v9.0) coding dictionary applied.

Table 3.3.2.2
Maraviroc Summary of Clinical Safety
Medical History
Phase 3 Treatment Experienced CCR5 Tropic Studies

	maraviroc QD			maraviroc BID			Placebo		
Number of Subjects	414			426			209		
	Past	Present	Unknown	Past	Present	Unknown	Past	Present	Unknown
Prehypertension	0	1	0	0	0	0	0	0	0
Raynaud's phenomenon	0	0	0	2	0	0	0	1	0
Subclavian artery stenosis	1	0	0	0	0	0	0	0	0
Thrombophlebitis	1	0	0	1	0	0	1	0	0
Thrombosis	1	0	0	1	0	0	1	0	0
Varicose vein	1	1	0	1	1	0	1	2	0
Vascular calcification	0	0	0	1	1	0	0	0	0
Vasculitis	1	1	0	1	0	0	0	1	0
Venous insufficiency	0	0	0	0	0	0	0	1	0
Venous stasis	0	0	0	1	0	0	0	0	0
Venous thrombosis	1	0	0	0	0	0	0	0	0

Subjects are counted only once for each specific disease/syndrome in the table body.
MedDRA (v9.0) coding dictionary applied.

	maraviroc QD	maraviroc BID	Placebo
Number of Subjects	414	426	209
Number (%) of Subjects With Any Drug Treatment	362 (87.4)	382 (89.7)	192 (91.9)
ACEBUTOLOL	1	0	0
ACETORPHAN	1	1	0
ACETYLCARNITINE	0	3	0
ACETYLCYSTEINE	4	5	2
ACETYLSALICYLATE LYSINE	0	1	0
ACETYLSALICYLIC ACID	34	41	22
ACICLOVIR	61	67	33
ACIPIMOX	0	0	1
ADAPALENE	1	0	0
ALBENDAZOLE	1	1	0
ALBUMIN HUMAN	1	0	0
ALCLOMETASONE DIPROPIONATE	1	0	0
ALENDRONATE SODIUM	4	3	2
ALENDRONIC ACID	3	0	0
ALIMEMAZINE	1	0	0
ALKALOL	1	0	0
ALL OTHER THERAPEUTIC PRODUCTS	0	1	0
ALLEGRA-D	4	4	2
ALLERGOSPASMIN	1	0	0
ALLOPURINOL	2	7	3
ALOE BARBADENSIS	1	1	0
ALPHA-D-GALACTOSIDASE	0	1	0
ALPRAZOLAM	15	22	11
ALPROSTADIL	1	1	0
ALTEPLASE	1	0	0
ALUMINIUM ACETATE	1	0	0
ALUMINIUM HYDROXIDE/DIPHENHYDRAMINE/MAGNESIUM HYDROXIDE/LIDOCAINE	1	1	0
ALUMINIUM MAGNESIUM SILICATE	0	0	1
AMCINONIDE	0	2	0
AMILORIDE W/HYDROCHLOROTHIAZIDE	0	1	0
AMINO ACIDS	1	2	0
AMITRIPTYLINE	11	9	5
AMITRIPTYLINE HYDROCHLORIDE	1	3	5
AMLODIPINE	1	3	2
AMLODIPINE BESILATE	9	9	2
AMMONIUM LACTATE	3	2	1

Excludes both optimized background therapy and anti-retroviral medication.

	maraviroc QD	maraviroc BID	Placebo
AMOSAN	0	1	0
AMOXICILLIN	3	2	2
AMOXICILLIN TRIHYDRATE	0	1	0
AMPHOTERICIN B	3	2	1
ANABOLIC STEROIDS	0	1	0
ANDROGENS	0	1	1
ANDROSTENEDIONE	0	1	0
ANTIMIGRAINE PREPARATIONS	1	0	0
ANTIOXIDANTS	0	2	0
ANUSOL	0	2	0
ANUSOL-HC	1	0	0
ARGININE	2	1	0
ARGININE/BETA-HYDROXY-BETA-METHYLBUTYRATE/GLUTAMINE	0	1	1
ARIPIPRAZOLE	0	1	0
ARTHROTEC	0	1	1
ASASANTIN	1	0	0
ASCORBIC ACID	15	19	12
ATENOLOL	14	10	6
ATOMOXETINE HYDROCHLORIDE	0	2	0
ATORVASTATIN	25	32	10
ATORVASTATIN CALCIUM	0	2	2
ATOVAQUONE	15	13	7
ATROPINE SULFATE	0	1	0
AXOTAL (OLD FORM)	0	1	1
AZELASTINE	1	0	1
AZELASTINE HYDROCHLORIDE	1	1	1
AZITHROMYCIN	62	68	37
AZITHROMYCIN DIHYDRATE	0	1	0
B-KOMPLEX "LECIVA"	4	2	3
BACLOFEN	3	2	0
sulfamethoxazole/trimethoprim*	140	163	72
BAMIPINE LACTATE	0	1	0
BECLOMETASONE	0	1	0
BECLOMETASONE DIPROPIONATE	2	0	1
BECOSYM FORTE	5	2	1
BEMINAL WITH C FORTIS	1	0	0
BENAZEPRIL	2	0	0
BENAZEPRIL HYDROCHLORIDE	0	0	1

Excludes both optimized background therapy and anti-retroviral medication.

* ：新薬承認情報提供時に置換えた。

	maraviroc QD	maraviroc BID	Placebo
BENFLUOREX	0	1	0
BENZATROPINE MESILATE	2	0	0
BENZOYL PEROXIDE	1	1	0
BETACAROTENE	1	2	1
BETAMETHASONE	1	0	0
BETAMETHASONE DIPROPIONATE	0	0	1
BETAMETHASONE VALERATE	2	0	0
BEZAFIBRATE	1	1	0
BIMATOPROST	2	0	0
BISACODYL	0	0	1
BISOPROLOL	1	1	0
BISOPROLOL FUMARATE	0	2	0
BLOPRESS PLUS	0	1	0
BOOST	0	1	0
BORAGE OIL	0	1	0
BOSENTAN	1	0	0
BRIMONIDINE TARTRATE/TIMOLOL MALEATE	1	0	0
BROMAZEPAM	2	2	2
BUDESONIDE	2	4	2
BUPROPION	5	4	4
BUPROPION HYDROCHLORIDE	20	14	5
BUSPIRONE	0	1	0
BUSPIRONE HYDROCHLORIDE	2	0	0
CALCITONIN, SALMON	1	0	0
CALCIUM	10	8	5
CALCIUM ASCORBATE	0	0	1
CALCIUM CARBONATE	8	2	1
CALCIUM CITRATE	2	1	0
CALCIUM FOLINATE	5	1	2
CALCIUM W/MAGNESIUM	2	1	1
CALCIUM WITH VITAMIN D	1	0	0
CALCIUM, COMBINATIONS WITH OTHER DRUGS	1	0	0
CALCIUM/MINERALS NOS	1	0	0
CANDESARTAN	0	2	0
CANDESARTAN CILEXETIL	0	1	0
CANESTEN-HC	0	1	0
CANNABIS	0	1	0
CAPSAICIN	1	0	0

Excludes both optimized background therapy and anti-retroviral medication.

	maraviroc QD	maraviroc BID	Placebo
CAPTOPRIL	2	1	0
CARBAMAZEPINE	1	2	1
CARISOPRODOL	1	2	0
CARNITINE	2	0	1
CARVEDILOL	0	3	0
CASPOFUNGIN	1	0	0
CASPOFUNGIN ACETATE	1	0	0
CEFALEXIN	3	0	0
CEFALEXIN MONOHYDRATE	2	1	0
CEFPODOXIME	0	1	0
CEFTRIAXONE	0	1	0
CEFUROXIME	1	0	0
CELECOXIB	0	4	1
CELIPROLOL	0	1	0
CENTRUM	2	5	3
CENTRUM SILVER	0	1	0
CETIRIZINE	2	1	2
CETIRIZINE HYDROCHLORIDE	8	13	3
CETIRIZINE/PSEUDOEPHEDRINE	1	0	1
CEVIMELINE HYDROCHLORIDE	0	2	0
CHARCOAL, ACTIVATED	0	1	0
CHERATUSSIN COUGH SYRUP	1	0	0
CHLORHEXIDINE	0	0	1
CHLOROPHYLLIN SODIUM COPPER COMPLEX	1	0	0
CHLORPHENAMINE	1	0	0
CHLORPROMAZINE HYDROCHLORIDE	0	0	2
CHLORTALIDONE	0	1	0
CHOLESTEROL- AND TRIGLYCERIDE REDUCERS	0	1	0
CHOLINE MAGNESIUM TRISALICYLATE	1	0	0
CHONDROITIN/GLUCOSAMINE	2	0	0
CHONDROITIN/GLUCOSAMINE/METHYLSULFONYLMETHANE	0	1	0
CHORIONIC GONADOTROPHIN	1	0	0
CHROMIUM	0	1	0
CHROMIUM PICOLINATE	0	1	0
CICLOPIROX OLAMINE	0	2	0
CILAZAPRIL	1	1	0
CILEST	0	1	0
CIMETIDINE	1	0	0

Excludes both optimized background therapy and anti-retroviral medication.

	maraviroc QD	maraviroc BID	Placebo
CINCHOCAINE HCL/ESCULOSIDE/HYDROCORTISONE ACETATE/NEOMYCIN SULFATE	0	1	0
CIPROFLOXACIN	4	2	4
CIPROFLOXACIN HYDROCHLORIDE	1	0	0
CITALOPRAM	5	4	3
CITALOPRAM HYDROBROMIDE	7	3	5
CITRACAL + D	1	0	0
CLARITHROMYCIN	2	4	2
CLAVULIN	0	1	1
CLINDAMYCIN	5	0	0
CLINDAMYCIN HYDROCHLORIDE	1	0	0
CLINDAMYCIN PHOSPHATE	0	2	0
CLOBETASOL PROPIONATE	1	0	1
CLOBUTINOL HYDROCHLORIDE	0	0	1
CLONAZEPAM	16	17	7
CLONIDINE	4	0	1
CLONIDINE HYDROCHLORIDE	0	1	0
CLOPIDOGREL	3	1	0
CLOPIDOGREL SULFATE	2	0	0
CLORAZEPATE DIPOTASSIUM	0	0	1
CLOTRASON	0	1	0
CLOTRIMAZOLE	7	5	5
CLOXACILLIN	0	1	0
CO-DIOVAN	1	0	0
COAL TAR	1	0	0
COCAINE	0	1	0
COD-LIVER OIL	1	0	0
CODEINE	1	0	0
CODICLEAR	1	1	0
COLCHICINE	0	4	0
COLESEVELAM HYDROCHLORIDE	0	1	0
COLESTYRAMINE	1	0	1
COLOSTRUM	0	1	0
COMBINATIONS OF VITAMINS	1	0	0
COMBIVENT	0	0	1
COMTREX	1	0	0
COPPER	1	0	0
CORTICOSTEROID NOS	1	0	0
CORTICOSTEROIDS	0	0	1

Excludes both optimized background therapy and anti-retroviral medication.

	maraviroc QD	maraviroc BID	Placebo
CORTISONE ACETATE	1	1	0
COSOPT	3	1	0
CREATINE	1	0	0
CROMOGLICATE SODIUM	0	1	1
CROTAMITON	0	0	1
CYANOCOBALAMIN	14	16	8
CYCLOBENZAPRINE	0	2	2
CYCLOBENZAPRINE HYDROCHLORIDE	3	1	0
CYNARA SCOLYMUS	0	1	0
CYPROHEPTADINE	2	0	0
DAPSONE	35	36	21
DARBEPOETIN ALFA	1	1	0
DAY & NIGHT COLD & FLU TABLETS	0	1	0
DESIPRAMINE	1	0	0
DESLORATADINE	3	2	2
DESONIDE	0	2	0
DESOXIMETASONE	0	1	0
DEXA-RHINOSPRAY N	1	0	0
DEXAMETHASONE	0	1	0
DEXAMFETAMINE	0	0	2
DEXAMYTREX	1	0	0
DEXPANTHENOL/RETINOL PALMITATE/UREA	0	1	0
DEXTROPROPOXYPHENE NAPSILATE	1	0	0
DIAGNOSTIC AGENTS	1	0	0
DIAZEPAM	11	9	6
DICLOFENAC	2	3	0
DICLOFENAC POTASSIUM	0	0	1
DICLOFENAC SODIUM	1	4	3
DICYCLOVERINE	1	0	0
DIGESTIVES, INCL ENZYMES	1	0	0
DIGOXIN	1	1	1
DIHYDROCODEINE	1	1	0
DILTIAZEM	0	3	0
DILTIAZEM HYDROCHLORIDE	2	1	1
DIMENHYDRINATE	1	1	0
DIMETICONE, ACTIVATED	1	1	1
DIOSMIN	0	1	0
DIPHENHYDRAMINE	3	2	1

Excludes both optimized background therapy and anti-retroviral medication.

	maraviroc QD	maraviroc BID	Placebo
DIPHENHYDRAMINE HYDROCHLORIDE	3	7	1
DIPHENOXYLATE	2	0	1
DOCUSATE	1	1	0
DOCUSATE SODIUM	2	2	2
DOLASETRON MESILATE	0	0	1
DOMPERIDONE	0	1	2
DONEPEZIL HYDROCHLORIDE	0	2	0
DONTISOLON	1	0	0
DOSULEPIN	0	0	1
DOXAZOSIN	0	2	2
DOXAZOSIN MESILATE	1	1	0
DOXEPIN	3	3	0
DOXORUBICIN HYDROCHLORIDE	0	1	0
DOXYCYCLINE	4	5	2
DOXYLAMINE SUCCINATE	1	0	0
DRIXORAL	0	1	0
DRONABINOL	10	12	9
DROPERIDOL	1	0	0
DROTAVERINE HYDROCHLORIDE	0	0	1
DULOXETINE HYDROCHLORIDE	2	2	1
DUTASTERIDE	0	3	0
DYAZIDE	2	3	2
E45	1	0	0
ECHINACEA	1	0	1
ECONAZOLE NITRATE	1	0	0
EDUCTYL	0	1	0
EMEDASTINE FUMARATE	0	1	0
EMOLLIENTS AND PROTECTIVES	2	1	0
ENALAPRIL	6	2	2
ENALAPRIL MALEATE	1	3	2
ENSURE	6	0	1
ENSURE PLUS	0	1	1
EPINEPHRINE	1	0	0
EPOETIN ALFA	1	1	2
EPROSARTAN MESILATE/HYDROCHLOROTHIAZIDE	1	1	0
EPTACOG ALFA	1	0	0
ERGOCALCIFEROL	4	1	0
ERYTHROPOIETIN	9	6	2

Excludes both optimized background therapy and anti-retroviral medication.

	maraviroc QD	maraviroc BID	Placebo
ERYTHROPOIETIN HUMAN	0	1	0
ESCITALOPRAM	9	12	6
ESOMEPRAZOLE	10	14	5
ESOMEPRAZOLE MAGNESIUM	1	1	0
ESTAZOLAM	0	1	0
ESTRADIOL	3	1	0
ESTRADIOL VALERATE	0	2	0
ESTROGENS	0	1	0
ESTROGENS CONJUGATED	3	1	0
ESTROPIPATE	0	1	0
ESZOPICLONE	3	2	3
ETHAMBUTOL	4	4	2
ETHAMBUTOL DIHYDROCHLORIDE	1	1	0
ETHINYLESTRADIOL/NORELGESTROMIN	0	1	0
ETODOLAC	0	0	1
ETORICOXIB	0	1	0
EUCERIN CREME	0	1	0
EVENING PRIMROSE OIL	0	0	1
EXTENDRYL	0	1	0
EZETIMIBE	7	4	1
EZETIMIBE/SIMVASTATIN	0	1	0
FACTOR VIII (ANTIHAEMOPHILIC FACTOR)	0	1	0
FAMCICLOVIR	7	6	3
FAMOTIDINE	2	5	3
FANSIDAR	1	0	0
FAT/CARBOHYDRATES/PROTEINS/MINERALS/VITAMINS,	1	0	0
FELODIPINE	0	1	0
FENOFIBRATE	21	33	12
FENOTEROL HYDROBROMIDE	1	0	0
FENTANYL	4	5	2
FENTANYL CITRATE	0	1	0
FERRO "SANOL" /OLD FORM/	1	0	0
FERRO-FOLSAN	0	0	1
FERROUS FUMARATE	1	0	0
FERROUS GLYCINE SULFATE	1	0	0
FERROUS SULFATE	3	2	4
FEXOFENADINE	4	4	0
FEXOFENADINE HYDROCHLORIDE	8	6	4

Excludes both optimized background therapy and anti-retroviral medication.

	maraviroc QD	maraviroc BID	Placebo
FILGRASTIM	10	5	5
FINASTERIDE	2	2	4
FIORINAL-C 1/4	0	1	0
FISH OIL	17	15	4
FLECAINIDE ACETATE	0	1	0
FLOXIN OTIC	0	0	1
FLUCLOXACILLIN	0	0	1
FLUCONAZOLE	68	65	34
FLUDROCORTISONE	0	1	1
FLUDROCORTISONE ACETATE	2	2	0
FLUNISOLIDE	2	6	2
FLUOCINOLONE ACETONIDE	1	0	0
FLUOCINONIDE	1	0	1
FLUOROURACIL	1	2	0
FLUOXETINE	5	6	0
FLUOXETINE HYDROCHLORIDE	5	8	3
FLUPENTIXOL	1	0	0
FLUPHENAZINE DECANOATE	1	0	0
FLURAZEPAM	1	1	0
FLUTICASONE	5	2	3
FLUTICASONE PROPIONATE	17	12	5
FLUVASTATIN	2	2	0
FLUVASTATIN SODIUM	0	1	0
FLUVOXAMINE MALEATE	1	0	0
FOLIC ACID	7	7	4
FOLINIC ACID	1	1	2
FORMOTEROL FUMARATE	0	0	1
FOSCARNET	0	2	0
FOSCARNET SODIUM	1	0	0
FOSINOPRIL	2	3	0
FOSINOPRIL SODIUM	2	1	0
FRESUBIN	1	0	0
FUROSEMIDE	4	3	1
FUSIDATE SODIUM	0	1	0
FUSIDIC ACID	1	1	1
GABAPENTIN	25	25	17
GALENIC /FLUTICASONE/SALMETEROL/	1	0	0
GALENIC /GUAIFENESIN/HYDROCODONE/	1	0	0

Excludes both optimized background therapy and anti-retroviral medication.

	maraviroc QD	maraviroc BID	Placebo
GALENIC /PARACETAMOL/CODEINE/	0	0	1
GAMMA-AMINOBUTYRIC ACID	1	0	0
GANCICLOVIR	1	1	1
GARLIC	0	2	1
GATIFLOXACIN	0	2	0
GELATIN	0	1	0
GEMFIBROZIL	11	16	7
GENERAL NUTRIENTS	1	1	5
GENERAL NUTRIENTS/HERBAL NOS/MINERALS NOS/VITAMINS NOS	1	0	0
GENERAL NUTRIENTS/MINERALS/VITAMINS	0	0	1
GENERAL NUTRIENTS/VITAMINS NOS	2	0	0
GINKGO BILOBA	0	1	0
GINSENG	0	2	0
GIVALEX	0	1	0
GLIBENCLAMIDE	4	4	3
GLIBOMET	0	1	0
GLICLAZIDE	0	1	0
GLIMEPIRIDE	1	1	1
GLIPIZIDE	6	3	2
GLUCOSAMINE	2	1	2
GLUCOSAMINE WITH MSM	0	1	0
GLYCERYL TRINITRATE	1	0	0
GRANULOCYTE COLONY STIMULATING FACTOR	2	0	0
GUAIFENESIN	3	1	2
HARPAGOPHYTUM PROCUMBENS	0	1	0
HEPARIN-FRACTION, SODIUM SALT	1	1	0
HEPATITIS A VACCINE	1	0	0
HERBAL PREPARATION	0	2	0
HEXACHLOROPHENE	1	1	0
HOMEOPATIC PREPARATION	0	1	0
HUMULIN 70/30	1	0	0
HYDRALAZINE	0	1	0
HYDROCHLOROTHIAZIDE	7	13	5
HYDROCODONE	7	8	4
HYDROCORTISONE	4	7	4
HYDROCORTISONE ACETATE	0	2	0
HYDROCORTISONE VALERATE	1	0	0
HYDROMORPHONE	0	1	1

Excludes both optimized background therapy and anti-retroviral medication.

	maraviroc QD	maraviroc BID	Placebo
HYDROMORPHONE HYDROCHLORIDE	1	0	1
HYDROQUINONE	1	0	0
HYDROXYCHLOROQUINE	0	1	0
HYDROXYZINE	4	2	3
HYDROXYZINE HYDROCHLORIDE	3	4	5
HYOSCINE BUTYLBROMIDE	0	1	1
HYPROMELLOSE	0	1	0
HYZAAR	0	0	1
IBUPROFEN	26	44	15
IMIPRAMINE	0	1	0
IMIPRAMINE HYDROCHLORIDE	0	1	0
IMIQUIMOD	5	4	1
IMMUNOGLOBULIN HUMAN NORMAL	0	1	0
IMMUNOGLOBULINS	1	2	1
INDAPAMIDE	0	1	0
INDOMETACIN	1	0	0
INFLUENZA VACCINE	4	2	1
INFLUENZA VIRUS VACCINE POLYVALENT	0	0	1
INOSITOL	0	1	0
INSULIN	4	3	2
INSULIN ASPART	1	4	3
INSULIN GLARGINE	4	4	2
INSULIN HUMAN	1	1	0
INSULIN HUMAN INJECTION, ISOPHANE	1	0	0
INSULIN INJECTION, ISOPHANE	0	2	0
INSULIN ISOPHANE, HUMAN BIOSYNTHETIC	0	0	1
INSULIN LISPRO	2	0	0
INSULIN NOVOLIN 70/30	0	2	0
IODINE	0	1	0
IPRATROPIUM BROMIDE	1	1	0
IRBESARTAN	2	1	0
IRON	2	2	1
ISONIAZID	0	1	0
ISOSORBIDE	0	1	0
ISOSORBIDE DINITRATE	2	1	0
ISOSORBIDE MONONITRATE	1	0	0
ISPAGHULA HUSK	1	0	0
ITRACONAZOLE	9	6	2

Excludes both optimized background therapy and anti-retroviral medication.

	maraviroc QD	maraviroc BID	Placebo
IVERMECTIN	0	1	0
KALINOR-BRAUSETABLETTEN	0	1	0
KARVEA HCT	4	0	0
KETOCONAZOLE	5	9	3
KETOPROFEN	0	2	1
LACTIC ACID	1	0	0
LACTOBACILLUS ACIDOPHILUS	6	2	3
LACTULOSE	0	1	1
LAMOTRIGINE	2	0	2
LANREOTIDE	1	0	0
LANSOPRAZOLE	15	12	8
LATANOPROST	1	0	1
LAXATIVES	1	0	0
LECITHIN	2	1	0
LEKOVIT CA	2	0	0
LERCANIDIPINE	0	1	0
LEUPRORELIN	0	1	0
LEVETIRACETAM	0	2	0
LEVOCARNITINE	10	3	3
LEVOCETIRIZINE	1	0	0
LEVOFLOXACIN	5	2	1
LEVOGLUTAMIDE	4	0	1
LEVOSALBUTAMOL	1	0	0
LEVOTHYROXINE	3	5	0
LEVOTHYROXINE SODIUM	8	10	3
LIDOCAINE	1	2	0
LIDOCAINE HYDROCHLORIDE	2	1	0
LINSEED OIL	3	4	0
LIOTHYRONINE	1	0	0
LISINOPRIL	17	7	8
LITHIUM	1	1	1
LITHIUM CARBONATE	3	1	0
LOMOTIL	20	16	12
LOPERAMIDE	15	14	9
LOPERAMIDE HYDROCHLORIDE	15	25	16
LORATADINE	6	13	2
LORAZEPAM	18	25	13
LORMETAZEPAM	0	0	1

Excludes both optimized background therapy and anti-retroviral medication.

	maraviroc QD	maraviroc BID	Placebo
LOSARTAN	2	0	0
LOSARTAN POTASSIUM	2	2	2
LOTREL	0	3	0
LOTRISONE	2	2	1
LOVASTATIN	0	0	1
LOXAPINE	1	1	0
LYSINE	2	1	0
LYSPAFEN	0	1	0
MAALOX	1	0	0
MACROGOL	0	1	0
MAGNESIUM	1	3	0
MAGNESIUM HYDROXIDE	0	1	0
MAGNESIUM OXIDE	3	0	1
MAPROTILINE	0	0	1
MAXEPA	1	0	0
MAXIDEX	0	0	1
MECLOZINE	0	2	0
MECLOZINE HYDROCHLORIDE	0	1	0
MEDIVITAN N INJECTION	1	0	0
MEDROXYPROGESTERONE	1	0	0
MEDROXYPROGESTERONE ACETATE	1	0	0
MEGESTROL	1	0	1
MEGESTROL ACETATE	3	2	4
MELALEUCA ALTERNIFOLIA OIL	0	2	0
MELATONIN	1	3	1
MELOXICAM	2	4	2
MEMANTINE HYDROCHLORIDE	0	1	0
MEPREDNISONE	0	1	0
MESALAZINE	0	0	2
METAMIZOLE SODIUM	3	0	0
METFORMIN	12	5	4
METFORMIN HYDROCHLORIDE	3	5	4
METFORMIN HYDROCHLORIDE/ROSIGLITAZONE	2	0	1
METHADONE	2	2	5
METHADONE HYDROCHLORIDE	0	0	1
METHAMPHETAMINE	0	1	0
METHIONINE	1	0	0
METHOCARBAMOL	0	2	0

Excludes both optimized background therapy and anti-retroviral medication.

	maraviroc QD	maraviroc BID	Placebo
METHYLPHENIDATE	1	4	0
METHYLPHENIDATE HYDROCHLORIDE	3	2	1
METHYLPREDNISOLONE	0	0	3
METHYLSULFONYLMETHANE	1	0	0
METOCLOPRAMIDE	5	6	4
METOCLOPRAMIDE HYDROCHLORIDE	0	0	1
METOLAZONE	1	0	0
METOPROLOL	13	5	2
METOPROLOL SUCCINATE	2	12	1
METOPROLOL TARTRATE	4	3	0
METRONIDAZOLE	5	3	3
MEXILETINE	1	0	0
MIANSERIN	0	1	0
MICONAZOLE NITRATE	0	1	0
MIDRID	1	0	0
MINERALS NOS	2	1	0
MINOCYCLINE	3	1	0
MINOXIDIL	1	0	0
MIRTAZAPINE	7	9	7
MODAFINIL	2	0	0
MOMETASONE	1	0	3
MOMETASONE FUROATE	2	6	5
MONTELUKAST	0	1	1
MONTELUKAST SODIUM	6	6	1
MORPHINE	2	3	1
MORPHINE SULFATE	2	3	3
MOXIFLOXACIN	0	0	1
MOXIFLOXACIN HYDROCHLORIDE	1	1	0
MULTIPLE VITAMINS	0	2	1
MULTIVITAMIN AND MINERAL SUPPLEMENT	2	0	0
MULTIVITAMINS	15	14	3
MULTIVITAMINS WITH MINERALS	0	2	1
MULTIVITAMINS, PLAIN	45	49	26
MUPIROCIN	2	3	1
MYCOLOG	1	0	0
NABUMETONE	2	0	1
NADOLOL	0	0	1
NAFTIFINE HYDROCHLORIDE	0	0	1

Excludes both optimized background therapy and anti-retroviral medication.

	maraviroc QD	maraviroc BID	Placebo
NALTREXONE	0	1	1
NANDROLONE	5	5	2
NANDROLONE DECANOATE	4	6	5
NAPHAZOLINE HYDROCHLORIDE	0	1	0
NAPROXEN	5	5	3
NAPROXEN SODIUM	0	4	2
NARATRIPTAN HYDROCHLORIDE	0	1	0
NARINE REPETABS	2	2	1
NATEGLINIDE	0	1	0
NEBIVOLOL	0	1	0
NEFAZODONE HYDROCHLORIDE	0	2	0
NEUROTRAT S FORTE	1	0	0
NICOTINAMIDE	0	1	0
NICOTINE	3	1	2
NICOTINIC ACID	12	5	1
NIFEDIPINE	3	2	2
NITAZOXANIDE	1	0	0
NITRAZEPAM	0	0	1
NITROFURANTOIN	0	0	1
NIZATIDINE	0	1	0
NORTRIPTYLINE	0	2	0
NORTRIPTYLINE HYDROCHLORIDE	2	0	0
NOVOLIN 20/80	1	0	0
NYSTADERM COMP	1	0	0
NYSTADERMAL	0	1	0
NYSTATIN	9	3	2
OBETROL	0	0	1
OCADRIK	0	1	0
OCTREOTIDE	1	1	0
OCTREOTIDE ACETATE	0	0	1
OLANZAPINE	2	4	5
OLMESARTAN MEDOXOMIL	1	1	0
OLOPATADINE	0	0	1
OLOPATADINE HYDROCHLORIDE	0	1	0
OMEGA	0	0	1
OMEGA-3 MARINE TRIGLYCERIDES	0	2	0
OMEGA-3 TRIGLYCERIDES	5	4	0
OMEPRAZOLE	14	18	5

Excludes both optimized background therapy and anti-retroviral medication.

	maraviroc QD	maraviroc BID	Placebo
ONCE-A-DAY	0	0	1
ONDANSETRON	2	1	3
ONDANSETRON HYDROCHLORIDE	2	1	2
ONE-A-DAY	0	1	0
OPIPRAMOL	0	1	0
OPIUM TINCTURE	7	1	4
ORLISTAT	1	0	0
ORPHENADRINE	1	0	0
OSELTAMIVIR	1	0	0
OSMOSAL	1	0	0
OTOLOGICALS	0	1	0
OTOSPORIN	1	0	0
OXANDROLONE	10	16	11
OXAZEPAM	1	0	1
OXCARBAZEPINE	1	0	0
OXICONAZOLE	0	1	0
OXYBUTYNIN	1	1	1
OXYBUTYNIN HYDROCHLORIDE	2	0	0
OXYCOCET	3	5	7
OXYCODONE	5	7	3
OXYCODONE HYDROCHLORIDE	4	6	0
OXYGEN	0	1	0
OXYMETAZOLINE	0	1	0
OXYMETAZOLINE HYDROCHLORIDE	0	1	0
OXYMETHOLONE	1	0	1
PANADEINE CO	4	10	3
PANCREATIN	2	0	0
PANCRELIPASE	3	3	2
PANTOPRAZOLE	5	3	4
PANTOPRAZOLE SODIUM	2	3	2
PARA-SELTZER	0	1	0
PARACETAMOL	21	16	5
PARAMOL-118	1	0	0
PAREGORIC	0	0	2
PAROMOMYCIN	1	0	0
PAROMOMYCIN SULFATE	0	1	1
PAROXETINE	7	3	0
PAROXETINE HYDROCHLORIDE	5	6	2

Excludes both optimized background therapy and anti-retroviral medication.

	maraviroc QD	maraviroc BID	Placebo
PEGFILGRASTIM	0	2	0
PEMIROLAST POTASSIUM	0	1	0
PENICILLIN NOS	1	1	0
PENTAMIDINE	10	7	2
PENTAMIDINE DIMESILATE	1	0	0
PENTAMIDINE ISETHIONATE	2	2	1
PENTOXIFYLLINE	0	0	2
oxycodone/aspirin*	1	1	0
PERI-COLACE	0	0	1
PERINDOPRIL ERBUMINE	0	1	0
PHENAZOPYRIDINE	0	0	1
PHENERGAN WITH CODEINE	0	1	0
PHENTOLAMINE MESILATE	0	1	0
PHENYLEPHRINE HYDROCHLORIDE	1	0	0
PHENYTOIN	1	1	1
PHENYTOIN SODIUM	1	4	2
PHOSPHATE-SANDOZ	1	0	0
PHOSPHATIDYL CHOLINE	0	1	0
PHOSPHORUS	1	0	0
PILOCARPINE HYDROCHLORIDE	1	0	0
PIMECROLIMUS	1	2	0
PIOGLITAZONE	3	4	0
PIRBUTEROL	0	1	0
PIRBUTEROL ACETATE	1	0	0
PIRETANIDE	0	1	0
PITUITARY AND HYPOTHALAMIC HORMONES	0	2	0
PODOPHYLLOTOXIN	1	0	0
POLY-L-LACTIC ACID	1	1	1
POLYCARBOPHIL CALCIUM	0	1	0
POLYLACTIC ACID	1	0	0
POTASSIUM	3	3	1
POTASSIUM CHLORIDE	6	7	2
POTASSIUM CITRATE	0	1	0
POTASSIUM PHOSPHATE	1	1	0
PRASTERONE	3	5	0
PRAVASTATIN	8	6	1
PRAVASTATIN SODIUM	7	6	3
PRAZEPAM	0	1	1

Excludes both optimized background therapy and anti-retroviral medication.

* ：新薬承認情報提供時に置換えた。

	maraviroc QD	maraviroc BID	Placebo
PREDNICARBATE	0	1	0
PREDNISOLONE ACETATE	0	0	1
PREDNISONE	5	8	1
PREGABALIN	2	2	4
PRENATAL VITAMINS	1	3	0
PRIMIDONE	1	1	0
PRINZIDE	1	1	0
PRIORIN	0	1	0
PROCAINE	1	0	0
PROCHLORPERAZINE	4	2	2
PROCHLORPERAZINE EDISYLATE	0	2	1
PROCHLORPERAZINE MALEATE	1	0	0
PROCTOFOAM HC	1	0	0
PROMETHAZINE	0	3	0
PROPACET	2	4	1
PROPANOL	0	1	0
PROPOFOL	0	1	0
PROPRANOLOL	0	1	2
PROPRANOLOL HYDROCHLORIDE	0	2	0
PROTEIN SUPPLEMENTS	3	2	0
PSEUDOEPHEDRINE	3	2	2
PSEUDOEPHEDRINE HYDROCHLORIDE	2	2	1
PSYLLIUM	0	1	1
PSYLLIUM HYDROPHILIC MUCILLOID	2	3	1
PYRIDOXINE	1	1	0
PYRIDOXINE HYDROCHLORIDE	1	2	2
PYRIMETHAMINE	4	2	5
QUERCETIN	0	1	0
QUETIAPINE	1	2	0
QUETIAPINE FUMARATE	3	5	1
QUINAPRIL HYDROCHLORIDE	0	3	0
QUININE	0	1	0
QUININE SULFATE	1	2	0
RABEPRAZOLE SODIUM	6	4	2
RAMIPRIL	3	5	3
RANITIDINE	5	7	5
RANITIDINE HYDROCHLORIDE	3	1	2
REPAGLINIDE	0	1	0

Excludes both optimized background therapy and anti-retroviral medication.

	maraviroc QD	maraviroc BID	Placebo
RESPAIRE-SR-120	1	0	0
RETINOL	1	3	1
RHINARIS	0	0	1
RIBOFLAVIN	1	1	1
RIFABUTIN	0	3	0
RISEDRONATE SODIUM	3	2	0
RISPERIDONE	3	2	0
RIZATRIPTAN	2	0	0
RIZATRIPTAN BENZOATE	1	0	0
ROBITUSSIN-DM	2	0	0
ROPINIROLE HYDROCHLORIDE	1	0	0
ROSIGLITAZONE	1	1	0
ROSIGLITAZONE MALEATE	5	8	3
ROSUVASTATIN	7	2	3
SACCHAROMYCES BOULARDII	0	0	1
SALBUTAMOL	28	22	17
SALBUTAMOL SULFATE	2	0	0
SALICYLIC ACID	0	1	0
SALMETEROL XINAFOATE	2	1	1
SALMON OIL	1	1	0
SELEGILINE	1	0	1
SELENIDE SODIUM	0	1	0
SELENIUM	1	5	1
SELENIUM SULFIDE	1	0	0
SENNA	1	0	0
SENNA FRUIT	1	0	0
SERENOA REPENS	3	2	2
SERETIDE MITE	5	5	4
SERTRALINE	1	3	5
SERTRALINE HYDROCHLORIDE	7	12	4
SHARK-LIVER OIL	0	0	1
SILDENAFIL	5	8	5
SILDENAFIL CITRATE	16	16	5
SILYMARIN	2	5	1
SIMVASTATIN	1	0	2
SINEMET	0	0	1
SODIUM BICARBONATE	3	1	0
SODIUM CHLORIDE	1	2	1

Excludes both optimized background therapy and anti-retroviral medication.

	maraviroc QD	maraviroc BID	Placebo
SODIUM FLUORIDE	1	0	0
SOFTENERS, EMOLLIENTS	0	0	1
SOLIDAGO VIRGAUREA HERB	0	1	0
SOLIFENACIN SUCCINATE	1	0	0
SOLUTIONS FOR PARENTERAL NUTRITION	2	0	0
SOMATROPIN	9	6	4
SPIRONOLACTONE	0	2	0
SPIRULINA	0	2	0
SUCRALFATE	0	0	1
SULFACET-R	0	1	0
SULFACETAMIDE SODIUM	0	1	0
SULFADIAZINE	0	1	1
SULFAMETHOXAZOLE	1	3	2
SULFASALAZINE	1	1	0
SUMATRIPTAN	0	3	1
SUMATRIPTAN SUCCINATE	4	2	2
SUPER VITAMIN B COMPLEX	0	1	0
SUPRADYN	1	0	0
SUSTANON	1	1	0
SYMBICORT TURBUHALER "DRACO"	0	1	0
TACROLIMUS	1	0	1
TADALAFIL	8	9	5
TAMOXIFEN	0	1	0
TAMOXIFEN CITRATE	0	1	0
TAMSULOSIN	1	2	0
TAMSULOSIN HYDROCHLORIDE	4	5	3
TARAXACUM	0	1	0
TELITHROMYCIN	1	0	0
TELMISARTAN	0	1	0
TEMAZEPAM	13	15	8
TENOXICAM	0	0	1
TERAZOSIN	2	0	0
TERBINAFINE	2	0	0
TERBINAFINE HYDROCHLORIDE	2	3	1
TERBUTALINE	0	1	0
TESTOSTERONE	50	59	29
TESTOSTERONE CIPIONATE	9	7	8
TESTOSTERONE ENANTATE	2	3	1

Excludes both optimized background therapy and anti-retroviral medication.

	maraviroc QD	maraviroc BID	Placebo
TESTOSTERONE PROPIONATE	1	0	1
TESTOSTERONE UNDECANOATE	2	2	0
TETRACYCLINE	1	1	0
TETRAZEPAM	0	1	1
THALIDOMIDE	0	0	1
THERAGRAN	0	1	0
THIAMINE	0	1	0
THIAMINE HYDROCHLORIDE	0	0	2
THIOCTIC ACID	5	3	3
THOMAPYRIN N	1	2	0
THYROID	1	0	0
TIAGABINE HYDROCHLORIDE	0	1	1
TILACTASE	0	2	0
TIMOLOL	0	0	1
TINIDAZOLE	0	1	0
TIOTROPIUM	0	1	0
TIOTROPIUM BROMIDE	1	1	0
TIZANIDINE	0	0	1
TOBRADEX	2	0	0
TOCOPHEROL	8	13	7
TOCOPHERYL ACETATE	1	0	0
TOLAZAMIDE	0	0	1
TOLTERODINE L-TARTRATE	0	0	2
TOPIRAMATE	2	1	1
TRAMADOL	1	2	3
TRAMADOL HYDROCHLORIDE	0	3	1
TRANDOLAPRIL	1	1	0
TRAPIDIL	0	1	0
TRAZODONE	16	18	8
TRAZODONE HYDROCHLORIDE	1	0	1
TRETINOIN	0	4	0
TRIAMCINOLONE	3	7	3
TRIAMCINOLONE ACETONIDE	4	4	3
TRIAZOLAM	1	0	0
TRIFLURIDINE	0	1	0
TRIHEXYPHENIDYL	0	1	0
TRIHEXYPHENIDYL HYDROCHLORIDE	0	1	0
TRIMETAZIDINE	1	0	0

Excludes both optimized background therapy and anti-retroviral medication.

	maraviroc QD	maraviroc BID	Placebo
TRIMETHOBENZAMIDE HYDROCHLORIDE	0	0	1
TRIMETHOPRIM	1	1	0
TRIMIPRAMINE	1	0	0
TRIOBE	0	2	0
TYLENOL PM	0	5	0
TYLENOL SINUS MEDICATION	1	0	0
UBIDECARENONE	10	3	2
UMCKALOABO	0	0	1
URALYT URATO	0	0	1
UREA	0	1	0
UREMOL HC	0	1	0
VACCINIUM MACROCARPON	1	1	0
VALACICLOVIR	18	18	12
VALACICLOVIR HYDROCHLORIDE	19	21	12
VALDECOXIB	0	0	1
VALGANCICLOVIR	8	5	3
VALGANCICLOVIR HYDROCHLORIDE	6	6	2
VALPROATE SEMISODIUM	2	2	1
VALPROATE SODIUM	1	2	0
VALPROIC ACID	3	1	1
VALSARTAN	3	3	0
VARDENAFIL	2	1	1
VARDENAFIL HYDROCHLORIDE	2	9	3
VENLAFAXINE	4	5	2
VENLAFAXINE HYDROCHLORIDE	9	14	6
VERAPAMIL HYDROCHLORIDE	0	1	1
acetaminophen/hydrocodone bitartrate*	12	16	6
VICOPROFEN	0	1	1
VINCENTS TABLETS	0	1	0
VIT B1,IN COMBINATION WITH VITAMIN B6 AND B12	0	0	1
VITACAL	3	1	0
VITAMIN B	1	1	4
VITAMIN B-COMPLEX	4	3	1
VITAMIN B-COMPLEX WITH VITAMIN C	0	1	0
VITAMINS	0	2	1
VITAMINS, OTHER COMBINATIONS	1	0	0
VITIS VINIFERA EXTRACT	1	0	0
VORICONAZOLE	4	6	1

Excludes both optimized background therapy and anti-retroviral medication.

* ：新薬承認情報提供時に置換えた。

	maraviroc QD	maraviroc BID	Placebo
WARFARIN	3	4	1
WARFARIN SODIUM	3	4	0
ZALEPLON	2	1	0
ZINC	2	4	0
ZIPRASIDONE	1	0	0
ZIPRASIDONE HYDROCHLORIDE	1	1	0
ZOLMITRIPTAN	0	0	1
ZOLPIDEM	5	9	6
ZOLPIDEM TARTRATE	19	22	10
ZOPICLONE	2	4	3
ZUCLOPENTHIXOL DECANOATE	1	0	0

Excludes both optimized background therapy and anti-retroviral medication.

Table 3.3.3.2
Maraviroc Summary of Clinical Safety
HIV/AIDS Drug Treatment Prior to Start of Study Treatment
Phase 3 Treatment Experienced CCR5 Tropic Studies

	maraviroc QD	maraviroc BID	Placebo
Number of Subjects	414	426	209
Number (%) of Subjects With Any Drug Treatment	414 (100.0)	424 (99.5)	209 (100.0)
A-80987	0	0	1
ABACAVIR	284	287	143
ADEFOVIR	14	14	9
ALOVUDINE	2	2	0
AMDOXOVIR	0	1	0
AMPRENAVIR	211	207	97
ATAZANAVIR	156	122	62
AXD 455	1	0	0
BLINDED THERAPY	1	7	2
CAPRAVIRINE	3	2	0
DELAVIRDINE	54	48	27
DIDANOSINE	338	344	160
EFAVIRENZ	267	271	134
EMIVIRINE	0	1	0
EMTRICITABINE	86	92	46
ENFUVIRTIDE	138	142	62
HYDROXYCARBAMIDE	44	47	16
INDINAVIR	267	255	127

Low-dose Ritonavir is doses of 200mg BID and below.
Amprenavir and Fosamprenavir have been combined and reported as Amprenavir.
Salt forms have been reported under the name of the active drug substance to which they correspond.
Fixed dose combinations have been slpit into individual components.

Table 3.3.3.2
Maraviroc Summary of Clinical Safety
HIV/AIDS Drug Treatment Prior to Start of Study Treatment
Phase 3 Treatment Experienced CCR5 Tropic Studies

	maraviroc QD	maraviroc BID	Placebo
INVESTIGATIONAL DRUG	10	8	2
LAMIVUDINE	393	393	195
LOPINAVIR	297	303	157
LOVIRIDE	3	2	2
NELFINAVIR	240	233	110
NEVIRAPINE	230	225	118
R-278474	0	1	0
RITONAVIR	378	384	198
RITONAVIR LOW-DOSE	11	16	10
SAQUINAVIR	266	265	135
STAVUDINE	354	344	167
T-1249	1	1	0
TENOFOVIR	322	320	171
TIPRANAVIR	59	74	44
TMC-114	6	1	4
VICRIVIROC	1	0	0
ZALCITABINE	136	111	63
ZIDOVUDINE	347	343	172

Low-dose Ritonavir is doses of 200mg BID and below.
Amprenavir and Fosamprenavir have been combined and reported as Amprenavir.
Salt forms have been reported under the name of the active drug substance to which they correspond.
Fixed dose combinations have been slpit into individual components.

Table 3.3.3.3
Maraviroc Summary of Clinical Safety
Summary of ARV Drug Treatment Experience Prior to Start of Study Treatment
Phase 3 Treatment Experienced CCR5 Tropic Studies

	maraviroc QD (N=414)*	maraviroc BID (N=426)*	Placebo (N=209)*
Median Number of ARVs taken	11	11	11
Median Duration (years) of ARVs	9.9	9.8	10.0
Minimum, Maximum Duration (years) of ARVs	0.1, 20.6	0.0, 39.1	1.1, 19.2

* This is the number of subjects in the treatment group in the indicated population.
ARVs are Antiretrovirals.
Different preferred terms count as one ARV.
Combination drugs have been split into individual ARVs so each component drug contributes as one drug in the count of ARVs.

Table 3.3.3.4
Maraviroc Summary of Clinical Safety
Summary of ARV Drug Treatment Experience Prior to Start of Study Treatment
Phase 2b Treatment Experienced Non-CCR5 Tropic Studies

	maraviroc QD (N=63)*	maraviroc BID (N=61)*	Placebo (N=62)*
Median Number of ARVs taken	12	10	11
Median Duration (years) of ARVs	9.6	9.4	9.0
Minimum, Maximum Duration (years) of ARVs	1.3, 17.4	1.2, 21.3	1.2, 19.3

* This is the number of subjects in the treatment group in the indicated population.
ARVs are Antiretrovirals.
Different preferred terms count as one ARV.
Combination drugs have been split into individual ARVs so each component drug contributes as one drug in the count of ARVs.

Table 3.3.3.5
Maraviroc Summary of Clinical Safety
Non-Drug Treatment Prior to Start of Study Treatment
Phase 3 Treatment Experienced CCR5 Tropic Studies

	maraviroc QD		maraviroc BID		Placebo	
Number of Subjects	414		426		209	
Number (%) of Subjects With Any Nondrug Treatment:	17	(4.1)	14	(3.3)	7	(3.3)
INFECTIONS AND INFESTATIONS	1	(0.2)	0		0	
Catheter sepsis	1		0		0	
INVESTIGATIONS	10	(2.4)	5	(1.2)	1	(0.5)
Biopsy cervix	0		0		1	
Chest X-ray	2		0		0	
Computerised tomogram	1		1		0	
Computerised tomogram abdomen	2		1		0	
Computerised tomogram thorax	1		0		0	
Electrocardiogram	1		0		0	
Electrocardiogram ambulatory	1		0		0	
Exercise electrocardiogram	1		0		0	
Nuclear magnetic resonance imaging	1		1		0	
Nuclear magnetic resonance imaging abdominal	1		0		0	
Proctoscopy	2		1		0	
Scan myocardial perfusion	1		0		0	
Ultrasound abdomen	1		0		0	
Ultrasound scan	1		0		0	
X-ray	1		0		0	
X-ray limb	0		1		0	
X-ray limb normal	0		1		0	

Includes investigations and procedures.

	maraviroc QD		maraviroc BID		Placebo	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	1	(0.2)	0		0	
Basal cell carcinoma	1		0		0	
SURGICAL AND MEDICAL PROCEDURES	9	(2.2)	9	(2.1)	7	(3.3)
Acupuncture	0		0		3	
Bladder catheterisation	0		1		0	
Catheter removal	1		0		0	
Central venous catheterisation	1		0		0	
Chiropractic	1		1		0	
Cholecystectomy	1		0		0	
Continuous positive airway pressure	0		0		1	
Cryotherapy	2		0		0	
Ear irrigation	0		1		0	
Haemorrhoid operation	0		1		0	
Intervertebral disc operation	0		0		1	
Malignant tumour excision	0		1		0	
Massage	1		0		1	
Medical diet	1		0		0	
Nutritional support	0		2		0	
Office visit	1		0		1	
Photodynamic therapy	0		1		0	
Phototherapy	1		0		0	
Psychotherapy	0		0		1	

Includes investigations and procedures.

Maraviroc Summary of Clinical Safety
Non-Drug Treatment Prior to Start of Study Treatment
Phase 3 Treatment Experienced CCR5 Tropic Studies

	maraviroc QD	maraviroc BID	Placebo
Skin lesion excision	0	1	0
Skin neoplasm excision	0	1	0
Therapeutic procedure	1	0	0
Wart excision	1	0	0
Whole blood transfusion	0	1	0

Includes investigations and procedures.

Table 3.4.1.1
Maraviroc Summary of Clinical Safety
Treatment-Emergent Adverse Events (All Causalities)
Phase 2b/3 Studies All Maraviroc Therapy

	maraviroc	
	n	(%)
Number (%) of subjects:		
Subjects evaluable for adverse events	1212	
Number of adverse events	5808	
Subjects with adverse events	1054	(87.0)
Subjects with serious adverse events	169	(13.9)
Subjects with grade 3 adverse events	222	(18.3)
Subjects with grade 4 adverse events	112	(9.2)
Subjects discontinued due to adverse events	56	(4.6)
Subjects with dose reduced or temporary discontinuation due to adverse events	61	(5.0)

Includes data up to 7 days after last dose of study drug.
Except for the Number of Adverse Events subjects are counted only once per treatment in each row.
Serious Adverse Events - according to the investigator's assessment.
For the grade 3/grade 4 rows, if the same subject in a given treatment had more than one occurrence in the same preferred term event category, only the most severe (grade 4) occurrence is taken. If the same subject had two different preferred term events, one classified as grade 3, one as grade 4, they will be present in both rows.
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.
For protocol 1026 only the QD arm is included. For 1027 and 1028 both blinded and open label treatment are included.

Table 3.4.1.2
Maraviroc Summary of Clinical Safety
Treatment-Emergent Adverse Events by System Organ Class (All Causalities)
Phase 2b/3 Studies All Maraviroc Therapy

	maraviroc	
	n	(%)
Number (%) of Subjects:		
Evaluable for adverse events	1212	
With adverse events	1054	(87.0)
Discontinued due to adverse events	56	(4.6)
Number (%) of Subjects with Adverse Events by System Organ Class:		
Blood and lymphatic system disorders	88	(7.3)
Cardiac disorders	25	(2.1)
Congenital, familial and genetic disorders	2	(0.2)
Ear and labyrinth disorders	44	(3.6)
Endocrine disorders	13	(1.1)
Eye disorders	101	(8.3)
Gastrointestinal disorders	585	(48.3)
General disorders and administration site conditions	406	(33.5)
Hepatobiliary disorders	32	(2.6)
Immune system disorders	29	(2.4)
Infections and infestations	561	(46.3)
Injury, poisoning and procedural complications	79	(6.5)
Investigations	207	(17.1)
Metabolism and nutrition disorders	144	(11.9)
Musculoskeletal and connective tissue disorders	232	(19.1)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	60	(5.0)
Nervous system disorders	384	(31.7)
Pregnancy, puerperium and perinatal conditions	2	(0.2)
Psychiatric disorders	215	(17.7)
Renal and urinary disorders	92	(7.6)
Reproductive system and breast disorders	64	(5.3)
Respiratory, thoracic and mediastinal disorders	265	(21.9)
Skin and subcutaneous tissue disorders	323	(26.7)
Social circumstances	4	(0.3)
Surgical and medical procedures	21	(1.7)
Vascular disorders	61	(5.0)

Subjects are only counted once per treatment for each row.
Includes data up to 7 days after last dose of study drug.
MedDRA (v9.0) coding dictionary applied.
For protocol 1026 only the QD arm is included. For 1027 and 1028 both blinded and open label treatment are included.

Table 3.4.1.3
Maraviroc Summary of Clinical Safety
Incidence and Severity of Treatment-Emergent Adverse Events (All Causalities)
Phase 2b/3 Studies All Maraviroc Therapy

Number of Subjects evaluable for adverse events	maraviroc (n=1212)					
			Severity Grade*			
	N	(%)	1	2	3	4
System Organ Class and MedDRA (v9.0) preferred term						
BLOOD AND LYMPHATIC SYSTEM DISORDERS	88	(7.3)	33	26	15	14
Anaemia	40	(3.3)	15	13	6	6
Bone marrow failure	1	(0.1)	0	1	0	0
Coagulopathy	1	(0.1)	1	0	0	0
Febrile neutropenia	1	(0.1)	0	1	0	0
Haemolytic anaemia	1	(0.1)	0	0	0	1
Iron deficiency anaemia	1	(0.1)	1	0	0	0
Leukopenia	1	(0.1)	0	1	0	0
Lymph node pain	2	(0.2)	2	0	0	0
Lymphadenitis	2	(0.2)	1	0	0	1
Lymphadenopathy	21	(1.7)	14	7	0	0
Neutropenia	21	(1.7)	1	5	8	7
Pancytopenia	3	(0.2)	0	1	2	0
Splenomegaly	1	(0.1)	0	0	0	1
Thrombocytopenia	1	(0.1)	0	1	0	0
CARDIAC DISORDERS	25	(2.1)	10	5	7	3
Acute myocardial infarction	1	(0.1)	0	0	1	0
Angina pectoris	3	(0.2)	2	0	1	0
Angina unstable	2	(0.2)	1	0	1	0
Arrhythmia	1	(0.1)	0	0	0	1
Atrioventricular block first degree	3	(0.2)	3	0	0	0
Bradycardia	3	(0.2)	0	3	0	0

* If the same subject in a given treatment had more than one occurrence in the same preferred term event category, only the most severe occurrence is taken. Subjects are counted only once per treatment in each row. For the TESS algorithm any missing severities have been imputed as grade 4 unless the subject experienced another occurrence of the same event in a given treatment for which severity was recorded.
In this case, the reported severity is summarized. Missing baseline severities are imputed as grade 1.
Includes data up to 7 days after last dose of study drug.
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.
For protocol 1026 only the QD arm is included. For 1027 and 1028 both blinded and open label treatment are included.

Table 3.4.1.3
Maraviroc Summary of Clinical Safety
Incidence and Severity of Treatment-Emergent Adverse Events (All Causalities)
Phase 2b/3 Studies All Maraviroc Therapy

Number of Subjects evaluable for adverse events	maraviroc (n=1212)					
			Severity Grade*			
	N	(%)	1	2	3	4
System Organ Class and MedDRA (v9.0) preferred term						
Cardiac failure acute	1	(0.1)	0	0	0	1
Coronary artery disease	2	(0.2)	0	1	1	0
Coronary artery occlusion	2	(0.2)	0	1	1	0
Myocardial infarction	2	(0.2)	0	0	1	1
Myocardial ischaemia	2	(0.2)	1	0	1	0
Palpitations	3	(0.2)	3	0	0	0
Pericardial effusion	1	(0.1)	0	0	1	0
Prinzmetal angina	1	(0.1)	0	1	0	0
Sinus bradycardia	1	(0.1)	1	0	0	0
Tachycardia	3	(0.2)	2	1	0	0
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	2	(0.2)	2	0	0	0
Gilbert's syndrome	1	(0.1)	1	0	0	0
Hydrocele	1	(0.1)	1	0	0	0
EAR AND LABYRINTH DISORDERS	44	(3.6)	31	11	2	0
Cerumen impaction	4	(0.3)	3	1	0	0
Deafness	2	(0.2)	2	0	0	0
Ear congestion	2	(0.2)	1	1	0	0
Ear discomfort	3	(0.2)	2	1	0	0
Ear disorder	1	(0.1)	1	0	0	0
Ear haemorrhage	1	(0.1)	1	0	0	0
Ear pain	9	(0.7)	6	3	0	0
Hyperacusis	1	(0.1)	1	0	0	0

* If the same subject in a given treatment had more than one occurrence in the same preferred term event category, only the most severe occurrence is taken. Subjects are counted only once per treatment in each row. For the TESS algorithm any missing severities have been imputed as grade 4 unless the subject experienced another occurrence of the same event in a given treatment for which severity was recorded.
In this case, the reported severity is summarized. Missing baseline severities are imputed as grade 1.
Includes data up to 7 days after last dose of study drug.
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.
For protocol 1026 only the QD arm is included. For 1027 and 1028 both blinded and open label treatment are included.

Table 3.4.1.3
Maraviroc Summary of Clinical Safety
Incidence and Severity of Treatment-Emergent Adverse Events (All Causalities)
Phase 2b/3 Studies All Maraviroc Therapy

Number of Subjects evaluable for adverse events	maraviroc (n=1212)					
			Severity Grade*			
	N	(%)	1	2	3	4
System Organ Class and MedDRA (v9.0) preferred term						
Motion sickness	2	(0.2)	1	1	0	0
Otorrhoea	2	(0.2)	2	0	0	0
Tinnitus	7	(0.6)	5	2	0	0
Tympanic membrane hyperaemia	1	(0.1)	1	0	0	0
Vertigo	12	(1.0)	8	2	2	0
Vertigo positional	1	(0.1)	1	0	0	0
ENDOCRINE DISORDERS	13	(1.1)	6	7	0	0
Adrenal insufficiency	1	(0.1)	0	1	0	0
Adrenal mass	1	(0.1)	1	0	0	0
Basedow's disease	1	(0.1)	1	0	0	0
Hypogonadism	6	(0.5)	3	3	0	0
Hypothyroidism	4	(0.3)	1	3	0	0
EYE DISORDERS	101	(8.3)	72	25	2	2
Amblyopia	1	(0.1)	1	0	0	0
Blepharitis	1	(0.1)	1	0	0	0
Blindness unilateral	1	(0.1)	0	0	0	1
Cataract	2	(0.2)	2	0	0	0
Cataract subcapsular	1	(0.1)	1	0	0	0
Conjunctival irritation	1	(0.1)	1	0	0	0
Conjunctivitis	19	(1.6)	13	6	0	0
Conjunctivitis allergic	1	(0.1)	1	0	0	0
Dacryoadenitis acquired	1	(0.1)	1	0	0	0

* If the same subject in a given treatment had more than one occurrence in the same preferred term event category, only the most severe occurrence is taken.
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Includes data up to 7 days after last dose of study drug.
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MedDRA (v9.0) coding dictionary applied.
For protocol 1026 only the QD arm is included. For 1027 and 1028 both blinded and open label treatment are included.

Table 3.4.1.3
Maraviroc Summary of Clinical Safety
Incidence and Severity of Treatment-Emergent Adverse Events (All Causalities)
Phase 2b/3 Studies All Maraviroc Therapy

Number of Subjects evaluable for adverse events	maraviroc (n=1212)					
			Severity Grade*			
	N	(%)	1	2	3	4
System Organ Class and MedDRA (v9.0) preferred term						
Diplopia	2	(0.2)	1	0	1	0
Dry eye	10	(0.8)	6	4	0	0
Erythema of eyelid	1	(0.1)	1	0	0	0
Exophthalmos	1	(0.1)	0	0	1	0
Eye allergy	1	(0.1)	0	1	0	0
Eye disorder	1	(0.1)	1	0	0	0
Eye irritation	10	(0.8)	10	0	0	0
Eye oedema	1	(0.1)	1	0	0	0
Eye pain	7	(0.6)	6	1	0	0
Eye pruritus	3	(0.2)	3	0	0	0
Eyelid disorder	1	(0.1)	1	0	0	0
Eyelid oedema	2	(0.2)	2	0	0	0
Eyelid ptosis	1	(0.1)	1	0	0	0
Glaucoma	1	(0.1)	0	1	0	0
Keratoconjunctivitis sicca	1	(0.1)	1	0	0	0
Lacrimation increased	3	(0.2)	3	0	0	0
Ocular hyperaemia	6	(0.5)	5	1	0	0
Ocular icterus	5	(0.4)	3	2	0	0
Photophobia	1	(0.1)	1	0	0	0
Photopsia	2	(0.2)	1	1	0	0
Presbyopia	2	(0.2)	2	0	0	0
Punctate keratitis	1	(0.1)	1	0	0	0
Retinal detachment	2	(0.2)	0	2	0	0
Retinal tear	1	(0.1)	0	1	0	0
Scleritis	1	(0.1)	1	0	0	0
Strabismus	1	(0.1)	1	0	0	0

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			Severity Grade*			
	N	(%)	1	2	3	4
System Organ Class and MedDRA (v9.0) preferred term						
Vision blurred	13	(1.1)	10	3	0	0
Visual acuity reduced	4	(0.3)	2	1	1	0
Visual disturbance	7	(0.6)	4	2	0	1
Vitreous floaters	5	(0.4)	4	1	0	0
Vitritis	1	(0.1)	0	1	0	0
Xerophthalmia	1	(0.1)	1	0	0	0
GASTROINTESTINAL DISORDERS	585	(48.3)	339	208	31	7
Abdominal discomfort	9	(0.7)	7	2	0	0
Abdominal distension	38	(3.1)	30	7	1	0
Abdominal pain	60	(5.0)	33	22	5	0
Abdominal pain lower	6	(0.5)	6	0	0	0
Abdominal pain upper	42	(3.5)	27	12	2	1
Abdominal tenderness	4	(0.3)	3	1	0	0
Abnormal faeces	4	(0.3)	4	0	0	0
Anal fissure	1	(0.1)	0	1	0	0
Anal fistula	1	(0.1)	0	1	0	0
Anal haemorrhage	1	(0.1)	0	1	0	0
Anal ulcer	1	(0.1)	1	0	0	0
Anogenital dysplasia	1	(0.1)	0	1	0	0
Anorectal disorder	1	(0.1)	1	0	0	0
Aphthous stomatitis	17	(1.4)	12	5	0	0
Ascites	2	(0.2)	0	0	1	1
Bowel sounds abnormal	1	(0.1)	1	0	0	0
Chapped lips	1	(0.1)	1	0	0	0

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			Severity Grade*			
	N	(%)	1	2	3	4
System Organ Class and MedDRA (v9.0) preferred term						
Cheilitis	3	(0.2)	3	0	0	0
Colitis	1	(0.1)	1	0	0	0
Constipation	61	(5.0)	44	14	3	0
Diarrhoea	239	(19.7)	143	87	7	2
Diarrhoea haemorrhagic	1	(0.1)	0	0	0	1
Diverticulum intestinal haemorrhagic	1	(0.1)	0	0	0	1
Dry mouth	16	(1.3)	13	3	0	0
Dyspepsia	33	(2.7)	23	10	0	0
Dysphagia	6	(0.5)	2	2	1	1
Enteritis	3	(0.2)	1	2	0	0
Epigastric discomfort	1	(0.1)	1	0	0	0
Eructation	4	(0.3)	3	1	0	0
Faecal incontinence	1	(0.1)	0	1	0	0
Faeces discoloured	2	(0.2)	0	2	0	0
Faeces pale	2	(0.2)	2	0	0	0
Flatulence	38	(3.1)	31	7	0	0
Food poisoning	3	(0.2)	1	2	0	0
Gastritis	12	(1.0)	7	5	0	0
Gastrointestinal disorder	1	(0.1)	0	1	0	0
Gastrointestinal pain	1	(0.1)	1	0	0	0
Gastrooesophageal reflux disease	14	(1.2)	12	2	0	0
Gingival bleeding	1	(0.1)	1	0	0	0
Gingival pain	2	(0.2)	1	1	0	0
Gingivitis	9	(0.7)	6	3	0	0
Gingivitis ulcerative	1	(0.1)	1	0	0	0
Glossitis	1	(0.1)	1	0	0	0

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			Severity Grade*			
	N	(%)	1	2	3	4
System Organ Class and MedDRA (v9.0) preferred term						
Glossodynia	2	(0.2)	1	1	0	0
Haematochezia	6	(0.5)	4	1	1	0
Haemorrhoids	14	(1.2)	8	6	0	0
Hiatus hernia	2	(0.2)	2	0	0	0
Hypoaesthesia oral	6	(0.5)	5	1	0	0
Intestinal mass	1	(0.1)	0	1	0	0
Intestinal spasm	1	(0.1)	1	0	0	0
Leukoplakia oral	1	(0.1)	1	0	0	0
Lip blister	1	(0.1)	1	0	0	0
Mouth ulceration	10	(0.8)	8	2	0	0
Nausea	217	(17.9)	153	53	10	1
Odynophagia	2	(0.2)	0	1	0	1
Oesophagitis	1	(0.1)	1	0	0	0
Oral mucosal blistering	1	(0.1)	0	1	0	0
Oral pain	1	(0.1)	0	1	0	0
Oral soft tissue disorder	4	(0.3)	4	0	0	0
Painful defaecation	1	(0.1)	1	0	0	0
Pancreatitis	2	(0.2)	1	1	0	0
Paraesthesia oral	8	(0.7)	8	0	0	0
Parotid duct obstruction	1	(0.1)	0	1	0	0
Parotid gland enlargement	2	(0.2)	1	1	0	0
Proctalgia	4	(0.3)	3	1	0	0
Rectal haemorrhage	5	(0.4)	2	3	0	0
Rectal ulcer	2	(0.2)	0	0	1	1
Regurgitation of food	1	(0.1)	1	0	0	0
Retching	1	(0.1)	1	0	0	0

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Phase 2b/3 Studies All Maraviroc Therapy

Number of Subjects evaluable for adverse events	maraviroc (n=1212)					
			Severity Grade*			
	N	(%)	1	2	3	4
System Organ Class and MedDRA (v9.0) preferred term						
Salivary gland mucocoele	1	(0.1)	0	1	0	0
Salivary hypersecretion	1	(0.1)	0	1	0	0
Sensitivity of teeth	2	(0.2)	2	0	0	0
Small intestinal obstruction	1	(0.1)	0	0	1	0
Stomach discomfort	4	(0.3)	4	0	0	0
Stomatitis	2	(0.2)	2	0	0	0
Tongue disorder	2	(0.2)	2	0	0	0
Tongue ulceration	2	(0.2)	2	0	0	0
Tooth disorder	1	(0.1)	1	0	0	0
Toothache	8	(0.7)	2	5	1	0
Umbilical hernia	2	(0.2)	2	0	0	0
Varices oesophageal	1	(0.1)	0	0	0	1
Vomiting	103	(8.5)	69	26	7	1
GENERAL DISORDERS AND ADMINISTRATION SITE						
Adverse drug reaction	2	(0.2)	0	1	1	0
Asthenia	37	(3.1)	18	11	7	1
Axillary pain	2	(0.2)	2	0	0	0
Chest discomfort	4	(0.3)	4	0	0	0
Chest pain	20	(1.7)	6	6	6	2
Chills	13	(1.1)	11	1	1	0
Condition aggravated	1	(0.1)	1	0	0	0
Cyst	1	(0.1)	1	0	0	0
Drug intolerance	1	(0.1)	1	0	0	0

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			Severity Grade*			
	N	(%)	1	2	3	4
System Organ Class and MedDRA (v9.0) preferred term						
Facial pain	1	(0.1)	1	0	0	0
Fat tissue increased	8	(0.7)	5	3	0	0
Fatigue	148	(12.2)	97	43	8	0
Feeling abnormal	2	(0.2)	2	0	0	0
Feeling cold	1	(0.1)	0	1	0	0
Feeling drunk	1	(0.1)	1	0	0	0
Feeling hot	4	(0.3)	4	0	0	0
Gait disturbance	1	(0.1)	1	0	0	0
General physical health deterioration	1	(0.1)	0	1	0	0
Generalised oedema	1	(0.1)	1	0	0	0
Hernia pain	1	(0.1)	1	0	0	0
Hunger	1	(0.1)	1	0	0	0
Hyperthermia	1	(0.1)	0	1	0	0
Hypothermia	1	(0.1)	1	0	0	0
Impaired healing	1	(0.1)	1	0	0	0
Induration	4	(0.3)	2	2	0	0
Inflammation	4	(0.3)	2	2	0	0
Influenza like illness	10	(0.8)	7	3	0	0
Infusion site reaction	1	(0.1)	1	0	0	0
Injection site erythema	6	(0.5)	2	4	0	0
Injection site haemorrhage	1	(0.1)	0	1	0	0
Injection site induration	8	(0.7)	6	2	0	0
Injection site mass	1	(0.1)	1	0	0	0
Injection site nodule	9	(0.7)	7	2	0	0
Injection site pain	6	(0.5)	4	1	1	0
Injection site reaction	79	(6.5)	57	20	2	0

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			Severity Grade*			
	N	(%)	1	2	3	4
System Organ Class and MedDRA (v9.0) preferred term						
Injection site swelling	2	(0.2)	0	2	0	0
Injection site urticaria	2	(0.2)	2	0	0	0
Irritability	5	(0.4)	4	1	0	0
Local swelling	1	(0.1)	1	0	0	0
Malaise	11	(0.9)	7	3	1	0
Mass	1	(0.1)	0	0	0	1
Nodule	3	(0.2)	3	0	0	0
Oedema peripheral	27	(2.2)	20	6	1	0
Pain	17	(1.4)	12	5	0	0
Pitting oedema	1	(0.1)	1	0	0	0
Pyrexia	104	(8.6)	62	26	11	5
Thirst	2	(0.2)	1	1	0	0
Upper extremity mass	1	(0.1)	1	0	0	0
HEPATOBILIARY DISORDERS	32	(2.6)	14	4	8	6
Cholecystitis	1	(0.1)	0	0	1	0
Cholecystitis acute	1	(0.1)	0	0	1	0
Cholelithiasis	4	(0.3)	1	3	0	0
Hepatic cirrhosis	2	(0.2)	0	0	1	1
Hepatic failure	1	(0.1)	0	0	0	1
Hepatitis toxic	1	(0.1)	0	0	0	1
Hepatomegaly	4	(0.3)	3	1	0	0
Hepatosplenomegaly	3	(0.2)	3	0	0	0
Hyperbilirubinaemia	7	(0.6)	0	0	5	2
Jaundice	8	(0.7)	8	0	0	0

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			Severity Grade*			
	N	(%)	1	2	3	4
System Organ Class and MedDRA (v9.0) preferred term						
Jaundice cholestatic	1	(0.1)	0	0	0	1
Liver tenderness	1	(0.1)	1	0	0	0
Portal vein thrombosis	1	(0.1)	0	0	0	1
IMMUNE SYSTEM DISORDERS	29	(2.4)	16	6	6	1
Allergy to arthropod bite	1	(0.1)	1	0	0	0
Antiphospholipid syndrome	1	(0.1)	0	1	0	0
Drug hypersensitivity	6	(0.5)	0	3	3	0
Food allergy	1	(0.1)	1	0	0	0
Hypersensitivity	3	(0.2)	0	0	2	1
Immune reconstitution syndrome	2	(0.2)	1	0	1	0
Multiple allergies	2	(0.2)	2	0	0	0
Seasonal allergy	13	(1.1)	11	2	0	0
INFECTIONS AND INFESTATIONS	561	(46.3)	260	239	34	28
AIDS encephalopathy	1	(0.1)	0	1	0	0
Abdominal wall abscess	1	(0.1)	0	0	0	1
Abscess	3	(0.2)	1	2	0	0
Abscess limb	1	(0.1)	1	0	0	0
Abscess of eyelid	1	(0.1)	0	1	0	0
Acarodermatitis	2	(0.2)	0	2	0	0
Acquired immunodeficiency syndrome	1	(0.1)	0	0	0	1
Acute sinusitis	3	(0.2)	2	1	0	0
Acute tonsillitis	1	(0.1)	1	0	0	0

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Phase 2b/3 Studies All Maraviroc Therapy

Number of Subjects evaluable for adverse events	maraviroc (n=1212)					
			Severity Grade*			
	N	(%)	1	2	3	4
System Organ Class and MedDRA (v9.0) preferred term						
Amoebic colitis	1	(0.1)	0	1	0	0
Anal chlamydia infection	1	(0.1)	0	1	0	0
Appendicitis	1	(0.1)	0	0	1	0
Aspergillosis	2	(0.2)	0	1	0	1
Bacteraemia	1	(0.1)	0	1	0	0
Balanitis candida	1	(0.1)	1	0	0	0
Blister infected	2	(0.2)	2	0	0	0
Body tinea	5	(0.4)	3	2	0	0
Bronchitis	58	(4.8)	30	28	0	0
Bronchitis acute	7	(0.6)	5	2	0	0
Bronchitis bacterial	2	(0.2)	1	1	0	0
Bronchitis chronic	1	(0.1)	0	1	0	0
Bronchopneumonia	1	(0.1)	0	0	0	1
Campylobacter infection	2	(0.2)	1	0	1	0
Candidiasis	13	(1.1)	7	6	0	0
Carbuncle	2	(0.2)	1	1	0	0
Cavernous sinus thrombosis	1	(0.1)	0	0	0	1
Cellulitis	16	(1.3)	5	8	2	1
Cellulitis orbital	1	(0.1)	0	1	0	0
Cervicitis	1	(0.1)	1	0	0	0
Chest wall abscess	1	(0.1)	0	1	0	0
Chronic sinusitis	1	(0.1)	1	0	0	0
Clostridium difficile colitis	1	(0.1)	0	0	1	0
Condyloma acuminatum	26	(2.1)	17	7	1	1
Cystitis	4	(0.3)	2	2	0	0
Cytomegalovirus chorioretinitis	3	(0.2)	0	1	2	0

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Phase 2b/3 Studies All Maraviroc Therapy

Number of Subjects evaluable for adverse events	maraviroc (n=1212)					
			Severity Grade*			
	N	(%)	1	2	3	4
System Organ Class and MedDRA (v9.0) preferred term						
Cytomegalovirus gastrointestinal infection	1	(0.1)	0	1	0	0
Cytomegalovirus infection	1	(0.1)	0	1	0	0
Disseminated tuberculosis	1	(0.1)	0	0	0	1
Ear infection	9	(0.7)	3	5	1	0
Endocarditis	1	(0.1)	0	0	0	1
Erysipelas	1	(0.1)	0	1	0	0
Eye infection	3	(0.2)	2	1	0	0
Eyelid infection	3	(0.2)	1	2	0	0
Folliculitis	29	(2.4)	18	11	0	0
Fungal infection	3	(0.2)	1	1	0	1
Fungal rash	1	(0.1)	1	0	0	0
Fungal skin infection	8	(0.7)	7	1	0	0
Furuncle	4	(0.3)	2	2	0	0
Gangrene	1	(0.1)	0	1	0	0
Gastric infection	1	(0.1)	0	1	0	0
Gastritis viral	1	(0.1)	1	0	0	0
Gastroenteritis	13	(1.1)	4	7	2	0
Gastroenteritis bacterial	1	(0.1)	0	1	0	0
Gastroenteritis viral	8	(0.7)	6	1	1	0
Gastrointestinal infection	2	(0.2)	1	1	0	0
Genitourinary tract infection	1	(0.1)	0	0	0	1
Giardiasis	3	(0.2)	0	3	0	0
Gingival infection	1	(0.1)	1	0	0	0
Gonorrhoea	3	(0.2)	1	2	0	0
HIV infection	1	(0.1)	0	0	0	1
HIV wasting syndrome	1	(0.1)	0	1	0	0

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Includes data up to 7 days after last dose of study drug.
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MedDRA (v9.0) coding dictionary applied.
For protocol 1026 only the QD arm is included. For 1027 and 1028 both blinded and open label treatment are included.

Table 3.4.1.3
Maraviroc Summary of Clinical Safety
Incidence and Severity of Treatment-Emergent Adverse Events (All Causalities)
Phase 2b/3 Studies All Maraviroc Therapy

Number of Subjects evaluable for adverse events	maraviroc (n=1212)					
			Severity Grade*			
	N	(%)	1	2	3	4
System Organ Class and MedDRA (v9.0) preferred term						
Helicobacter gastritis	1	(0.1)	0	1	0	0
Helicobacter infection	1	(0.1)	1	0	0	0
Hepatitis C	5	(0.4)	4	1	0	0
Herpes simplex	52	(4.3)	32	18	2	0
Herpes virus infection	9	(0.7)	7	1	1	0
Herpes zoster	16	(1.3)	6	10	0	0
Histoplasmosis	1	(0.1)	0	1	0	0
Hordeolum	3	(0.2)	3	0	0	0
Human ehrlichiosis	1	(0.1)	0	1	0	0
Impetigo	1	(0.1)	0	1	0	0
Incision site infection	1	(0.1)	1	0	0	0
Infected sebaceous cyst	3	(0.2)	2	1	0	0
Infective myositis	1	(0.1)	0	0	0	1
Influenza	31	(2.6)	22	9	0	0
Injection site abscess	2	(0.2)	0	2	0	0
Injection site infection	2	(0.2)	2	0	0	0
Klebsiella sepsis	1	(0.1)	0	0	0	1
Laryngitis	1	(0.1)	0	1	0	0
Laryngopharyngitis	1	(0.1)	0	1	0	0
Lice infestation	1	(0.1)	1	0	0	0
Lobar pneumonia	2	(0.2)	1	1	0	0
Localised infection	4	(0.3)	1	3	0	0
Lower respiratory tract infection	8	(0.7)	5	3	0	0
Lymph gland infection	1	(0.1)	0	1	0	0
Lymphangitis	2	(0.2)	1	0	1	0
Malaria	1	(0.1)	0	1	0	0

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			Severity Grade*			
	N	(%)	1	2	3	4
System Organ Class and MedDRA (v9.0) preferred term						
Mastitis	1	(0.1)	0	1	0	0
Meningitis viral	2	(0.2)	0	1	0	1
Molluscum contagiosum	4	(0.3)	4	0	0	0
Mycobacterial infection	1	(0.1)	0	0	1	0
Mycobacterium avium complex infection	4	(0.3)	0	2	1	1
Mycoplasma infection	1	(0.1)	0	0	1	0
Nail bed infection	1	(0.1)	0	1	0	0
Nail candida	1	(0.1)	1	0	0	0
Nasopharyngitis	79	(6.5)	59	20	0	0
Neurosyphilis	1	(0.1)	0	1	0	0
Oesophageal candidiasis	17	(1.4)	2	9	1	5
Onychomycosis	11	(0.9)	6	5	0	0
Oral candidiasis	29	(2.4)	17	11	1	0
Oral fungal infection	2	(0.2)	0	2	0	0
Oral hairy leukoplakia	1	(0.1)	1	0	0	0
Oral infection	1	(0.1)	0	1	0	0
Oropharyngeal candidiasis	2	(0.2)	2	0	0	0
Osteomyelitis	1	(0.1)	0	1	0	0
Otitis externa	3	(0.2)	3	0	0	0
Otitis media	9	(0.7)	6	3	0	0
Papilloma viral infection	3	(0.2)	3	0	0	0
Parainfluenzae virus infection	1	(0.1)	1	0	0	0
Paronychia	1	(0.1)	0	1	0	0
Parotitis	1	(0.1)	0	1	0	0
Perianal abscess	1	(0.1)	0	1	0	0
Perirectal abscess	1	(0.1)	0	1	0	0

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Incidence and Severity of Treatment-Emergent Adverse Events (All Causalities)
Phase 2b/3 Studies All Maraviroc Therapy

Number of Subjects evaluable for adverse events	maraviroc (n=1212)					
			Severity Grade*			
	N	(%)	1	2	3	4
System Organ Class and MedDRA (v9.0) preferred term						
Pertussis	1	(0.1)	1	0	0	0
Pharyngeal candidiasis	1	(0.1)	1	0	0	0
Pharyngitis	14	(1.2)	6	7	1	0
Pharyngotonsillitis	1	(0.1)	1	0	0	0
Pneumococcal sepsis	1	(0.1)	0	0	1	0
Pneumocystis jiroveci pneumonia	7	(0.6)	0	2	1	4
Pneumonia	20	(1.7)	2	10	3	5
Pneumonia bacterial	3	(0.2)	1	1	0	1
Postoperative wound infection	2	(0.2)	1	1	0	0
Proctitis herpes	1	(0.1)	1	0	0	0
Progressive multifocal leukoencephalopathy	1	(0.1)	0	0	1	0
Pulmonary tuberculosis	1	(0.1)	0	0	1	0
Pyelonephritis	4	(0.3)	1	2	1	0
Rash pustular	3	(0.2)	2	1	0	0
Rectal abscess	1	(0.1)	0	0	1	0
Respiratory moniliasis	1	(0.1)	0	1	0	0
Respiratory tract infection	9	(0.7)	6	3	0	0
Rhinitis	15	(1.2)	10	5	0	0
Secondary syphilis	1	(0.1)	0	0	1	0
Septic shock	1	(0.1)	0	0	0	1
Sexual transmission of infection	1	(0.1)	1	0	0	0
Sinobronchitis	1	(0.1)	0	1	0	0
Sinusitis	46	(3.8)	21	22	2	1
Skin bacterial infection	2	(0.2)	0	2	0	0
Skin infection	1	(0.1)	0	0	1	0
Staphylococcal abscess	3	(0.2)	2	0	1	0

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Phase 2b/3 Studies All Maraviroc Therapy

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			Severity Grade*			
	N	(%)	1	2	3	4
System Organ Class and MedDRA (v9.0) preferred term						
Staphylococcal infection	9	(0.7)	4	5	0	0
Streptococcal infection	1	(0.1)	0	1	0	0
Subcutaneous abscess	7	(0.6)	1	6	0	0
Sycosis barbae	1	(0.1)	1	0	0	0
Syphilis	5	(0.4)	2	3	0	0
Tinea cruris	7	(0.6)	5	2	0	0
Tinea infection	1	(0.1)	1	0	0	0
Tinea pedis	8	(0.7)	5	3	0	0
Tinea versicolour	1	(0.1)	1	0	0	0
Tonsillitis	2	(0.2)	2	0	0	0
Tooth abscess	4	(0.3)	2	1	1	0
Tooth infection	2	(0.2)	1	1	0	0
Upper respiratory tract infection	108	(8.9)	67	40	1	0
Urethritis	1	(0.1)	0	1	0	0
Urethritis gonococcal	1	(0.1)	1	0	0	0
Urinary tract infection	14	(1.2)	8	5	1	0
Vaginal candidiasis	3	(0.2)	3	0	0	0
Vaginitis bacterial	1	(0.1)	0	1	0	0
Viral infection	4	(0.3)	2	2	0	0
Viral upper respiratory tract infection	8	(0.7)	7	1	0	0
Vulvitis	1	(0.1)	0	1	0	0
Vulvovaginal mycotic infection	1	(0.1)	0	1	0	0
Wound infection	1	(0.1)	1	0	0	0
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	79	(6.5)	41	31	7	0

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Table 3.4.1.3
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Incidence and Severity of Treatment-Emergent Adverse Events (All Causalities)
Phase 2b/3 Studies All Maraviroc Therapy

Number of Subjects evaluable for adverse events	maraviroc (n=1212)					
			Severity Grade*			
	N	(%)	1	2	3	4
System Organ Class and MedDRA (v9.0) preferred term						
Animal bite	1	(0.1)	1	0	0	0
Ankle fracture	2	(0.2)	0	1	1	0
Arthropod bite	2	(0.2)	2	0	0	0
Back injury	3	(0.2)	0	3	0	0
Bite	1	(0.1)	0	1	0	0
Burns first degree	1	(0.1)	1	0	0	0
Burns second degree	1	(0.1)	0	1	0	0
Contusion	7	(0.6)	6	1	0	0
Corneal abrasion	1	(0.1)	0	1	0	0
Ear injury	1	(0.1)	1	0	0	0
Epicondylitis	4	(0.3)	3	1	0	0
Excoriation	1	(0.1)	0	1	0	0
Facial bones fracture	1	(0.1)	0	0	1	0
Fall	5	(0.4)	2	2	1	0
Foot fracture	6	(0.5)	1	4	1	0
Hand fracture	2	(0.2)	2	0	0	0
Heat exhaustion	1	(0.1)	0	0	1	0
Heat stroke	1	(0.1)	1	0	0	0
Humerus fracture	1	(0.1)	0	1	0	0
Joint injury	2	(0.2)	1	1	0	0
Joint sprain	7	(0.6)	5	2	0	0
Laceration	1	(0.1)	0	1	0	0
Limb injury	1	(0.1)	0	1	0	0
Muscle injury	2	(0.2)	2	0	0	0
Muscle strain	2	(0.2)	1	1	0	0
Neck injury	1	(0.1)	0	1	0	0

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Table 3.4.1.3
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Incidence and Severity of Treatment-Emergent Adverse Events (All Causalities)
Phase 2b/3 Studies All Maraviroc Therapy

Number of Subjects evaluable for adverse events	maraviroc (n=1212)					
			Severity Grade*			
	N	(%)	1	2	3	4
System Organ Class and MedDRA (v9.0) preferred term						
Open wound	1	(0.1)	1	0	0	0
Post procedural complication	1	(0.1)	0	1	0	0
Post-traumatic pain	2	(0.2)	1	1	0	0
Procedural pain	3	(0.2)	1	1	1	0
Radiation skin injury	1	(0.1)	0	1	0	0
Rib fracture	6	(0.5)	2	3	1	0
Self mutilation	1	(0.1)	0	1	0	0
Skeletal injury	1	(0.1)	1	0	0	0
Skin laceration	7	(0.6)	5	1	1	0
Sternal fracture	1	(0.1)	0	0	1	0
Stress fracture	2	(0.2)	1	1	0	0
Sunburn	1	(0.1)	1	0	0	0
Venom poisoning	1	(0.1)	1	0	0	0
Whiplash injury	1	(0.1)	0	1	0	0
Wound	1	(0.1)	1	0	0	0
INVESTIGATIONS	207	(17.1)	70	59	49	29
Alanine aminotransferase increased	27	(2.2)	1	10	11	5
Aspartate aminotransferase	1	(0.1)	0	0	0	1
Aspartate aminotransferase increased	32	(2.6)	2	12	13	5
Aspiration biopsy	1	(0.1)	0	1	0	0
Aspiration bursa	1	(0.1)	0	1	0	0
Bacteria stool identified	1	(0.1)	0	1	0	0
Blast cells present	1	(0.1)	1	0	0	0
Bleeding time prolonged	1	(0.1)	1	0	0	0

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Phase 2b/3 Studies All Maraviroc Therapy

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			Severity Grade*			
	N	(%)	1	2	3	4
System Organ Class and MedDRA (v9.0) preferred term						
Blood alkaline phosphatase increased	2	(0.2)	1	0	1	0
Blood amylase	2	(0.2)	0	0	1	1
Blood amylase increased	7	(0.6)	1	2	3	1
Blood bilirubin	1	(0.1)	0	0	1	0
Blood bilirubin increased	12	(1.0)	2	5	4	1
Blood cholesterol increased	4	(0.3)	1	3	0	0
Blood creatine increased	2	(0.2)	0	2	0	0
Blood creatine phosphokinase increased	16	(1.3)	5	5	3	3
Blood creatinine increased	12	(1.0)	7	4	1	0
Blood glucose	1	(0.1)	0	0	1	0
Blood glucose increased	7	(0.6)	4	1	2	0
Blood iron decreased	1	(0.1)	0	1	0	0
Blood lactate dehydrogenase increased	5	(0.4)	1	3	0	1
Blood magnesium decreased	1	(0.1)	0	1	0	0
Blood potassium decreased	2	(0.2)	2	0	0	0
Blood potassium increased	1	(0.1)	0	1	0	0
Blood pressure increased	5	(0.4)	3	1	1	0
Blood sodium increased	1	(0.1)	1	0	0	0
Blood testosterone decreased	1	(0.1)	0	1	0	0
Blood triglycerides abnormal	1	(0.1)	0	0	0	1
Blood triglycerides increased	15	(1.2)	3	6	4	2
Blood urea increased	4	(0.3)	2	2	0	0
Blood uric acid increased	2	(0.2)	1	1	0	0
Blood urine present	1	(0.1)	1	0	0	0
Body temperature	1	(0.1)	1	0	0	0
Body temperature increased	3	(0.2)	2	1	0	0

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			Severity Grade*			
	N	(%)	1	2	3	4
System Organ Class and MedDRA (v9.0) preferred term						
Breath sounds abnormal	1	(0.1)	1	0	0	0
Cardiac murmur	1	(0.1)	0	1	0	0
Creatinine renal clearance decreased	1	(0.1)	0	1	0	0
Crystal urine	1	(0.1)	1	0	0	0
Cytomegalovirus antibody positive	1	(0.1)	1	0	0	0
Electrocardiogram QT prolonged	1	(0.1)	0	1	0	0
Electrocardiogram abnormal	1	(0.1)	1	0	0	0
Gamma-glutamyltransferase	2	(0.2)	0	0	2	0
Gamma-glutamyltransferase increased	17	(1.4)	1	3	5	8
Haematocrit decreased	3	(0.2)	3	0	0	0
Haemoglobin decreased	4	(0.3)	3	0	1	0
Heart rate increased	4	(0.3)	4	0	0	0
Hepatic enzyme increased	5	(0.4)	1	2	2	0
International normalised ratio increased	1	(0.1)	0	0	1	0
Investigation	1	(0.1)	0	1	0	0
Lipase	1	(0.1)	0	0	1	0
Lipase increased	6	(0.5)	1	0	3	2
Lipids increased	1	(0.1)	0	1	0	0
Liver function test abnormal	5	(0.4)	1	0	3	1
Neutrophil count abnormal	1	(0.1)	0	0	0	1
Neutrophil count decreased	3	(0.2)	1	0	1	1
Neutrophil count increased	4	(0.3)	0	0	2	2
Neutrophil hypersegmented morphology present	1	(0.1)	1	0	0	0
Nuclear magnetic resonance imaging brain	1	(0.1)	0	0	0	1
Platelet count decreased	1	(0.1)	0	1	0	0
Prostate examination abnormal	2	(0.2)	1	1	0	0

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Phase 2b/3 Studies All Maraviroc Therapy

Number of Subjects evaluable for adverse events	maraviroc (n=1212)					
			Severity Grade*			
	N	(%)	1	2	3	4
System Organ Class and MedDRA (v9.0) preferred term						
Prostatic specific antigen increased	1	(0.1)	0	1	0	0
Protein urine	3	(0.2)	1	2	0	0
Red blood cell count decreased	1	(0.1)	1	0	0	0
Syphilis test positive	2	(0.2)	2	0	0	0
Transaminases increased	3	(0.2)	0	1	1	1
Urine output decreased	1	(0.1)	0	1	0	0
Urine output increased	1	(0.1)	1	0	0	0
Viral load increased	1	(0.1)	1	0	0	0
Viral test	2	(0.2)	2	0	0	0
Weight decreased	37	(3.1)	22	15	0	0
Weight increased	10	(0.8)	9	1	0	0
White blood cell count decreased	1	(0.1)	0	0	1	0
METABOLISM AND NUTRITION DISORDERS	144	(11.9)	73	56	9	6
Alcohol intolerance	1	(0.1)	1	0	0	0
Anorexia	47	(3.9)	26	20	1	0
Cachexia	3	(0.2)	1	1	1	0
Central obesity	1	(0.1)	1	0	0	0
Decreased appetite	34	(2.8)	22	12	0	0
Dehydration	9	(0.7)	0	4	4	1
Diabetes mellitus	2	(0.2)	0	2	0	0
Diabetes mellitus non-insulin-dependent	1	(0.1)	0	0	0	1
Fluid retention	1	(0.1)	1	0	0	0
Food craving	1	(0.1)	0	1	0	0
Gout	8	(0.7)	4	3	0	1

* If the same subject in a given treatment had more than one occurrence in the same preferred term event category, only the most severe occurrence is taken. Subjects are counted only once per treatment in each row. For the TESS algorithm any missing severities have been imputed as grade 4 unless the subject experienced another occurrence of the same event in a given treatment for which severity was recorded.
In this case, the reported severity is summarized. Missing baseline severities are imputed as grade 1.
Includes data up to 7 days after last dose of study drug.
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.
For protocol 1026 only the QD arm is included. For 1027 and 1028 both blinded and open label treatment are included.

Table 3.4.1.3
Maraviroc Summary of Clinical Safety
Incidence and Severity of Treatment-Emergent Adverse Events (All Causalities)
Phase 2b/3 Studies All Maraviroc Therapy

Number of Subjects evaluable for adverse events	maraviroc (n=1212)					
			Severity Grade*			
	N	(%)	1	2	3	4
System Organ Class and MedDRA (v9.0) preferred term						
Hyperamylasaemia	1	(0.1)	1	0	0	0
Hypercholesterolaemia	1	(0.1)	0	0	0	1
Hypercreatininaemia	1	(0.1)	0	1	0	0
Hyperglycaemia	7	(0.6)	1	5	1	0
Hyperkalaemia	1	(0.1)	0	1	0	0
Hyperlipidaemia	5	(0.4)	3	1	1	0
Hypertriglyceridaemia	9	(0.7)	2	5	0	2
Hypervitaminosis	1	(0.1)	1	0	0	0
Hypocalcaemia	1	(0.1)	0	0	1	0
Hypoglycaemia	4	(0.3)	2	1	0	1
Hypokalaemia	4	(0.3)	0	3	1	0
Hyponatraemia	1	(0.1)	0	0	1	0
Hypovolaemia	1	(0.1)	0	1	0	0
Increased appetite	8	(0.7)	7	1	0	0
Insulin resistant diabetes	1	(0.1)	0	1	0	0
Iron deficiency	2	(0.2)	2	0	0	0
Polydipsia	1	(0.1)	1	0	0	0
Tetany	1	(0.1)	1	0	0	0
Vitamin B12 deficiency	2	(0.2)	2	0	0	0
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	232	(19.1)	145	66	15	6
Arthralgia	51	(4.2)	35	14	1	1
Arthritis	5	(0.4)	2	3	0	0
Arthropathy	1	(0.1)	1	0	0	0
Back pain	57	(4.7)	38	15	4	0

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			Severity Grade*			
	N	(%)	1	2	3	4
System Organ Class and MedDRA (v9.0) preferred term						
Bone pain	3	(0.2)	2	0	1	0
Bursitis	4	(0.3)	3	1	0	0
Buttock pain	1	(0.1)	0	1	0	0
Exostosis	1	(0.1)	0	1	0	0
Flank pain	7	(0.6)	4	2	0	1
Ganglion	2	(0.2)	2	0	0	0
Gouty arthritis	1	(0.1)	0	1	0	0
Groin pain	1	(0.1)	0	1	0	0
Intervertebral disc degeneration	2	(0.2)	1	0	1	0
Intervertebral disc disorder	1	(0.1)	1	0	0	0
Joint stiffness	1	(0.1)	1	0	0	0
Joint swelling	9	(0.7)	4	5	0	0
Monarthritis	2	(0.2)	2	0	0	0
Muscle fatigue	1	(0.1)	1	0	0	0
Muscle spasms	24	(2.0)	22	2	0	0
Muscle tightness	2	(0.2)	2	0	0	0
Muscle twitching	2	(0.2)	2	0	0	0
Muscular weakness	4	(0.3)	3	0	1	0
Musculoskeletal chest pain	3	(0.2)	2	0	1	0
Musculoskeletal discomfort	1	(0.1)	0	1	0	0
Musculoskeletal pain	2	(0.2)	1	1	0	0
Musculoskeletal stiffness	6	(0.5)	4	2	0	0
Myalgia	44	(3.6)	29	11	4	0
Myopathy	1	(0.1)	1	0	0	0
Myositis	1	(0.1)	0	0	1	0
Neck pain	7	(0.6)	5	2	0	0

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Phase 2b/3 Studies All Maraviroc Therapy

Number of Subjects evaluable for adverse events	maraviroc (n=1212)					
			Severity Grade*			
	N	(%)	1	2	3	4
System Organ Class and MedDRA (v9.0) preferred term						
Osteoarthritis	4	(0.3)	3	1	0	0
Osteonecrosis	3	(0.2)	1	0	1	1
Osteopenia	1	(0.1)	1	0	0	0
Osteoporosis	3	(0.2)	1	2	0	0
Pain in extremity	35	(2.9)	22	10	2	1
Plantar fasciitis	1	(0.1)	1	0	0	0
Rhabdomyolysis	5	(0.4)	1	0	2	2
Rotator cuff syndrome	2	(0.2)	1	1	0	0
Shoulder pain	7	(0.6)	3	4	0	0
Spinal disorder	1	(0.1)	0	0	1	0
Synovial cyst	1	(0.1)	1	0	0	0
Tendon disorder	1	(0.1)	1	0	0	0
Tendonitis	3	(0.2)	3	0	0	0
Tenosynovitis	1	(0.1)	1	0	0	0
Vertebral column mass	1	(0.1)	0	1	0	0
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL						
Abdominal neoplasm	1	(0.1)	0	1	0	0
Acrochordon	1	(0.1)	1	0	0	0
Anal cancer	6	(0.5)	0	2	0	4
Anal cancer stage 0	1	(0.1)	0	0	1	0
B-cell lymphoma	1	(0.1)	0	0	0	1
Basal cell carcinoma	2	(0.2)	2	0	0	0
Benign neoplasm of orbit	1	(0.1)	1	0	0	0

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			Severity Grade*			
	N	(%)	1	2	3	4
System Organ Class and MedDRA (v9.0) preferred term						
Benign oesophageal neoplasm	1	(0.1)	1	0	0	0
Bowen's disease	1	(0.1)	0	0	1	0
Bowenoid papulosis	1	(0.1)	0	0	1	0
Conjunctival neoplasm	1	(0.1)	1	0	0	0
Haemangioma	1	(0.1)	1	0	0	0
Haemangioma of liver	1	(0.1)	1	0	0	0
Kaposi's sarcoma	4	(0.3)	3	0	0	1
Lipoma	1	(0.1)	1	0	0	0
Lymphoma	3	(0.2)	0	1	0	2
Metastases to liver	1	(0.1)	0	1	0	0
Neoplasm	1	(0.1)	0	1	0	0
Neoplasm skin	1	(0.1)	1	0	0	0
Oesophageal carcinoma	1	(0.1)	0	0	0	1
Seborrhoeic keratosis	3	(0.2)	2	1	0	0
Skin cancer	1	(0.1)	0	1	0	0
Skin papilloma	26	(2.1)	23	3	0	0
Squamous cell carcinoma	2	(0.2)	0	2	0	0
Squamous cell carcinoma of skin	1	(0.1)	1	0	0	0
Sweat gland tumour	2	(0.2)	1	0	0	1
Testicular neoplasm	1	(0.1)	1	0	0	0
Tongue neoplasm malignant stage unspecified	1	(0.1)	0	0	1	0
NERVOUS SYSTEM DISORDERS	384	(31.7)	245	115	16	8
Ageusia	1	(0.1)	1	0	0	0
Amnesia	8	(0.7)	8	0	0	0

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Phase 2b/3 Studies All Maraviroc Therapy

Number of Subjects evaluable for adverse events	maraviroc (n=1212)					
			Severity Grade*			
	N	(%)	1	2	3	4
System Organ Class and MedDRA (v9.0) preferred term						
Areflexia	5	(0.4)	5	0	0	0
Balance disorder	3	(0.2)	2	1	0	0
Burning sensation	3	(0.2)	2	1	0	0
Carpal tunnel syndrome	2	(0.2)	1	1	0	0
Cerebral haemorrhage	1	(0.1)	0	1	0	0
Cerebral infarction	1	(0.1)	0	0	0	1
Cerebrovascular accident	3	(0.2)	0	0	0	3
Convulsion	4	(0.3)	0	1	1	2
Coordination abnormal	1	(0.1)	1	0	0	0
Depressed level of consciousness	1	(0.1)	1	0	0	0
Disturbance in attention	9	(0.7)	7	2	0	0
Dizziness	105	(8.7)	89	15	1	0
Dizziness postural	8	(0.7)	7	1	0	0
Dysaesthesia	1	(0.1)	0	1	0	0
Dysgeusia	24	(2.0)	19	5	0	0
Epilepsy	3	(0.2)	0	1	2	0
Facial palsy	1	(0.1)	1	0	0	0
Formication	1	(0.1)	0	1	0	0
Headache	170	(14.0)	121	43	5	1
Hyperaesthesia	6	(0.5)	4	2	0	0
Hypersomnia	1	(0.1)	0	1	0	0
Hypoaesthesia	30	(2.5)	25	5	0	0
Lethargy	15	(1.2)	10	4	1	0
Loss of consciousness	1	(0.1)	0	1	0	0
Memory impairment	4	(0.3)	3	0	1	0
Mental impairment	1	(0.1)	1	0	0	0

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Phase 2b/3 Studies All Maraviroc Therapy

Number of Subjects evaluable for adverse events	maraviroc (n=1212)					
			Severity Grade*			
	N	(%)	1	2	3	4
System Organ Class and MedDRA (v9.0) preferred term						
Migraine	6	(0.5)	0	6	0	0
Movement disorder	1	(0.1)	1	0	0	0
Nervous system disorder	1	(0.1)	0	1	0	0
Neuralgia	3	(0.2)	0	3	0	0
Neuritis	1	(0.1)	1	0	0	0
Neuropathy	9	(0.7)	3	5	1	0
Neuropathy peripheral	22	(1.8)	12	8	2	0
Paraesthesia	31	(2.6)	28	3	0	0
Parkinsonism	1	(0.1)	0	1	0	0
Petit mal epilepsy	1	(0.1)	0	1	0	0
Polyneuropathy	3	(0.2)	3	0	0	0
Poor quality sleep	4	(0.3)	2	2	0	0
Psychomotor hyperactivity	4	(0.3)	3	1	0	0
Radicular pain	1	(0.1)	1	0	0	0
Radiculopathy	1	(0.1)	0	1	0	0
Restless legs syndrome	4	(0.3)	4	0	0	0
Sciatica	3	(0.2)	0	3	0	0
Sedation	2	(0.2)	1	0	0	1
Sensory disturbance	1	(0.1)	0	0	1	0
Sinus headache	6	(0.5)	4	2	0	0
Somnolence	22	(1.8)	19	2	1	0
Speech disorder	1	(0.1)	1	0	0	0
Syncope	8	(0.7)	3	4	0	1
Tremor	12	(1.0)	10	0	2	0
Trigeminal neuralgia	1	(0.1)	1	0	0	0
Vocal cord paralysis	1	(0.1)	0	1	0	0

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Phase 2b/3 Studies All Maraviroc Therapy

Number of Subjects evaluable for adverse events	maraviroc (n=1212)					
			Severity Grade*			
	N	(%)	1	2	3	4
System Organ Class and MedDRA (v9.0) preferred term						
PREGNANCY, PUERPERIUM AND PERINATAL CONDITIONS	2	(0.2)	2	0	0	0
Pregnancy	2	(0.2)	2	0	0	0
PSYCHIATRIC DISORDERS	215	(17.7)	127	75	12	1
Abnormal dreams	33	(2.7)	21	10	2	0
Affect lability	1	(0.1)	0	0	1	0
Affective disorder	2	(0.2)	2	0	0	0
Aggression	1	(0.1)	0	1	0	0
Agitation	1	(0.1)	0	0	1	0
Alcoholism	2	(0.2)	1	1	0	0
Anxiety	29	(2.4)	15	12	2	0
Apathy	1	(0.1)	1	0	0	0
Attention deficit/hyperactivity disorder	2	(0.2)	2	0	0	0
Completed suicide	1	(0.1)	0	0	0	1
Confusional state	2	(0.2)	1	1	0	0
Cyclothymic disorder	1	(0.1)	1	0	0	0
Decreased interest	1	(0.1)	1	0	0	0
Depressed mood	3	(0.2)	1	2	0	0
Depression	44	(3.6)	16	25	3	0
Depression suicidal	1	(0.1)	0	0	1	0
Disorientation	4	(0.3)	3	1	0	0
Dissociation	1	(0.1)	0	1	0	0
Dysthymic disorder	1	(0.1)	0	1	0	0

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Phase 2b/3 Studies All Maraviroc Therapy

Number of Subjects evaluable for adverse events	maraviroc (n=1212)					
			Severity Grade*			
	N	(%)	1	2	3	4
System Organ Class and MedDRA (v9.0) preferred term						
Euphoric mood	2	(0.2)	2	0	0	0
Excitability	2	(0.2)	1	1	0	0
Flat affect	1	(0.1)	1	0	0	0
Hallucination	3	(0.2)	2	1	0	0
Hallucination, auditory	1	(0.1)	1	0	0	0
Initial insomnia	1	(0.1)	1	0	0	0
Insomnia	78	(6.4)	57	20	1	0
Libido decreased	10	(0.8)	6	4	0	0
Loss of libido	1	(0.1)	0	1	0	0
Mental status changes	3	(0.2)	1	1	1	0
Mood altered	2	(0.2)	2	0	0	0
Mood swings	4	(0.3)	3	1	0	0
Nervousness	2	(0.2)	2	0	0	0
Nightmare	12	(1.0)	7	5	0	0
Panic attack	2	(0.2)	0	2	0	0
Restlessness	1	(0.1)	1	0	0	0
Sleep disorder	20	(1.7)	15	5	0	0
Stress	1	(0.1)	1	0	0	0
Suicidal ideation	1	(0.1)	1	0	0	0
RENAL AND URINARY DISORDERS	92	(7.6)	54	30	5	3
Bladder pain	1	(0.1)	1	0	0	0
Chromaturia	5	(0.4)	4	1	0	0
Dysuria	18	(1.5)	16	2	0	0
Haematuria	7	(0.6)	6	1	0	0

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Phase 2b/3 Studies All Maraviroc Therapy

Number of Subjects evaluable for adverse events	maraviroc (n=1212)					
			Severity Grade*			
	N	(%)	1	2	3	4
System Organ Class and MedDRA (v9.0) preferred term						
Micturition urgency	1	(0.1)	0	0	1	0
Nephrolithiasis	11	(0.9)	2	4	2	3
Nocturia	15	(1.2)	9	6	0	0
Oliguria	1	(0.1)	1	0	0	0
Pollakiuria	11	(0.9)	7	4	0	0
Polyuria	3	(0.2)	2	1	0	0
Proteinuria	4	(0.3)	3	1	0	0
Renal colic	3	(0.2)	0	1	1	1
Renal failure	7	(0.6)	2	4	1	0
Renal failure acute	2	(0.2)	0	2	0	0
Renal impairment	2	(0.2)	1	1	0	0
Renal pain	2	(0.2)	1	1	0	0
Urethral discharge	2	(0.2)	1	1	0	0
Urinary hesitation	1	(0.1)	1	0	0	0
Urinary incontinence	4	(0.3)	2	2	0	0
Urinary retention	1	(0.1)	0	1	0	0
Urine abnormality	1	(0.1)	1	0	0	0
Urine odour abnormal	4	(0.3)	1	2	1	0
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	64	(5.3)	40	21	2	1
Amenorrhoea	1	(0.1)	1	0	0	0
Balanitis	2	(0.2)	1	1	0	0
Benign prostatic hyperplasia	6	(0.5)	2	4	0	0
Breast atrophy	1	(0.1)	1	0	0	0
Breast discharge	1	(0.1)	1	0	0	0

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Phase 2b/3 Studies All Maraviroc Therapy

Number of Subjects evaluable for adverse events	maraviroc (n=1212)					
			Severity Grade*			
	N	(%)	1	2	3	4
System Organ Class and MedDRA (v9.0) preferred term						
Breast mass	3	(0.2)	3	0	0	0
Breast pain	3	(0.2)	2	1	0	0
Breast tenderness	4	(0.3)	3	1	0	0
Cervical dysplasia	1	(0.1)	1	0	0	0
Cervix haemorrhage uterine	1	(0.1)	0	0	0	1
Dysmenorrhoea	1	(0.1)	1	0	0	0
Epididymitis	4	(0.3)	2	2	0	0
Erectile dysfunction	13	(1.1)	8	4	1	0
Genital erythema	1	(0.1)	1	0	0	0
Genital lesion	2	(0.2)	2	0	0	0
Genital pain female	1	(0.1)	1	0	0	0
Genital pruritus male	1	(0.1)	1	0	0	0
Genital rash	1	(0.1)	1	0	0	0
Genital ulceration	1	(0.1)	1	0	0	0
Haematospermia	1	(0.1)	0	1	0	0
Hypertrophy breast	1	(0.1)	0	1	0	0
Metrorrhagia	1	(0.1)	0	0	1	0
Nipple disorder	1	(0.1)	1	0	0	0
Oedema genital	1	(0.1)	1	0	0	0
Ovulation pain	1	(0.1)	1	0	0	0
Pelvic pain	2	(0.2)	2	0	0	0
Prostatitis	6	(0.5)	6	0	0	0
Pruritus genital	1	(0.1)	1	0	0	0
Scrotal mass	1	(0.1)	1	0	0	0
Scrotal pain	1	(0.1)	0	1	0	0
Scrotal swelling	1	(0.1)	0	1	0	0

* If the same subject in a given treatment had more than one occurrence in the same preferred term event category, only the most severe occurrence is taken. Subjects are counted only once per treatment in each row. For the TESS algorithm any missing severities have been imputed as grade 4 unless the subject experienced another occurrence of the same event in a given treatment for which severity was recorded.
In this case, the reported severity is summarized. Missing baseline severities are imputed as grade 1.
Includes data up to 7 days after last dose of study drug.
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.
For protocol 1026 only the QD arm is included. For 1027 and 1028 both blinded and open label treatment are included.

Table 3.4.1.3
Maraviroc Summary of Clinical Safety
Incidence and Severity of Treatment-Emergent Adverse Events (All Causalities)
Phase 2b/3 Studies All Maraviroc Therapy

Number of Subjects evaluable for adverse events	maraviroc (n=1212)					
			Severity Grade*			
	N	(%)	1	2	3	4
System Organ Class and MedDRA (v9.0) preferred term						
Semen discolouration	1	(0.1)	1	0	0	0
Sexual dysfunction	2	(0.2)	0	2	0	0
Testicular atrophy	1	(0.1)	1	0	0	0
Testicular disorder	1	(0.1)	0	1	0	0
Testicular pain	1	(0.1)	0	1	0	0
Uterine cervical laceration	1	(0.1)	0	0	0	1
Vaginal discharge	1	(0.1)	1	0	0	0
Vaginal disorder	1	(0.1)	0	1	0	0
Vaginal erythema	1	(0.1)	0	1	0	0
Vaginal haemorrhage	1	(0.1)	1	0	0	0
Vaginal swelling	1	(0.1)	0	1	0	0
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	265	(21.9)	178	74	8	5
Allergic sinusitis	2	(0.2)	2	0	0	0
Asthma	10	(0.8)	3	7	0	0
Atelectasis	3	(0.2)	2	1	0	0
Bronchial disorder	1	(0.1)	1	0	0	0
Bronchospasm	4	(0.3)	4	0	0	0
Chronic obstructive pulmonary disease	2	(0.2)	1	0	0	1
Cough	105	(8.7)	78	25	1	1
Dysphonia	7	(0.6)	7	0	0	0
Dyspnoea	29	(2.4)	18	7	3	1
Dyspnoea exacerbated	1	(0.1)	0	1	0	0
Dyspnoea exertional	5	(0.4)	2	3	0	0
Emphysema	3	(0.2)	1	1	1	0

* If the same subject in a given treatment had more than one occurrence in the same preferred term event category, only the most severe occurrence is taken. Subjects are counted only once per treatment in each row. For the TESS algorithm any missing severities have been imputed as grade 4 unless the subject experienced another occurrence of the same event in a given treatment for which severity was recorded.
In this case, the reported severity is summarized. Missing baseline severities are imputed as grade 1.
Includes data up to 7 days after last dose of study drug.
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.
For protocol 1026 only the QD arm is included. For 1027 and 1028 both blinded and open label treatment are included.

Table 3.4.1.3
Maraviroc Summary of Clinical Safety
Incidence and Severity of Treatment-Emergent Adverse Events (All Causalities)
Phase 2b/3 Studies All Maraviroc Therapy

Number of Subjects evaluable for adverse events	maraviroc (n=1212)					
			Severity Grade*			
	N	(%)	1	2	3	4
System Organ Class and MedDRA (v9.0) preferred term						
Epistaxis	5	(0.4)	4	1	0	0
Haemoptysis	3	(0.2)	2	1	0	0
Hiccups	3	(0.2)	2	1	0	0
Hypoxia	1	(0.1)	0	1	0	0
Increased upper airway secretion	1	(0.1)	1	0	0	0
Lung disorder	2	(0.2)	0	1	1	0
Lung infiltration	2	(0.2)	0	1	1	0
Nasal congestion	27	(2.2)	23	3	1	0
Nasal dryness	1	(0.1)	1	0	0	0
Nasal septum deviation	2	(0.2)	0	2	0	0
Nasal ulcer	2	(0.2)	2	0	0	0
Obstructive airways disorder	1	(0.1)	0	1	0	0
Paranasal sinus hypersecretion	2	(0.2)	1	1	0	0
Pharyngeal erythema	2	(0.2)	1	1	0	0
Pharyngolaryngeal pain	38	(3.1)	33	5	0	0
Pharynx discomfort	1	(0.1)	1	0	0	0
Pleural effusion	1	(0.1)	0	0	1	0
Pleurisy	1	(0.1)	1	0	0	0
Pleuritic pain	2	(0.2)	0	2	0	0
Pneumonitis	1	(0.1)	0	0	0	1
Postnasal drip	6	(0.5)	6	0	0	0
Productive cough	14	(1.2)	9	5	0	0
Pulmonary congestion	1	(0.1)	0	1	0	0
Pulmonary embolism	1	(0.1)	0	0	0	1
Pulmonary hypertension	1	(0.1)	0	1	0	0
Rales	2	(0.2)	2	0	0	0

* If the same subject in a given treatment had more than one occurrence in the same preferred term event category, only the most severe occurrence is taken. Subjects are counted only once per treatment in each row. For the TESS algorithm any missing severities have been imputed as grade 4 unless the subject experienced another occurrence of the same event in a given treatment for which severity was recorded.
In this case, the reported severity is summarized. Missing baseline severities are imputed as grade 1.
Includes data up to 7 days after last dose of study drug.
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.
For protocol 1026 only the QD arm is included. For 1027 and 1028 both blinded and open label treatment are included.

Table 3.4.1.3
Maraviroc Summary of Clinical Safety
Incidence and Severity of Treatment-Emergent Adverse Events (All Causalities)
Phase 2b/3 Studies All Maraviroc Therapy

Number of Subjects evaluable for adverse events	maraviroc (n=1212)					
			Severity Grade*			
	N	(%)	1	2	3	4
System Organ Class and MedDRA (v9.0) preferred term						
Respiratory disorder	4	(0.3)	2	2	0	0
Respiratory distress	1	(0.1)	1	0	0	0
Respiratory failure	2	(0.2)	0	1	0	1
Respiratory tract congestion	11	(0.9)	6	5	0	0
Rhinitis allergic	9	(0.7)	7	2	0	0
Rhinitis seasonal	1	(0.1)	1	0	0	0
Rhinorrhoea	20	(1.7)	18	2	0	0
Rhonchi	1	(0.1)	1	0	0	0
Sinus congestion	15	(1.2)	14	1	0	0
Sneezing	6	(0.5)	5	1	0	0
Sputum discoloured	1	(0.1)	1	0	0	0
Throat irritation	1	(0.1)	0	1	0	0
Throat tightness	1	(0.1)	1	0	0	0
Tonsillar disorder	1	(0.1)	1	0	0	0
Tonsillar hypertrophy	1	(0.1)	0	1	0	0
Upper respiratory tract congestion	1	(0.1)	1	0	0	0
Vocal cord polyp	1	(0.1)	0	1	0	0
Wheezing	4	(0.3)	3	1	0	0
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	323	(26.7)	219	84	17	3
Acne	9	(0.7)	9	0	0	0
Acne pustular	1	(0.1)	1	0	0	0
Actinic keratosis	1	(0.1)	1	0	0	0
Alopecia	11	(0.9)	9	1	1	0
Angioneurotic oedema	1	(0.1)	0	1	0	0

* If the same subject in a given treatment had more than one occurrence in the same preferred term event category, only the most severe occurrence is taken. Subjects are counted only once per treatment in each row. For the TESS algorithm any missing severities have been imputed as grade 4 unless the subject experienced another occurrence of the same event in a given treatment for which severity was recorded.
In this case, the reported severity is summarized. Missing baseline severities are imputed as grade 1.
Includes data up to 7 days after last dose of study drug.
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.
For protocol 1026 only the QD arm is included. For 1027 and 1028 both blinded and open label treatment are included.

Table 3.4.1.3
Maraviroc Summary of Clinical Safety
Incidence and Severity of Treatment-Emergent Adverse Events (All Causalities)
Phase 2b/3 Studies All Maraviroc Therapy

Number of Subjects evaluable for adverse events	maraviroc (n=1212)					
			Severity Grade*			
	N	(%)	1	2	3	4
System Organ Class and MedDRA (v9.0) preferred term						
Blister	4	(0.3)	4	0	0	0
Cold sweat	1	(0.1)	1	0	0	0
Comedone	1	(0.1)	0	1	0	0
Dandruff	1	(0.1)	1	0	0	0
Dermal cyst	1	(0.1)	1	0	0	0
Dermatitis	12	(1.0)	10	2	0	0
Dermatitis contact	4	(0.3)	4	0	0	0
Dermatitis exfoliative	1	(0.1)	1	0	0	0
Drug eruption	4	(0.3)	1	2	1	0
Dry skin	22	(1.8)	20	2	0	0
Dyshidrosis	1	(0.1)	1	0	0	0
Ecchymosis	1	(0.1)	1	0	0	0
Eczema	10	(0.8)	9	1	0	0
Eosinophilic pustular folliculitis	1	(0.1)	0	1	0	0
Erythema	13	(1.1)	12	1	0	0
Exfoliative rash	2	(0.2)	2	0	0	0
Fat atrophy	2	(0.2)	1	0	1	0
Hair texture abnormal	1	(0.1)	1	0	0	0
Hand dermatitis	1	(0.1)	1	0	0	0
Heat rash	1	(0.1)	0	1	0	0
Hyperhidrosis	9	(0.7)	6	3	0	0
Hyperkeratosis	3	(0.2)	1	2	0	0
Hypertrichosis	1	(0.1)	1	0	0	0
Hypoaesthesia facial	1	(0.1)	1	0	0	0
Ingrowing nail	1	(0.1)	0	1	0	0
Lichen planus	1	(0.1)	0	1	0	0

* If the same subject in a given treatment had more than one occurrence in the same preferred term event category, only the most severe occurrence is taken. Subjects are counted only once per treatment in each row. For the TESS algorithm any missing severities have been imputed as grade 4 unless the subject experienced another occurrence of the same event in a given treatment for which severity was recorded.
In this case, the reported severity is summarized. Missing baseline severities are imputed as grade 1.
Includes data up to 7 days after last dose of study drug.
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.
For protocol 1026 only the QD arm is included. For 1027 and 1028 both blinded and open label treatment are included.

Table 3.4.1.3
Maraviroc Summary of Clinical Safety
Incidence and Severity of Treatment-Emergent Adverse Events (All Causalities)
Phase 2b/3 Studies All Maraviroc Therapy

Number of Subjects evaluable for adverse events	maraviroc (n=1212)					
			Severity Grade*			
	N	(%)	1	2	3	4
System Organ Class and MedDRA (v9.0) preferred term						
Lipoatrophy	4	(0.3)	3	0	0	1
Lipodystrophy acquired	9	(0.7)	6	3	0	0
Lipohypertrophy	10	(0.8)	7	2	1	0
Nail discolouration	4	(0.3)	4	0	0	0
Nail disorder	2	(0.2)	1	1	0	0
Nail pigmentation	2	(0.2)	2	0	0	0
Night sweats	39	(3.2)	31	6	2	0
Onychoclasis	1	(0.1)	1	0	0	0
Onycholysis	1	(0.1)	0	1	0	0
Photosensitivity reaction	3	(0.2)	3	0	0	0
Prurigo	1	(0.1)	1	0	0	0
Pruritus	37	(3.1)	29	6	2	0
Pruritus generalised	3	(0.2)	2	1	0	0
Psoriasis	4	(0.3)	2	2	0	0
Purpura	1	(0.1)	0	1	0	0
Rash	86	(7.1)	54	26	5	1
Rash erythematous	7	(0.6)	4	3	0	0
Rash generalised	9	(0.7)	3	4	2	0
Rash macular	2	(0.2)	2	0	0	0
Rash maculo-papular	4	(0.3)	1	3	0	0
Rash papular	14	(1.2)	12	2	0	0
Rash pruritic	8	(0.7)	3	5	0	0
Scar	1	(0.1)	1	0	0	0
Seborrhoeic dermatitis	11	(0.9)	8	3	0	0
Skin discolouration	1	(0.1)	1	0	0	0
Skin exfoliation	1	(0.1)	1	0	0	0

* If the same subject in a given treatment had more than one occurrence in the same preferred term event category, only the most severe occurrence is taken. Subjects are counted only once per treatment in each row. For the TESS algorithm any missing severities have been imputed as grade 4 unless the subject experienced another occurrence of the same event in a given treatment for which severity was recorded.
In this case, the reported severity is summarized. Missing baseline severities are imputed as grade 1.
Includes data up to 7 days after last dose of study drug.
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.
For protocol 1026 only the QD arm is included. For 1027 and 1028 both blinded and open label treatment are included.

Table 3.4.1.3
Maraviroc Summary of Clinical Safety
Incidence and Severity of Treatment-Emergent Adverse Events (All Causalities)
Phase 2b/3 Studies All Maraviroc Therapy

Number of Subjects evaluable for adverse events	maraviroc (n=1212)					
			Severity Grade*			
	N	(%)	1	2	3	4
System Organ Class and MedDRA (v9.0) preferred term						
Skin hyperpigmentation	2	(0.2)	2	0	0	0
Skin irritation	3	(0.2)	2	0	1	0
Skin lesion	11	(0.9)	7	4	0	0
Skin nodule	2	(0.2)	1	1	0	0
Skin reaction	4	(0.3)	1	2	1	0
Skin striae	1	(0.1)	1	0	0	0
Skin swelling	1	(0.1)	1	0	0	0
Stasis dermatitis	1	(0.1)	1	0	0	0
Stevens-Johnson syndrome	1	(0.1)	0	0	0	1
Subcutaneous nodule	4	(0.3)	4	0	0	0
Swelling face	1	(0.1)	1	0	0	0
Telangiectasia	1	(0.1)	1	0	0	0
Urticaria	5	(0.4)	4	1	0	0
Urticaria papular	1	(0.1)	1	0	0	0
Xeroderma	1	(0.1)	1	0	0	0
SOCIAL CIRCUMSTANCES	4	(0.3)	1	2	1	0
Abstains from alcohol	1	(0.1)	0	1	0	0
Drug abuser	2	(0.2)	0	1	1	0
Stress at work	1	(0.1)	1	0	0	0
SURGICAL AND MEDICAL PROCEDURES	21	(1.7)	13	4	3	1
Abscess drainage	1	(0.1)	1	0	0	0
Anorectal operation	1	(0.1)	1	0	0	0

* If the same subject in a given treatment had more than one occurrence in the same preferred term event category, only the most severe occurrence is taken.
Subjects are counted only once per treatment in each row. For the TESS algorithm any missing severities have been imputed as grade 4 unless the subject experienced another occurrence of the same event in a given treatment for which severity was recorded.
In this case, the reported severity is summarized. Missing baseline severities are imputed as grade 1.
Includes data up to 7 days after last dose of study drug.
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.
For protocol 1026 only the QD arm is included. For 1027 and 1028 both blinded and open label treatment are included.

Table 3.4.1.3
Maraviroc Summary of Clinical Safety
Incidence and Severity of Treatment-Emergent Adverse Events (All Causalities)
Phase 2b/3 Studies All Maraviroc Therapy

Number of Subjects evaluable for adverse events	maraviroc (n=1212)					
			Severity Grade*			
	N	(%)	1	2	3	4
System Organ Class and MedDRA (v9.0) preferred term						
Arterial bypass operation	1	(0.1)	0	0	0	1
Central nervous system stimulation	1	(0.1)	1	0	0	0
Foot operation	1	(0.1)	0	1	0	0
Hip surgery	1	(0.1)	0	0	1	0
Limb operation	1	(0.1)	0	0	1	0
Rectal lesion excision	1	(0.1)	0	1	0	0
Sinus operation	7	(0.6)	6	1	0	0
Skin neoplasm excision	1	(0.1)	1	0	0	0
Suture insertion	1	(0.1)	0	1	0	0
Toe operation	1	(0.1)	0	0	1	0
Tooth extraction	1	(0.1)	1	0	0	0
Wart excision	2	(0.2)	2	0	0	0
VASCULAR DISORDERS	61	(5.0)	34	20	6	1
Arterial occlusive disease	1	(0.1)	0	0	1	0
Circulatory collapse	1	(0.1)	1	0	0	0
Essential hypertension	1	(0.1)	0	1	0	0
Flushing	5	(0.4)	5	0	0	0
Haematoma	3	(0.2)	2	0	0	1
Hot flush	8	(0.7)	7	1	0	0
Hyperaemia	1	(0.1)	1	0	0	0
Hypertension	22	(1.8)	11	11	0	0
Hypotension	7	(0.6)	2	2	3	0
Intermittent claudication	1	(0.1)	1	0	0	0
Orthostatic hypotension	4	(0.3)	0	3	1	0

* If the same subject in a given treatment had more than one occurrence in the same preferred term event category, only the most severe occurrence is taken. Subjects are counted only once per treatment in each row. For the TESS algorithm any missing severities have been imputed as grade 4 unless the subject experienced another occurrence of the same event in a given treatment for which severity was recorded.
In this case, the reported severity is summarized. Missing baseline severities are imputed as grade 1.
Includes data up to 7 days after last dose of study drug.
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.
For protocol 1026 only the QD arm is included. For 1027 and 1028 both blinded and open label treatment are included.

Table 3.4.1.3
Maraviroc Summary of Clinical Safety
Incidence and Severity of Treatment-Emergent Adverse Events (All Causalities)
Phase 2b/3 Studies All Maraviroc Therapy

Number of Subjects evaluable for adverse events	maraviroc (n=1212)					
			Severity Grade*			
	N	(%)	1	2	3	4
System Organ Class and MedDRA (v9.0) preferred term						
Peripheral embolism	1	(0.1)	0	0	1	0
Phlebitis	2	(0.2)	1	1	0	0
Raynaud's phenomenon	1	(0.1)	1	0	0	0
Varicose vein	2	(0.2)	1	1	0	0
Vasculitis	1	(0.1)	1	0	0	0
Venous thrombosis	1	(0.1)	1	0	0	0
Total preferred term events	5808		3584	1704	349	171

* If the same subject in a given treatment had more than one occurrence in the same preferred term event category, only the most severe occurrence is taken. Subjects are counted only once per treatment in each row. For the TESS algorithm any missing severities have been imputed as grade 4 unless the subject experienced another occurrence of the same event in a given treatment for which severity was recorded.
In this case, the reported severity is summarized. Missing baseline severities are imputed as grade 1.
Includes data up to 7 days after last dose of study drug.
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.
For protocol 1026 only the QD arm is included. For 1027 and 1028 both blinded and open label treatment are included.

Table 3.4.2.1
Maraviroc Summary of Clinical Safety
Treatment-Emergent Adverse Events (Treatment Related)
Phase 2b/3 Studies All Maraviroc Therapy

	maraviroc	
	n	(%)
Number (%) of subjects:		
Subjects evaluable for adverse events	1212	
Number of adverse events	1944	
Subjects with adverse events	618	(51.0)
Subjects with serious adverse events	28	(2.3)
Subjects with grade 3 adverse events	66	(5.4)
Subjects with grade 4 adverse events	24	(2.0)
Subjects discontinued due to adverse events	31	(2.6)
Subjects with dose reduced or temporary discontinuation due to adverse events	26	(2.1)

Includes data up to 7 days after last dose of study drug.
Except for the Number of Adverse Events subjects are counted only once per treatment in each row.
Serious Adverse Events - according to the investigator's assessment.
For the grade 3/grade 4 rows, if the same subject in a given treatment had more than one occurrence in the same preferred term event category, only the most severe (grade 4) occurrence is taken. If the same subject had two different preferred term events, one classified as grade 3, one as grade 4, they will be present in both rows.
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.
For protocol 1026 only the QD arm is included. For 1027 and 1028 both blinded and open label treatment are included.

Table 3.4.2.2
Maraviroc Summary of Clinical Safety
Treatment-Emergent Adverse Events by System Organ Class (Treatment Related)
Phase 2b/3 Studies All Maraviroc Therapy

	maraviroc	
	n	(%)
Number (%) of Subjects:		
Evaluable for adverse events	1212	
With adverse events	618	(51.0)
Discontinued due to adverse events	31	(2.6)
Number (%) of Subjects with Adverse Events by System Organ Class:		
Blood and lymphatic system disorders	25	(2.1)
Cardiac disorders	10	(0.8)
Congenital, familial and genetic disorders	1	(0.1)
Ear and labyrinth disorders	13	(1.1)
Eye disorders	38	(3.1)
Gastrointestinal disorders	338	(27.9)
General disorders and administration site conditions	155	(12.8)
Hepatobiliary disorders	7	(0.6)
Immune system disorders	1	(0.1)
Infections and infestations	44	(3.6)
Injury, poisoning and procedural complications	5	(0.4)
Investigations	81	(6.7)
Metabolism and nutrition disorders	71	(5.9)
Musculoskeletal and connective tissue disorders	64	(5.3)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	5	(0.4)
Nervous system disorders	228	(18.8)
Psychiatric disorders	113	(9.3)
Renal and urinary disorders	30	(2.5)
Reproductive system and breast disorders	17	(1.4)
Respiratory, thoracic and mediastinal disorders	55	(4.5)
Skin and subcutaneous tissue disorders	140	(11.6)
Social circumstances	1	(0.1)
Vascular disorders	24	(2.0)

Subjects are only counted once per treatment for each row.
Includes data up to 7 days after last dose of study drug.
MedDRA (v9.0) coding dictionary applied.
For protocol 1026 only the QD arm is included. For 1027 and 1028 both blinded and open label treatment are included.

Table 3.4.2.3
Maraviroc Summary of Clinical Safety
Incidence and Severity of Treatment-Emergent Adverse Events (Treatment Related)
Phase 2b/3 Studies All Maraviroc Therapy

Number of Subjects evaluable for adverse events	maraviroc (n=1212)					
			Severity Grade*			
	N	(%)	1	2	3	4
System Organ Class and MedDRA (v9.0) preferred term						
BLOOD AND LYMPHATIC SYSTEM DISORDERS	25	(2.1)	8	9	5	3
Anaemia	15	(1.2)	6	4	3	2
Lymphadenopathy	2	(0.2)	2	0	0	0
Neutropenia	8	(0.7)	0	4	2	2
Pancytopenia	1	(0.1)	0	0	1	0
Thrombocytopenia	1	(0.1)	0	1	0	0
CARDIAC DISORDERS	10	(0.8)	8	1	0	1
Angina pectoris	1	(0.1)	1	0	0	0
Atrioventricular block first degree	3	(0.2)	3	0	0	0
Bradycardia	1	(0.1)	0	1	0	0
Myocardial infarction	1	(0.1)	0	0	0	1
Myocardial ischaemia	1	(0.1)	1	0	0	0
Palpitations	1	(0.1)	1	0	0	0
Sinus bradycardia	1	(0.1)	1	0	0	0
Tachycardia	1	(0.1)	1	0	0	0
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	1	(0.1)	1	0	0	0
Gilbert's syndrome	1	(0.1)	1	0	0	0
EAR AND LABYRINTH DISORDERS	13	(1.1)	9	4	0	0

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Phase 2b/3 Studies All Maraviroc Therapy

Number of Subjects evaluable for adverse events	maraviroc (n=1212)					
			Severity Grade*			
	N	(%)	1	2	3	4
System Organ Class and MedDRA (v9.0) preferred term						
Ear disorder	1	(0.1)	1	0	0	0
Ear pain	2	(0.2)	1	1	0	0
Motion sickness	1	(0.1)	0	1	0	0
Otorrhoea	1	(0.1)	1	0	0	0
Tinnitus	3	(0.2)	2	1	0	0
Tympanic membrane hyperaemia	1	(0.1)	1	0	0	0
Vertigo	6	(0.5)	5	1	0	0
EYE DISORDERS	38	(3.1)	27	10	1	0
Amblyopia	1	(0.1)	1	0	0	0
Conjunctival irritation	1	(0.1)	1	0	0	0
Conjunctivitis	4	(0.3)	2	2	0	0
Conjunctivitis allergic	1	(0.1)	1	0	0	0
Diplopia	1	(0.1)	0	0	1	0
Dry eye	3	(0.2)	1	2	0	0
Eye disorder	1	(0.1)	1	0	0	0
Eye irritation	6	(0.5)	6	0	0	0
Eye pain	4	(0.3)	3	1	0	0
Ocular hyperaemia	3	(0.2)	2	1	0	0
Ocular icterus	1	(0.1)	0	1	0	0
Scleritis	1	(0.1)	1	0	0	0
Vision blurred	9	(0.7)	6	3	0	0
Visual acuity reduced	2	(0.2)	1	1	0	0
Visual disturbance	4	(0.3)	3	1	0	0
Vitreous floaters	1	(0.1)	1	0	0	0

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Phase 2b/3 Studies All Maraviroc Therapy

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			Severity Grade*			
	N	(%)	1	2	3	4
System Organ Class and MedDRA (v9.0) preferred term						
Xerophthalmia	1	(0.1)	1	0	0	0
GASTROINTESTINAL DISORDERS	338	(27.9)	216	107	15	0
Abdominal discomfort	2	(0.2)	2	0	0	0
Abdominal distension	23	(1.9)	19	4	0	0
Abdominal pain	35	(2.9)	22	11	2	0
Abdominal pain lower	1	(0.1)	1	0	0	0
Abdominal pain upper	25	(2.1)	15	8	2	0
Abdominal tenderness	1	(0.1)	1	0	0	0
Abnormal faeces	3	(0.2)	3	0	0	0
Anogenital dysplasia	1	(0.1)	0	1	0	0
Aphthous stomatitis	5	(0.4)	3	2	0	0
Chapped lips	1	(0.1)	1	0	0	0
Constipation	32	(2.6)	22	8	2	0
Diarrhoea	115	(9.5)	71	41	3	0
Dry mouth	12	(1.0)	10	2	0	0
Dyspepsia	19	(1.6)	14	5	0	0
Dysphagia	1	(0.1)	0	0	1	0
Eructation	3	(0.2)	2	1	0	0
Faeces pale	2	(0.2)	2	0	0	0
Flatulence	26	(2.1)	20	6	0	0
Gastritis	3	(0.2)	2	1	0	0
Gastrooesophageal reflux disease	8	(0.7)	7	1	0	0
Gingival bleeding	1	(0.1)	1	0	0	0
Gingivitis	2	(0.2)	2	0	0	0

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			Severity Grade*			
	N	(%)	1	2	3	4
System Organ Class and MedDRA (v9.0) preferred term						
Glossodynia	1	(0.1)	1	0	0	0
Haematochezia	1	(0.1)	1	0	0	0
Haemorrhoids	2	(0.2)	0	2	0	0
Hypoaesthesia oral	2	(0.2)	2	0	0	0
Intestinal spasm	1	(0.1)	1	0	0	0
Lip blister	1	(0.1)	1	0	0	0
Mouth ulceration	5	(0.4)	4	1	0	0
Nausea	143	(11.8)	105	33	5	0
Odynophagia	1	(0.1)	0	1	0	0
Oral mucosal blistering	1	(0.1)	0	1	0	0
Painful defaecation	1	(0.1)	1	0	0	0
Pancreatitis	2	(0.2)	1	1	0	0
Paraesthesia oral	5	(0.4)	5	0	0	0
Rectal haemorrhage	2	(0.2)	1	1	0	0
Retching	1	(0.1)	1	0	0	0
Salivary hypersecretion	1	(0.1)	0	1	0	0
Sensitivity of teeth	1	(0.1)	1	0	0	0
Stomach discomfort	3	(0.2)	3	0	0	0
Tongue ulceration	1	(0.1)	1	0	0	0
Toothache	1	(0.1)	0	1	0	0
Vomiting	51	(4.2)	34	13	4	0
GENERAL DISORDERS AND ADMINISTRATION SITE						
Asthenia	18	(1.5)	7	6	5	0

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Number of Subjects evaluable for adverse events	maraviroc (n=1212)					
			Severity Grade*			
	N	(%)	1	2	3	4
System Organ Class and MedDRA (v9.0) preferred term						
Axillary pain	1	(0.1)	1	0	0	0
Chest discomfort	1	(0.1)	1	0	0	0
Chest pain	6	(0.5)	2	2	2	0
Chills	3	(0.2)	3	0	0	0
Condition aggravated	1	(0.1)	1	0	0	0
Drug intolerance	1	(0.1)	1	0	0	0
Fat tissue increased	1	(0.1)	1	0	0	0
Fatigue	88	(7.3)	64	20	4	0
Feeling abnormal	2	(0.2)	2	0	0	0
Feeling drunk	1	(0.1)	1	0	0	0
Feeling hot	3	(0.2)	3	0	0	0
Generalised oedema	1	(0.1)	1	0	0	0
Hunger	1	(0.1)	1	0	0	0
Inflammation	1	(0.1)	1	0	0	0
Influenza like illness	4	(0.3)	4	0	0	0
Infusion site reaction	1	(0.1)	1	0	0	0
Injection site induration	1	(0.1)	1	0	0	0
Injection site nodule	1	(0.1)	1	0	0	0
Injection site pain	1	(0.1)	0	1	0	0
Injection site reaction	3	(0.2)	2	1	0	0
Irritability	4	(0.3)	3	1	0	0
Malaise	5	(0.4)	4	1	0	0
Oedema peripheral	8	(0.7)	5	3	0	0
Pain	5	(0.4)	4	1	0	0
Pyrexia	20	(1.7)	12	6	2	0
Thirst	1	(0.1)	1	0	0	0

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			Severity Grade*			
	N	(%)	1	2	3	4
System Organ Class and MedDRA (v9.0) preferred term						
HEPATOBILIARY DISORDERS	7	(0.6)	4	1	1	1
Hepatic cirrhosis	1	(0.1)	0	0	1	0
Hepatitis toxic	1	(0.1)	0	0	0	1
Hepatomegaly	2	(0.2)	1	1	0	0
Hepatosplenomegaly	1	(0.1)	1	0	0	0
Jaundice	1	(0.1)	1	0	0	0
Liver tenderness	1	(0.1)	1	0	0	0
IMMUNE SYSTEM DISORDERS	1	(0.1)	1	0	0	0
Food allergy	1	(0.1)	1	0	0	0
INFECTIONS AND INFESTATIONS	44	(3.6)	26	16	1	1
Body tinea	1	(0.1)	0	1	0	0
Bronchitis acute	1	(0.1)	1	0	0	0
Condyloma acuminatum	1	(0.1)	1	0	0	0
Ear infection	2	(0.2)	0	1	1	0
Folliculitis	7	(0.6)	6	1	0	0
Fungal infection	2	(0.2)	1	0	0	1
Furuncle	2	(0.2)	1	1	0	0
Gastroenteritis	1	(0.1)	0	1	0	0
Hepatitis C	1	(0.1)	1	0	0	0
Herpes simplex	3	(0.2)	3	0	0	0

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Phase 2b/3 Studies All Maraviroc Therapy

Number of Subjects evaluable for adverse events	maraviroc (n=1212)					
			Severity Grade*			
	N	(%)	1	2	3	4
System Organ Class and MedDRA (v9.0) preferred term						
Herpes virus infection	3	(0.2)	3	0	0	0
Herpes zoster	1	(0.1)	0	1	0	0
Hordeolum	1	(0.1)	1	0	0	0
Infective myositis	1	(0.1)	0	0	0	1
Influenza	3	(0.2)	0	3	0	0
Nasopharyngitis	7	(0.6)	6	1	0	0
Oesophageal candidiasis	3	(0.2)	1	2	0	0
Oral candidiasis	2	(0.2)	1	1	0	0
Oropharyngeal candidiasis	2	(0.2)	2	0	0	0
Pneumonia	1	(0.1)	0	1	0	0
Rhinitis	1	(0.1)	1	0	0	0
Sinusitis	2	(0.2)	0	2	0	0
Sycosis barbae	1	(0.1)	1	0	0	0
Tinea cruris	1	(0.1)	0	1	0	0
Tinea pedis	1	(0.1)	1	0	0	0
Tinea versicolour	1	(0.1)	1	0	0	0
Upper respiratory tract infection	3	(0.2)	3	0	0	0
Urinary tract infection	1	(0.1)	1	0	0	0
Viral infection	1	(0.1)	1	0	0	0
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	5	(0.4)	4	1	0	0
Contusion	1	(0.1)	1	0	0	0
Fall	3	(0.2)	2	1	0	0
Muscle injury	1	(0.1)	1	0	0	0
Rib fracture	1	(0.1)	1	0	0	0

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Phase 2b/3 Studies All Maraviroc Therapy

Number of Subjects evaluable for adverse events	maraviroc (n=1212)					
			Severity Grade*			
	N	(%)	1	2	3	4
System Organ Class and MedDRA (v9.0) preferred term						
INVESTIGATIONS	81	(6.7)	27	24	17	13
Alanine aminotransferase increased	18	(1.5)	1	7	7	3
Aspartate aminotransferase	1	(0.1)	0	0	0	1
Aspartate aminotransferase increased	20	(1.7)	0	9	7	4
Bleeding time prolonged	1	(0.1)	1	0	0	0
Blood alkaline phosphatase increased	1	(0.1)	0	0	1	0
Blood bilirubin increased	2	(0.2)	0	2	0	0
Blood cholesterol increased	1	(0.1)	0	1	0	0
Blood creatine increased	1	(0.1)	0	1	0	0
Blood creatine phosphokinase increased	5	(0.4)	1	1	1	2
Blood creatinine increased	2	(0.2)	1	1	0	0
Blood glucose increased	3	(0.2)	2	1	0	0
Blood iron decreased	1	(0.1)	0	1	0	0
Blood lactate dehydrogenase increased	2	(0.2)	0	1	0	1
Blood potassium decreased	1	(0.1)	1	0	0	0
Blood potassium increased	1	(0.1)	0	1	0	0
Blood pressure increased	2	(0.2)	1	0	1	0
Blood testosterone decreased	1	(0.1)	0	1	0	0
Blood triglycerides increased	7	(0.6)	2	3	1	1
Blood uric acid increased	1	(0.1)	1	0	0	0
Body temperature increased	1	(0.1)	1	0	0	0
Cardiac murmur	1	(0.1)	0	1	0	0
Electrocardiogram QT prolonged	1	(0.1)	0	1	0	0
Gamma-glutamyltransferase increased	10	(0.8)	1	2	4	3

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			Severity Grade*			
	N	(%)	1	2	3	4
System Organ Class and MedDRA (v9.0) preferred term						
Haematocrit decreased	2	(0.2)	2	0	0	0
Haemoglobin decreased	2	(0.2)	1	0	1	0
Heart rate increased	1	(0.1)	1	0	0	0
Hepatic enzyme increased	3	(0.2)	0	2	1	0
Liver function test abnormal	4	(0.3)	1	0	2	1
Neutrophil count decreased	1	(0.1)	0	0	0	1
Neutrophil count increased	2	(0.2)	0	0	1	1
Platelet count decreased	1	(0.1)	0	1	0	0
Prostate examination abnormal	1	(0.1)	1	0	0	0
Red blood cell count decreased	1	(0.1)	1	0	0	0
Transaminases increased	1	(0.1)	0	0	0	1
Urine output decreased	1	(0.1)	0	1	0	0
Viral load increased	1	(0.1)	1	0	0	0
Viral test	1	(0.1)	1	0	0	0
Weight decreased	11	(0.9)	9	2	0	0
Weight increased	5	(0.4)	5	0	0	0
White blood cell count decreased	1	(0.1)	0	0	1	0
METABOLISM AND NUTRITION DISORDERS	71	(5.9)	47	23	1	0
Alcohol intolerance	1	(0.1)	1	0	0	0
Anorexia	30	(2.5)	17	12	1	0
Central obesity	1	(0.1)	1	0	0	0
Decreased appetite	25	(2.1)	19	6	0	0
Fluid retention	1	(0.1)	1	0	0	0
Food craving	1	(0.1)	1	0	0	0

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Incidence and Severity of Treatment-Emergent Adverse Events (Treatment Related)
Phase 2b/3 Studies All Maraviroc Therapy

Number of Subjects evaluable for adverse events	maraviroc (n=1212)					
			Severity Grade*			
	N	(%)	1	2	3	4
System Organ Class and MedDRA (v9.0) preferred term						
Hyperamylasaemia	1	(0.1)	1	0	0	0
Hyperglycaemia	2	(0.2)	0	2	0	0
Hypertriglyceridaemia	3	(0.2)	1	2	0	0
Increased appetite	5	(0.4)	5	0	0	0
Insulin resistant diabetes	1	(0.1)	0	1	0	0
Polydipsia	1	(0.1)	1	0	0	0
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	64	(5.3)	50	10	4	0
Arthralgia	16	(1.3)	13	2	1	0
Back pain	11	(0.9)	9	1	1	0
Joint stiffness	1	(0.1)	1	0	0	0
Muscle spasms	16	(1.3)	16	0	0	0
Muscle tightness	1	(0.1)	1	0	0	0
Muscle twitching	1	(0.1)	1	0	0	0
Muscular weakness	2	(0.2)	1	0	1	0
Musculoskeletal stiffness	4	(0.3)	3	1	0	0
Myalgia	20	(1.7)	13	5	2	0
Myopathy	1	(0.1)	1	0	0	0
Myositis	1	(0.1)	0	0	1	0
Neck pain	1	(0.1)	1	0	0	0
Pain in extremity	10	(0.8)	7	2	1	0
Shoulder pain	1	(0.1)	1	0	0	0
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL						

* If the same subject in a given treatment had more than one occurrence in the same preferred term event category, only the most severe occurrence is taken. Subjects are counted only once per treatment in each row. For the TESS algorithm any missing severities have been imputed as grade 4 unless the subject experienced another occurrence of the same event in a given treatment for which severity was recorded.
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Includes data up to 7 days after last dose of study drug.
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.
For protocol 1026 only the QD arm is included. For 1027 and 1028 both blinded and open label treatment are included.

Table 3.4.2.3
Maraviroc Summary of Clinical Safety
Incidence and Severity of Treatment-Emergent Adverse Events (Treatment Related)
Phase 2b/3 Studies All Maraviroc Therapy

Number of Subjects evaluable for adverse events	maraviroc (n=1212)					
			Severity Grade*			
	N	(%)	1	2	3	4
System Organ Class and MedDRA (v9.0) preferred term						
B-cell lymphoma	1	(0.1)	0	0	0	1
Neoplasm skin	1	(0.1)	1	0	0	0
Seborrhoeic keratosis	1	(0.1)	1	0	0	0
Skin papilloma	3	(0.2)	3	0	0	0
NERVOUS SYSTEM DISORDERS	228	(18.8)	165	56	5	2
Ageusia	1	(0.1)	1	0	0	0
Amnesia	3	(0.2)	3	0	0	0
Areflexia	2	(0.2)	2	0	0	0
Carpal tunnel syndrome	1	(0.1)	1	0	0	0
Convulsion	2	(0.2)	0	1	0	1
Coordination abnormal	1	(0.1)	1	0	0	0
Disturbance in attention	6	(0.5)	5	1	0	0
Dizziness	62	(5.1)	55	7	0	0
Dizziness postural	6	(0.5)	5	1	0	0
Dysgeusia	19	(1.6)	16	3	0	0
Epilepsy	1	(0.1)	0	1	0	0
Facial palsy	1	(0.1)	1	0	0	0
Formication	1	(0.1)	0	1	0	0
Headache	111	(9.2)	80	28	3	0
Hyperaesthesia	4	(0.3)	3	1	0	0
Hypoaesthesia	6	(0.5)	5	1	0	0
Lethargy	8	(0.7)	6	1	1	0
Loss of consciousness	1	(0.1)	0	1	0	0

* If the same subject in a given treatment had more than one occurrence in the same preferred term event category, only the most severe occurrence is taken. Subjects are counted only once per treatment in each row. For the TESS algorithm any missing severities have been imputed as grade 4 unless the subject experienced another occurrence of the same event in a given treatment for which severity was recorded.
In this case, the reported severity is summarized. Missing baseline severities are imputed as grade 1.
Includes data up to 7 days after last dose of study drug.
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.
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Table 3.4.2.3
Maraviroc Summary of Clinical Safety
Incidence and Severity of Treatment-Emergent Adverse Events (Treatment Related)
Phase 2b/3 Studies All Maraviroc Therapy

Number of Subjects evaluable for adverse events	maraviroc (n=1212)					
			Severity Grade*			
	N	(%)	1	2	3	4
System Organ Class and MedDRA (v9.0) preferred term						
Memory impairment	2	(0.2)	2	0	0	0
Migraine	3	(0.2)	0	3	0	0
Neuropathy	2	(0.2)	2	0	0	0
Neuropathy peripheral	4	(0.3)	4	0	0	0
Paraesthesia	18	(1.5)	15	3	0	0
Petit mal epilepsy	1	(0.1)	0	1	0	0
Polyneuropathy	3	(0.2)	3	0	0	0
Poor quality sleep	2	(0.2)	2	0	0	0
Psychomotor hyperactivity	2	(0.2)	1	1	0	0
Restless legs syndrome	2	(0.2)	2	0	0	0
Sciatica	2	(0.2)	0	2	0	0
Sedation	1	(0.1)	1	0	0	0
Sensory disturbance	1	(0.1)	0	0	1	0
Sinus headache	1	(0.1)	1	0	0	0
Somnolence	16	(1.3)	13	2	1	0
Speech disorder	1	(0.1)	1	0	0	0
Syncope	5	(0.4)	2	2	0	1
Tremor	7	(0.6)	7	0	0	0
Trigeminal neuralgia	1	(0.1)	1	0	0	0
PSYCHIATRIC DISORDERS	113	(9.3)	72	37	4	0
Abnormal dreams	26	(2.1)	17	8	1	0
Affect lability	1	(0.1)	0	0	1	0
Affective disorder	2	(0.2)	2	0	0	0
Aggression	1	(0.1)	0	1	0	0

* If the same subject in a given treatment had more than one occurrence in the same preferred term event category, only the most severe occurrence is taken. Subjects are counted only once per treatment in each row. For the TESS algorithm any missing severities have been imputed as grade 4 unless the subject experienced another occurrence of the same event in a given treatment for which severity was recorded.
In this case, the reported severity is summarized. Missing baseline severities are imputed as grade 1.
Includes data up to 7 days after last dose of study drug.
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.
For protocol 1026 only the QD arm is included. For 1027 and 1028 both blinded and open label treatment are included.

Table 3.4.2.3
Maraviroc Summary of Clinical Safety
Incidence and Severity of Treatment-Emergent Adverse Events (Treatment Related)
Phase 2b/3 Studies All Maraviroc Therapy

Number of Subjects evaluable for adverse events	maraviroc (n=1212)					
			Severity Grade*			
	N	(%)	1	2	3	4
System Organ Class and MedDRA (v9.0) preferred term						
Alcoholism	1	(0.1)	0	1	0	0
Anxiety	6	(0.5)	2	4	0	0
Apathy	1	(0.1)	1	0	0	0
Confusional state	1	(0.1)	1	0	0	0
Cyclothymic disorder	1	(0.1)	1	0	0	0
Depression	12	(1.0)	2	9	1	0
Disorientation	1	(0.1)	1	0	0	0
Euphoric mood	2	(0.2)	2	0	0	0
Excitability	1	(0.1)	0	1	0	0
Flat affect	1	(0.1)	1	0	0	0
Hallucination	2	(0.2)	2	0	0	0
Insomnia	42	(3.5)	33	8	1	0
Libido decreased	9	(0.7)	5	4	0	0
Loss of libido	1	(0.1)	0	1	0	0
Mood altered	2	(0.2)	2	0	0	0
Mood swings	1	(0.1)	1	0	0	0
Nightmare	11	(0.9)	7	4	0	0
Restlessness	1	(0.1)	1	0	0	0
Sleep disorder	13	(1.1)	10	3	0	0
RENAL AND URINARY DISORDERS	30	(2.5)	21	8	1	0
Chromaturia	3	(0.2)	3	0	0	0
Dysuria	3	(0.2)	3	0	0	0
Haematuria	2	(0.2)	2	0	0	0
Nocturia	8	(0.7)	5	3	0	0

* If the same subject in a given treatment had more than one occurrence in the same preferred term event category, only the most severe occurrence is taken. Subjects are counted only once per treatment in each row. For the TESS algorithm any missing severities have been imputed as grade 4 unless the subject experienced another occurrence of the same event in a given treatment for which severity was recorded.
In this case, the reported severity is summarized. Missing baseline severities are imputed as grade 1.
Includes data up to 7 days after last dose of study drug.
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MedDRA (v9.0) coding dictionary applied.
For protocol 1026 only the QD arm is included. For 1027 and 1028 both blinded and open label treatment are included.

Table 3.4.2.3
Maraviroc Summary of Clinical Safety
Incidence and Severity of Treatment-Emergent Adverse Events (Treatment Related)
Phase 2b/3 Studies All Maraviroc Therapy

Number of Subjects evaluable for adverse events	maraviroc (n=1212)					
			Severity Grade*			
	N	(%)	1	2	3	4
System Organ Class and MedDRA (v9.0) preferred term						
Pollakiuria	6	(0.5)	3	3	0	0
Polyuria	3	(0.2)	2	1	0	0
Proteinuria	3	(0.2)	3	0	0	0
Renal failure	2	(0.2)	0	1	1	0
Urinary incontinence	1	(0.1)	1	0	0	0
Urine odour abnormal	1	(0.1)	0	1	0	0
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	17	(1.4)	10	7	0	0
Benign prostatic hyperplasia	2	(0.2)	1	1	0	0
Breast discharge	1	(0.1)	1	0	0	0
Breast mass	1	(0.1)	1	0	0	0
Breast pain	1	(0.1)	0	1	0	0
Breast tenderness	3	(0.2)	2	1	0	0
Erectile dysfunction	6	(0.5)	4	2	0	0
Genital pain female	1	(0.1)	1	0	0	0
Pelvic pain	1	(0.1)	1	0	0	0
Sexual dysfunction	2	(0.2)	0	2	0	0
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	55	(4.5)	43	9	3	0
Asthma	2	(0.2)	2	0	0	0
Bronchospasm	2	(0.2)	2	0	0	0
Cough	22	(1.8)	16	6	0	0
Dysphonia	3	(0.2)	3	0	0	0
Dyspnoea	6	(0.5)	3	2	1	0

* If the same subject in a given treatment had more than one occurrence in the same preferred term event category, only the most severe occurrence is taken. Subjects are counted only once per treatment in each row. For the TESS algorithm any missing severities have been imputed as grade 4 unless the subject experienced another occurrence of the same event in a given treatment for which severity was recorded.
In this case, the reported severity is summarized. Missing baseline severities are imputed as grade 1.
Includes data up to 7 days after last dose of study drug.
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MedDRA (v9.0) coding dictionary applied.
For protocol 1026 only the QD arm is included. For 1027 and 1028 both blinded and open label treatment are included.

Table 3.4.2.3
Maraviroc Summary of Clinical Safety
Incidence and Severity of Treatment-Emergent Adverse Events (Treatment Related)
Phase 2b/3 Studies All Maraviroc Therapy

Number of Subjects evaluable for adverse events	maraviroc (n=1212)					
			Severity Grade*			
	N	(%)	1	2	3	4
System Organ Class and MedDRA (v9.0) preferred term						
Dyspnoea exacerbated	1	(0.1)	0	1	0	0
Dyspnoea exertional	1	(0.1)	1	0	0	0
Emphysema	1	(0.1)	0	0	1	0
Epistaxis	1	(0.1)	1	0	0	0
Haemoptysis	1	(0.1)	0	1	0	0
Lung disorder	1	(0.1)	0	0	1	0
Nasal congestion	5	(0.4)	4	0	1	0
Nasal dryness	1	(0.1)	1	0	0	0
Pharyngeal erythema	1	(0.1)	1	0	0	0
Pharyngolaryngeal pain	6	(0.5)	6	0	0	0
Pharynx discomfort	1	(0.1)	1	0	0	0
Productive cough	4	(0.3)	3	1	0	0
Respiratory distress	1	(0.1)	1	0	0	0
Rhinitis allergic	1	(0.1)	1	0	0	0
Rhinitis seasonal	1	(0.1)	1	0	0	0
Rhinorrhoea	2	(0.2)	2	0	0	0
Sinus congestion	1	(0.1)	1	0	0	0
Sneezing	1	(0.1)	1	0	0	0
Throat tightness	1	(0.1)	1	0	0	0
Upper respiratory tract congestion	1	(0.1)	1	0	0	0
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	140	(11.6)	99	30	9	2
Acne	2	(0.2)	2	0	0	0
Alopecia	9	(0.7)	7	1	1	0
Cold sweat	1	(0.1)	1	0	0	0

* If the same subject in a given treatment had more than one occurrence in the same preferred term event category, only the most severe occurrence is taken. Subjects are counted only once per treatment in each row. For the TESS algorithm any missing severities have been imputed as grade 4 unless the subject experienced another occurrence of the same event in a given treatment for which severity was recorded.
In this case, the reported severity is summarized. Missing baseline severities are imputed as grade 1.
Includes data up to 7 days after last dose of study drug.
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.
For protocol 1026 only the QD arm is included. For 1027 and 1028 both blinded and open label treatment are included.

Table 3.4.2.3
Maraviroc Summary of Clinical Safety
Incidence and Severity of Treatment-Emergent Adverse Events (Treatment Related)
Phase 2b/3 Studies All Maraviroc Therapy

Number of Subjects evaluable for adverse events	maraviroc (n=1212)					
			Severity Grade*			
	N	(%)	1	2	3	4
System Organ Class and MedDRA (v9.0) preferred term						
Dermatitis	2	(0.2)	1	1	0	0
Drug eruption	1	(0.1)	0	1	0	0
Dry skin	9	(0.7)	9	0	0	0
Eczema	3	(0.2)	3	0	0	0
Erythema	5	(0.4)	4	1	0	0
Exfoliative rash	2	(0.2)	2	0	0	0
Fat atrophy	1	(0.1)	0	0	1	0
Hyperhidrosis	6	(0.5)	3	3	0	0
Hypertrichosis	1	(0.1)	1	0	0	0
Hypoaesthesia facial	1	(0.1)	1	0	0	0
Lichen planus	1	(0.1)	0	1	0	0
Lipoatrophy	3	(0.2)	2	0	0	1
Lipodystrophy acquired	6	(0.5)	5	1	0	0
Lipohypertrophy	3	(0.2)	2	1	0	0
Nail discolouration	3	(0.2)	3	0	0	0
Nail disorder	1	(0.1)	1	0	0	0
Nail pigmentation	1	(0.1)	1	0	0	0
Night sweats	16	(1.3)	14	0	2	0
Onychoclasis	1	(0.1)	1	0	0	0
Onycholysis	1	(0.1)	0	1	0	0
Pruritus	18	(1.5)	17	1	0	0
Pruritus generalised	2	(0.2)	1	1	0	0
Rash	43	(3.5)	26	14	3	0
Rash erythematous	2	(0.2)	2	0	0	0
Rash generalised	2	(0.2)	1	0	1	0
Rash macular	1	(0.1)	1	0	0	0

* If the same subject in a given treatment had more than one occurrence in the same preferred term event category, only the most severe occurrence is taken. Subjects are counted only once per treatment in each row. For the TESS algorithm any missing severities have been imputed as grade 4 unless the subject experienced another occurrence of the same event in a given treatment for which severity was recorded.
In this case, the reported severity is summarized. Missing baseline severities are imputed as grade 1.
Includes data up to 7 days after last dose of study drug.
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.
For protocol 1026 only the QD arm is included. For 1027 and 1028 both blinded and open label treatment are included.

Table 3.4.2.3
Maraviroc Summary of Clinical Safety
Incidence and Severity of Treatment-Emergent Adverse Events (Treatment Related)
Phase 2b/3 Studies All Maraviroc Therapy

Number of Subjects evaluable for adverse events	maraviroc (n=1212)					
			Severity Grade*			
	N	(%)	1	2	3	4
System Organ Class and MedDRA (v9.0) preferred term						
Rash maculo-papular	2	(0.2)	0	2	0	0
Rash papular	5	(0.4)	4	1	0	0
Rash pruritic	3	(0.2)	1	2	0	0
Seborrhoeic dermatitis	1	(0.1)	1	0	0	0
Skin exfoliation	1	(0.1)	1	0	0	0
Skin irritation	1	(0.1)	0	0	1	0
Skin lesion	1	(0.1)	1	0	0	0
Skin swelling	1	(0.1)	1	0	0	0
Stevens-Johnson syndrome	1	(0.1)	0	0	0	1
Telangiectasia	1	(0.1)	1	0	0	0
Urticaria	2	(0.2)	2	0	0	0
SOCIAL CIRCUMSTANCES	1	(0.1)	0	1	0	0
Abstains from alcohol	1	(0.1)	0	1	0	0
VASCULAR DISORDERS	24	(2.0)	16	6	2	0
Circulatory collapse	1	(0.1)	1	0	0	0
Flushing	4	(0.3)	4	0	0	0
Hot flush	5	(0.4)	4	1	0	0
Hypertension	6	(0.5)	4	2	0	0
Hypotension	3	(0.2)	2	0	1	0
Orthostatic hypotension	4	(0.3)	0	3	1	0
Raynaud's phenomenon	1	(0.1)	1	0	0	0
Total preferred term events	1944		1331	478	103	32

* If the same subject in a given treatment had more than one occurrence in the same preferred term event category, only the most severe occurrence is taken. Subjects are counted only once per treatment in each row. For the TESS algorithm any missing severities have been imputed as grade 4 unless the subject experienced another occurrence of the same event in a given treatment for which severity was recorded.
In this case, the reported severity is summarized. Missing baseline severities are imputed as grade 1.
Includes data up to 7 days after last dose of study drug.
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.
For protocol 1026 only the QD arm is included. For 1027 and 1028 both blinded and open label treatment are included.

Table 3.4.2.3
Maraviroc Summary of Clinical Safety
Incidence and Severity of Treatment-Emergent Adverse Events (Treatment Related)
Phase 2b/3 Studies All Maraviroc Therapy

Number of Subjects evaluable for adverse events	maraviroc (n=1212)					
			Severity Grade*			
	N	(%)	1	2	3	4
System Organ Class and MedDRA (v9.0) preferred term						

* If the same subject in a given treatment had more than one occurrence in the same preferred term event category, only the most severe occurrence is taken. Subjects are counted only once per treatment in each row. For the TESS algorithm any missing severities have been imputed as grade 4 unless the subject experienced another occurrence of the same event in a given treatment for which severity was recorded.
In this case, the reported severity is summarized. Missing baseline severities are imputed as grade 1.
Includes data up to 7 days after last dose of study drug.
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.
For protocol 1026 only the QD arm is included. For 1027 and 1028 both blinded and open label treatment are included.

Table 3.4.2.4
Maraviroc Summary of Clinical Safety
Treatment-Emergent Adverse Events by System Organ Class (All Causalities)
Phase 2b/3 Treatment Experienced Studies

	maraviroc QD		maraviroc BID		Placebo	
	n	(%)	n	(%)	n	(%)
Number (%) of Subjects:						
Evaluable for adverse events	477		487		271	
With adverse events	420	(88.1)	439	(90.1)	230	(84.9)
Discontinued due to adverse events	22	(4.6)	20	(4.1)	12	(4.4)
Number (%) of Subjects with Adverse Events by System Organ Class:						
Being queried	1	(0.2)	0		0	
Blood and lymphatic system disorders	29	(6.1)	37	(7.6)	21	(7.7)
Cardiac disorders	12	(2.5)	11	(2.3)	6	(2.2)
Ear and labyrinth disorders	14	(2.9)	22	(4.5)	10	(3.7)
Endocrine disorders	8	(1.7)	5	(1.0)	4	(1.5)
Eye disorders	39	(8.2)	46	(9.4)	19	(7.0)
Gastrointestinal disorders	232	(48.6)	237	(48.7)	137	(50.6)
General disorders and administration site conditions	160	(33.5)	181	(37.2)	107	(39.5)
Hepatobiliary disorders	10	(2.1)	18	(3.7)	8	(3.0)
Immune system disorders	16	(3.4)	11	(2.3)	8	(3.0)
Infections and infestations	226	(47.4)	239	(49.1)	103	(38.0)
Injury, poisoning and procedural complications	35	(7.3)	35	(7.2)	17	(6.3)
Investigations	82	(17.2)	90	(18.5)	33	(12.2)
Metabolism and nutrition disorders	52	(10.9)	61	(12.5)	26	(9.6)
Musculoskeletal and connective tissue disorders	103	(21.6)	92	(18.9)	47	(17.3)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	26	(5.5)	22	(4.5)	15	(5.5)
Nervous system disorders	158	(33.1)	152	(31.2)	80	(29.5)
Pregnancy, puerperium and perinatal conditions	2	(0.4)	0		0	
Psychiatric disorders	77	(16.1)	77	(15.8)	35	(12.9)
Renal and urinary disorders	39	(8.2)	47	(9.7)	15	(5.5)
Reproductive system and breast disorders	22	(4.6)	27	(5.5)	10	(3.7)
Respiratory, thoracic and mediastinal disorders	115	(24.1)	118	(24.2)	42	(15.5)
Skin and subcutaneous tissue disorders	115	(24.1)	137	(28.1)	54	(19.9)
Social circumstances	1	(0.2)	1	(0.2)	1	(0.4)
Surgical and medical procedures	11	(2.3)	9	(1.8)	3	(1.1)
Vascular disorders	23	(4.8)	31	(6.4)	9	(3.3)

Subjects are only counted once per treatment for each row.
Includes data up to 7 days after last dose of study drug.
MedDRA (v9.0) coding dictionary applied.

Table 3.4.2.5
Maraviroc Summary of Clinical Safety
Incidence and Severity of Treatment-Emergent Adverse Events (All Causalities)
Phase 2b/3 Treatment Experienced Studies

Number of Subjects evaluable for adverse events	maraviroc QD (n=477)						maraviroc BID (n=487)						Placebo (n=271)					
			Severity Grade*						Severity Grade*						Severity Grade*			
	N	(%)	1	2	3	4	N	(%)	1	2	3	4	N	(%)	1	2	3	4
System Organ Class and MedDRA (v9.0) preferred term																		
BEING QUERIED	1	(0.2)	0	0	1	0	0		0	0	0	0	0		0	0	0	0
WORSENING OF CANDIDIASIS	1	(0.2)	0	0	1	0	0		0	0	0	0	0		0	0	0	0
BLOOD AND LYMPHATIC SYSTEM DISORDERS	29	(6.1)	16	7	2	4	37	(7.6)	10	12	9	6	21	(7.7)	7	8	5	1
Anaemia	13	(2.7)	7	3	1	2	12	(2.5)	3	6	2	1	7	(2.6)	4	3	0	0
Bone marrow failure	1	(0.2)	0	1	0	0	0		0	0	0	0	0		0	0	0	0
Coagulopathy	1	(0.2)	1	0	0	0	0		0	0	0	0	0		0	0	0	0
Febrile neutropenia	0		0	0	0	0	1	(0.2)	0	1	0	0	1	(0.4)	0	0	0	1
Haemoglobinaemia	0		0	0	0	0	0		0	0	0	0	1	(0.4)	1	0	0	0
Haemolytic anaemia	0		0	0	0	0	1	(0.2)	0	0	0	1	0		0	0	0	0
Iron deficiency anaemia	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Leukopenia	0		0	0	0	0	1	(0.2)	0	1	0	0	2	(0.7)	0	2	0	0
Lymph node pain	1	(0.2)	1	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Lymphadenitis	0		0	0	0	0	2	(0.4)	1	0	0	1	0		0	0	0	0
Lymphadenopathy	10	(2.1)	7	3	0	0	8	(1.6)	5	3	0	0	6	(2.2)	3	2	1	0
Neutropenia	4	(0.8)	1	0	1	2	11	(2.3)	0	2	6	3	6	(2.2)	0	2	4	0
Pancytopenia	1	(0.2)	0	1	0	0	2	(0.4)	0	0	2	0	0		0	0	0	0
Splenomegaly	0		0	0	0	0	1	(0.2)	0	0	0	1	1	(0.4)	0	0	1	0
Thrombocytopenia	0		0	0	0	0	1	(0.2)	0	1	0	0	1	(0.4)	0	0	1	0
CARDIAC DISORDERS	12	(2.5)	6	1	3	2	11	(2.3)	3	4	3	1	6	(2.2)	2	2	2	0
Acute myocardial infarction	1	(0.2)	0	0	1	0	0		0	0	0	0	0		0	0	0	0

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In this case, the reported severity is summarized. Missing baseline severities are imputed as grade 1.
Includes data up to 7 days after last dose of study drug.
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Number of Subjects evaluable for adverse events	maraviroc QD (n=477)						maraviroc BID (n=487)						Placebo (n=271)					
			Severity Grade*						Severity Grade*						Severity Grade*			
	N	(%)	1	2	3	4	N	(%)	1	2	3	4	N	(%)	1	2	3	4
System Organ Class and MedDRA (v9.0) preferred term																		
Angina pectoris	2	(0.4)	2	0	0	0	1	(0.2)	0	0	1	0	0		0	0	0	0
Angina unstable	1	(0.2)	0	0	1	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Aortic valve disease	0		0	0	0	0	0		0	0	0	0	1	(0.4)	0	0	1	0
Arrhythmia	0		0	0	0	0	1	(0.2)	0	0	0	1	0		0	0	0	0
Atrioventricular block first degree	1	(0.2)	1	0	0	0	2	(0.4)	2	0	0	0	0		0	0	0	0
Bradycardia	0		0	0	0	0	3	(0.6)	0	3	0	0	0		0	0	0	0
Cardiac failure acute	1	(0.2)	0	0	0	1	0		0	0	0	0	0		0	0	0	0
Coronary artery disease	2	(0.4)	0	1	1	0	0		0	0	0	0	0		0	0	0	0
Coronary artery occlusion	2	(0.4)	0	1	1	0	0		0	0	0	0	0		0	0	0	0
Myocardial infarction	1	(0.2)	0	0	0	1	1	(0.2)	0	0	1	0	0		0	0	0	0
Myocardial ischaemia	0		0	0	0	0	2	(0.4)	1	0	1	0	0		0	0	0	0
Palpitations	1	(0.2)	1	0	0	0	1	(0.2)	1	0	0	0	4	(1.5)	2	2	0	0
Prinzmetal angina	0		0	0	0	0	1	(0.2)	0	1	0	0	0		0	0	0	0
Sinus bradycardia	1	(0.2)	1	0	0	0	0		0	0	0	0	0		0	0	0	0
Supraventricular tachyarrhythmia	0		0	0	0	0	0		0	0	0	0	1	(0.4)	0	0	1	0
Tachycardia	1	(0.2)	1	0	0	0	2	(0.4)	1	1	0	0	0		0	0	0	0
EAR AND LABYRINTH DISORDERS	14	(2.9)	10	3	1	0	22	(4.5)	13	8	1	0	10	(3.7)	5	4	0	1
Cerumen impaction	0		0	0	0	0	3	(0.6)	2	1	0	0	0		0	0	0	0
Deafness	1	(0.2)	1	0	0	0	1	(0.2)	1	0	0	0	1	(0.4)	0	0	0	1
Ear congestion	0		0	0	0	0	2	(0.4)	1	1	0	0	1	(0.4)	0	1	0	0
Ear discomfort	0		0	0	0	0	2	(0.4)	1	1	0	0	0		0	0	0	0
Ear disorder	0		0	0	0	0	1	(0.2)	1	0	0	0	1	(0.4)	0	1	0	0
Ear haemorrhage	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Ear pain	3	(0.6)	1	2	0	0	3	(0.6)	2	1	0	0	1	(0.4)	1	0	0	0

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Includes data up to 7 days after last dose of study drug.
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Maraviroc Summary of Clinical Safety
Incidence and Severity of Treatment-Emergent Adverse Events (All Causalities)
Phase 2b/3 Treatment Experienced Studies

Number of Subjects evaluable for adverse events	maraviroc QD (n=477)						maraviroc BID (n=487)						Placebo (n=271)					
			Severity Grade*						Severity Grade*						Severity Grade*			
	N	(%)	1	2	3	4	N	(%)	1	2	3	4	N	(%)	1	2	3	4
System Organ Class and MedDRA (v9.0) preferred term																		
Hyperacusis	1	(0.2)	1	0	0	0	0		0	0	0	0	0		0	0	0	0
Motion sickness	0		0	0	0	0	1	(0.2)	0	1	0	0	0		0	0	0	0
Otorrhoea	1	(0.2)	1	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Tinnitus	2	(0.4)	2	0	0	0	4	(0.8)	2	2	0	0	2	(0.7)	0	2	0	0
Tympanic membrane hyperaemia	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Vertigo	6	(1.3)	4	1	1	0	5	(1.0)	3	1	1	0	4	(1.5)	4	0	0	0
Vertigo positional	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
ENDOCRINE DISORDERS	8	(1.7)	4	4	0	0	5	(1.0)	2	3	0	0	4	(1.5)	2	2	0	0
Adrenal insufficiency	1	(0.2)	0	1	0	0	0		0	0	0	0	0		0	0	0	0
Adrenal mass	1	(0.2)	1	0	0	0	0		0	0	0	0	0		0	0	0	0
Basedow's disease	1	(0.2)	1	0	0	0	0		0	0	0	0	0		0	0	0	0
Hyperparathyroidism	0		0	0	0	0	0		0	0	0	0	1	(0.4)	0	1	0	0
Hypogonadism	2	(0.4)	1	1	0	0	4	(0.8)	2	2	0	0	1	(0.4)	1	0	0	0
Hypothyroidism	3	(0.6)	1	2	0	0	1	(0.2)	0	1	0	0	2	(0.7)	1	1	0	0
EYE DISORDERS	39	(8.2)	29	8	1	1	46	(9.4)	31	13	1	1	19	(7.0)	12	7	0	0
Amblyopia	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Blepharitis	1	(0.2)	1	0	0	0	0		0	0	0	0	2	(0.7)	1	1	0	0
Blindness unilateral	0		0	0	0	0	1	(0.2)	0	0	0	1	0		0	0	0	0
Cataract	1	(0.2)	1	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Cataract subcapsular	1	(0.2)	1	0	0	0	0		0	0	0	0	0		0	0	0	0
Chalazion	0		0	0	0	0	0		0	0	0	0	1	(0.4)	1	0	0	0
Conjunctival irritation	1	(0.2)	1	0	0	0	0		0	0	0	0	0		0	0	0	0

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MedDRA (v9.0) coding dictionary applied.

Maraviroc Summary of Clinical Safety
Incidence and Severity of Treatment-Emergent Adverse Events (All Causalities)
Phase 2b/3 Treatment Experienced Studies

Number of Subjects evaluable for adverse events	maraviroc QD (n=477)						maraviroc BID (n=487)						Placebo (n=271)					
			Severity Grade*						Severity Grade*						Severity Grade*			
	N	(%)	1	2	3	4	N	(%)	1	2	3	4	N	(%)	1	2	3	4
System Organ Class and MedDRA (v9.0) preferred term																		
Conjunctivitis	7	(1.5)	5	2	0	0	9	(1.8)	6	3	0	0	3	(1.1)	1	2	0	0
Conjunctivitis allergic	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Dacryoadenitis acquired	1	(0.2)	1	0	0	0	0		0	0	0	0	0		0	0	0	0
Dacryostenosis acquired	0		0	0	0	0	0		0	0	0	0	1	(0.4)	1	0	0	0
Diplopia	0		0	0	0	0	2	(0.4)	1	0	1	0	1	(0.4)	0	1	0	0
Dry eye	1	(0.2)	1	0	0	0	7	(1.4)	3	4	0	0	1	(0.4)	1	0	0	0
Erythema of eyelid	1	(0.2)	1	0	0	0	0		0	0	0	0	0		0	0	0	0
Exophthalmos	1	(0.2)	0	0	1	0	0		0	0	0	0	0		0	0	0	0
Eye allergy	0		0	0	0	0	1	(0.2)	0	1	0	0	0		0	0	0	0
Eye discharge	0		0	0	0	0	0		0	0	0	0	1	(0.4)	1	0	0	0
Eye disorder	1	(0.2)	1	0	0	0	0		0	0	0	0	0		0	0	0	0
Eye irritation	3	(0.6)	3	0	0	0	5	(1.0)	5	0	0	0	0		0	0	0	0
Eye oedema	1	(0.2)	1	0	0	0	0		0	0	0	0	0		0	0	0	0
Eye pain	1	(0.2)	0	1	0	0	3	(0.6)	3	0	0	0	0		0	0	0	0
Eye pruritus	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Eyelid disorder	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Eyelid oedema	2	(0.4)	2	0	0	0	0		0	0	0	0	0		0	0	0	0
Eyelid ptosis	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Glaucoma	1	(0.2)	0	1	0	0	0		0	0	0	0	0		0	0	0	0
Halo vision	0		0	0	0	0	0		0	0	0	0	1	(0.4)	1	0	0	0
Keratoconjunctivitis sicca	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Lacrimation increased	2	(0.4)	2	0	0	0	0		0	0	0	0	0		0	0	0	0
Ocular hyperaemia	3	(0.6)	2	1	0	0	2	(0.4)	2	0	0	0	1	(0.4)	0	1	0	0
Ocular icterus	2	(0.4)	2	0	0	0	3	(0.6)	1	2	0	0	0		0	0	0	0
Photophobia	1	(0.2)	1	0	0	0	0		0	0	0	0	0		0	0	0	0
Photopsia	1	(0.2)	1	0	0	0	0		0	0	0	0	0		0	0	0	0

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MedDRA (v9.0) coding dictionary applied.

Number of Subjects evaluable for adverse events	maraviroc QD (n=477)						maraviroc BID (n=487)						Placebo (n=271)					
			Severity Grade*						Severity Grade*						Severity Grade*			
	N	(%)	1	2	3	4	N	(%)	1	2	3	4	N	(%)	1	2	3	4
System Organ Class and MedDRA (v9.0) preferred term																		
Presbyopia	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Punctate keratitis	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Retinal degeneration	0		0	0	0	0	0		0	0	0	0	1	(0.4)	0	1	0	0
Retinal tear	1	(0.2)	0	1	0	0	0		0	0	0	0	0		0	0	0	0
Scleritis	1	(0.2)	1	0	0	0	0		0	0	0	0	0		0	0	0	0
Strabismus	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Vision blurred	6	(1.3)	5	1	0	0	5	(1.0)	4	1	0	0	4	(1.5)	4	0	0	0
Visual acuity reduced	2	(0.4)	1	1	0	0	1	(0.2)	0	0	1	0	3	(1.1)	2	1	0	0
Visual disturbance	5	(1.0)	3	1	0	1	1	(0.2)	0	1	0	0	1	(0.4)	1	0	0	0
Vitreous floaters	2	(0.4)	2	0	0	0	2	(0.4)	1	1	0	0	0		0	0	0	0
Vitritis	0		0	0	0	0	1	(0.2)	0	1	0	0	0		0	0	0	0
Xerophthalmia	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
GASTROINTESTINAL DISORDERS	232	(48.6)	130	89	10	3	237	(48.7)	138	81	14	4	137	(50.6)	70	57	8	2
Abdominal discomfort	2	(0.4)	2	0	0	0	6	(1.2)	4	2	0	0	3	(1.1)	0	2	1	0
Abdominal distension	15	(3.1)	11	3	1	0	12	(2.5)	11	1	0	0	8	(3.0)	5	3	0	0
Abdominal pain	20	(4.2)	10	9	1	0	19	(3.9)	11	6	2	0	10	(3.7)	4	4	2	0
Abdominal pain lower	3	(0.6)	3	0	0	0	2	(0.4)	2	0	0	0	1	(0.4)	1	0	0	0
Abdominal pain upper	22	(4.6)	16	5	1	0	15	(3.1)	9	4	1	1	8	(3.0)	7	1	0	0
Abdominal rigidity	0		0	0	0	0	0		0	0	0	0	1	(0.4)	0	0	1	0
Abdominal tenderness	2	(0.4)	2	0	0	0	1	(0.2)	0	1	0	0	3	(1.1)	3	0	0	0
Abnormal faeces	0		0	0	0	0	3	(0.6)	3	0	0	0	0		0	0	0	0
Anal fistula	1	(0.2)	0	1	0	0	0		0	0	0	0	0		0	0	0	0
Anal inflammation	0		0	0	0	0	0		0	0	0	0	1	(0.4)	0	1	0	0
Anal ulcer	1	(0.2)	1	0	0	0	0		0	0	0	0	1	(0.4)	1	0	0	0

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Number of Subjects evaluable for adverse events	maraviroc QD (n=477)						maraviroc BID (n=487)						Placebo (n=271)					
			Severity Grade*						Severity Grade*						Severity Grade*			
	N	(%)	1	2	3	4	N	(%)	1	2	3	4	N	(%)	1	2	3	4
System Organ Class and MedDRA (v9.0) preferred term																		
Anogenital dysplasia	1	(0.2)	0	1	0	0	0		0	0	0	0	1	(0.4)	0	1	0	0
Aphthous stomatitis	7	(1.5)	5	2	0	0	6	(1.2)	5	1	0	0	2	(0.7)	2	0	0	0
Ascites	0		0	0	0	0	1	(0.2)	0	0	0	1	1	(0.4)	0	0	1	0
Bowel sounds abnormal	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Chapped lips	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Cheilitis	2	(0.4)	2	0	0	0	0		0	0	0	0	1	(0.4)	1	0	0	0
Colitis	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Constipation	25	(5.2)	17	7	1	0	27	(5.5)	20	6	1	0	7	(2.6)	5	2	0	0
Diarrhoea	109	(22.9)	59	46	3	1	100	(20.5)	62	35	2	1	58	(21.4)	34	23	0	1
Diarrhoea haemorrhagic	1	(0.2)	0	0	0	1	0		0	0	0	0	0		0	0	0	0
Diverticulum intestinal	0		0	0	0	0	0		0	0	0	0	1	(0.4)	1	0	0	0
Diverticulum intestinal haemorrhagic	1	(0.2)	0	0	0	1	0		0	0	0	0	0		0	0	0	0
Dry mouth	4	(0.8)	3	1	0	0	6	(1.2)	4	2	0	0	5	(1.8)	4	1	0	0
Dyspepsia	11	(2.3)	9	2	0	0	11	(2.3)	6	5	0	0	5	(1.8)	2	3	0	0
Dysphagia	3	(0.6)	1	1	1	0	3	(0.6)	1	1	0	1	1	(0.4)	0	0	1	0
Enteritis	2	(0.4)	1	1	0	0	0		0	0	0	0	1	(0.4)	0	1	0	0
Eructation	2	(0.4)	1	1	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Faecal incontinence	1	(0.2)	0	1	0	0	0		0	0	0	0	0		0	0	0	0
Faeces discoloured	0		0	0	0	0	1	(0.2)	0	1	0	0	0		0	0	0	0
Faeces pale	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Flatulence	15	(3.1)	13	2	0	0	16	(3.3)	13	3	0	0	11	(4.1)	9	2	0	0
Food poisoning	1	(0.2)	1	0	0	0	0		0	0	0	0	1	(0.4)	1	0	0	0
Gastritis	8	(1.7)	5	3	0	0	2	(0.4)	1	1	0	0	0		0	0	0	0
Gastrointestinal disorder	0		0	0	0	0	1	(0.2)	0	1	0	0	0		0	0	0	0
Gastrointestinal pain	0		0	0	0	0	1	(0.2)	1	0	0	0	1	(0.4)	1	0	0	0
Gastrooesophageal reflux disease	5	(1.0)	3	2	0	0	7	(1.4)	7	0	0	0	3	(1.1)	2	1	0	0

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Number of Subjects evaluable for adverse events	maraviroc QD (n=477)						maraviroc BID (n=487)						Placebo (n=271)					
			Severity Grade*						Severity Grade*						Severity Grade*			
	N	(%)	1	2	3	4	N	(%)	1	2	3	4	N	(%)	1	2	3	4
System Organ Class and MedDRA (v9.0) preferred term																		
Gingival bleeding	1	(0.2)	1	0	0	0	0		0	0	0	0	1	(0.4)	1	0	0	0
Gingival pain	0		0	0	0	0	2	(0.4)	1	1	0	0	0		0	0	0	0
Gingivitis	4	(0.8)	1	3	0	0	4	(0.8)	4	0	0	0	2	(0.7)	1	1	0	0
Glossitis	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Glossodynia	1	(0.2)	0	1	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Haematochezia	3	(0.6)	1	1	1	0	0		0	0	0	0	2	(0.7)	2	0	0	0
Haemorrhoids	7	(1.5)	4	3	0	0	6	(1.2)	3	3	0	0	0		0	0	0	0
Hiatus hernia	1	(0.2)	1	0	0	0	0		0	0	0	0	0		0	0	0	0
Hypoaesthesia oral	5	(1.0)	4	1	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Inguinal hernia	0		0	0	0	0	0		0	0	0	0	1	(0.4)	1	0	0	0
Intestinal mass	1	(0.2)	0	1	0	0	0		0	0	0	0	0		0	0	0	0
Intestinal spasm	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Lip blister	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Lip dry	0		0	0	0	0	0		0	0	0	0	1	(0.4)	0	1	0	0
Melaena	0		0	0	0	0	0		0	0	0	0	1	(0.4)	0	1	0	0
Mesenteric artery stenosis	0		0	0	0	0	0		0	0	0	0	1	(0.4)	0	1	0	0
Mouth ulceration	2	(0.4)	2	0	0	0	7	(1.4)	6	1	0	0	2	(0.7)	2	0	0	0
Nausea	84	(17.6)	59	19	6	0	78	(16.0)	53	21	3	1	52	(19.2)	32	19	1	0
Odynophagia	1	(0.2)	0	1	0	0	1	(0.2)	0	0	0	1	0		0	0	0	0
Oesophagitis	0		0	0	0	0	1	(0.2)	1	0	0	0	1	(0.4)	1	0	0	0
Oral mucosal blistering	0		0	0	0	0	1	(0.2)	0	1	0	0	0		0	0	0	0
Oral pain	1	(0.2)	0	1	0	0	0		0	0	0	0	0		0	0	0	0
Oral soft tissue disorder	1	(0.2)	1	0	0	0	3	(0.6)	3	0	0	0	1	(0.4)	1	0	0	0
Painful defaecation	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Pancreatitis	1	(0.2)	1	0	0	0	1	(0.2)	0	1	0	0	2	(0.7)	0	1	0	1
Paraesthesia oral	5	(1.0)	5	0	0	0	3	(0.6)	3	0	0	0	2	(0.8)	2	0	0	0

* If the same subject in a given treatment had more than one occurrence in the same preferred term event category, only the most severe occurrence is taken. Subjects are counted only once per treatment in each row. For the TESS algorithm any missing severities have been imputed as grade 4 unless the subject experienced another occurrence of the same event in a given treatment for which severity was recorded.
In this case, the reported severity is summarized. Missing baseline severities are imputed as grade 1.
Includes data up to 7 days after last dose of study drug.
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Maraviroc Summary of Clinical Safety
Incidence and Severity of Treatment-Emergent Adverse Events (All Causalities)
Phase 2b/3 Treatment Experienced Studies

Number of Subjects evaluable for adverse events	maraviroc QD (n=477)						maraviroc BID (n=487)						Placebo (n=271)					
			Severity Grade*						Severity Grade*						Severity Grade*			
	N	(%)	1	2	3	4	N	(%)	1	2	3	4	N	(%)	1	2	3	4
System Organ Class and MedDRA (v9.0) preferred term																		
Parotid duct cyst	0		0	0	0	0	0		0	0	0	0	1	(0.4)	1	0	0	0
Parotid duct obstruction	1	(0.2)	0	1	0	0	0		0	0	0	0	0		0	0	0	0
Parotid gland enlargement	1	(0.2)	0	1	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Perianal erythema	0		0	0	0	0	0		0	0	0	0	1	(0.4)	1	0	0	0
Proctalgia	2	(0.4)	2	0	0	0	2	(0.4)	1	1	0	0	1	(0.4)	0	1	0	0
Rectal discharge	0		0	0	0	0	0		0	0	0	0	1	(0.4)	0	1	0	0
Rectal haemorrhage	4	(0.8)	2	2	0	0	0		0	0	0	0	1	(0.4)	1	0	0	0
Rectal ulcer	1	(0.2)	0	0	0	1	1	(0.2)	0	0	1	0	0		0	0	0	0
Retching	0		0	0	0	0	1	(0.2)	1	0	0	0	1	(0.4)	0	1	0	0
Sensitivity of teeth	0		0	0	0	0	2	(0.4)	2	0	0	0	1	(0.4)	1	0	0	0
Small intestinal obstruction	0		0	0	0	0	1	(0.2)	0	0	1	0	0		0	0	0	0
Stomach discomfort	1	(0.2)	1	0	0	0	1	(0.2)	1	0	0	0	1	(0.4)	1	0	0	0
Tongue black hairy	0		0	0	0	0	0		0	0	0	0	1	(0.4)	1	0	0	0
Tongue coated	0		0	0	0	0	0		0	0	0	0	1	(0.4)	0	1	0	0
Tongue disorder	1	(0.2)	1	0	0	0	1	(0.2)	1	0	0	0	1	(0.4)	1	0	0	0
Tongue ulceration	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Tooth disorder	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Toothache	2	(0.4)	1	1	0	0	5	(1.0)	1	3	1	0	4	(1.5)	0	4	0	0
Umbilical hernia	1	(0.2)	1	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Varices oesophageal	0		0	0	0	0	1	(0.2)	0	0	0	1	0		0	0	0	0
Vomiting	46	(9.6)	28	13	4	1	34	(7.0)	25	6	3	0	27	(10.0)	19	7	1	0
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	160	(33.5)	103	42	11	4	181	(37.2)	109	51	19	2	107	(39.5)	58	38	8	3
Adverse drug reaction	2	(0.4)	0	1	1	0	0		0	0	0	0	0		0	0	0	0

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In this case, the reported severity is summarized. Missing baseline severities are imputed as grade 1.
Includes data up to 7 days after last dose of study drug.
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Table 3.4.2.5
Maraviroc Summary of Clinical Safety
Incidence and Severity of Treatment-Emergent Adverse Events (All Causalities)
Phase 2b/3 Treatment Experienced Studies

Number of Subjects evaluable for adverse events	maraviroc QD (n=477)						maraviroc BID (n=487)						Placebo (n=271)					
			Severity Grade*						Severity Grade*						Severity Grade*			
	N	(%)	1	2	3	4	N	(%)	1	2	3	4	N	(%)	1	2	3	4
System Organ Class and MedDRA (v9.0) preferred term																		
Asthenia	17	(3.6)	12	3	2	0	12	(2.5)	4	4	3	1	11	(4.1)	4	5	0	2
Axillary pain	1	(0.2)	1	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Catheter related complication	0		0	0	0	0	0		0	0	0	0	1	(0.4)	1	0	0	0
Chest discomfort	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Chest pain	11	(2.3)	3	3	4	1	7	(1.4)	3	3	1	0	2	(0.7)	0	0	2	0
Chills	5	(1.0)	5	0	0	0	5	(1.0)	4	0	1	0	4	(1.5)	2	2	0	0
Chronic fatigue syndrome	0		0	0	0	0	0		0	0	0	0	1	(0.4)	1	0	0	0
Condition aggravated	1	(0.2)	1	0	0	0	0		0	0	0	0	1	(0.4)	0	0	0	1
Cyst	1	(0.2)	1	0	0	0	0		0	0	0	0	0		0	0	0	0
Drug intolerance	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Energy increased	0		0	0	0	0	0		0	0	0	0	1	(0.4)	0	1	0	0
Fat tissue increased	4	(0.8)	2	2	0	0	4	(0.8)	3	1	0	0	1	(0.4)	0	1	0	0
Fatigue	53	(11.1)	36	14	3	0	61	(12.5)	39	18	4	0	43	(15.9)	26	14	2	1
Feeling abnormal	1	(0.2)	1	0	0	0	1	(0.2)	1	0	0	0	1	(0.4)	1	0	0	0
Feeling cold	0		0	0	0	0	1	(0.2)	0	1	0	0	0		0	0	0	0
Feeling drunk	0		0	0	0	0	1	(0.2)	1	0	0	0	1	(0.4)	1	0	0	0
Feeling hot	0		0	0	0	0	3	(0.6)	3	0	0	0	1	(0.4)	1	0	0	0
Gait disturbance	1	(0.2)	1	0	0	0	0		0	0	0	0	0		0	0	0	0
General physical health deterioration	0		0	0	0	0	1	(0.2)	0	1	0	0	0		0	0	0	0
Generalised oedema	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Hernia pain	1	(0.2)	1	0	0	0	0		0	0	0	0	0		0	0	0	0
Hunger	1	(0.2)	1	0	0	0	0		0	0	0	0	0		0	0	0	0
Hyperthermia	0		0	0	0	0	1	(0.2)	0	1	0	0	0		0	0	0	0
Hypothermia	0		0	0	0	0	1	(0.2)	1	0	0	0	1	(0.4)	0	0	1	0
Impaired healing	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Induration	3	(0.6)	2	1	0	0	1	(0.2)	0	1	0	0	2	(0.7)	1	1	0	0

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In this case, the reported severity is summarized. Missing baseline severities are imputed as grade 1.
Includes data up to 7 days after last dose of study drug.
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Maraviroc Summary of Clinical Safety
Incidence and Severity of Treatment-Emergent Adverse Events (All Causalities)
Phase 2b/3 Treatment Experienced Studies

Number of Subjects evaluable for adverse events	maraviroc QD (n=477)						maraviroc BID (n=487)						Placebo (n=271)					
			Severity Grade*						Severity Grade*						Severity Grade*			
	N	(%)	1	2	3	4	N	(%)	1	2	3	4	N	(%)	1	2	3	4
System Organ Class and MedDRA (v9.0) preferred term																		
Inflammation	1	(0.2)	1	0	0	0	2	(0.4)	1	1	0	0	0		0	0	0	0
Influenza like illness	6	(1.3)	4	2	0	0	1	(0.2)	1	0	0	0	3	(1.1)	2	1	0	0
Infusion site reaction	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Injection site erythema	3	(0.6)	1	2	0	0	3	(0.6)	1	2	0	0	0		0	0	0	0
Injection site haemorrhage	1	(0.2)	0	1	0	0	0		0	0	0	0	0		0	0	0	0
Injection site induration	2	(0.4)	2	0	0	0	6	(1.2)	4	2	0	0	0		0	0	0	0
Injection site inflammation	0		0	0	0	0	0		0	0	0	0	1	(0.4)	0	0	1	0
Injection site mass	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Injection site nodule	6	(1.3)	4	2	0	0	3	(0.6)	3	0	0	0	2	(0.7)	1	1	0	0
Injection site pain	2	(0.4)	2	0	0	0	4	(0.8)	2	1	1	0	2	(0.7)	1	1	0	0
Injection site pruritus	0		0	0	0	0	0		0	0	0	0	1	(0.4)	0	1	0	0
Injection site reaction	34	(7.1)	23	10	1	0	43	(8.8)	33	9	1	0	27	(10.0)	18	9	0	0
Injection site swelling	1	(0.2)	0	1	0	0	1	(0.2)	0	1	0	0	0		0	0	0	0
Injection site urticaria	0		0	0	0	0	2	(0.4)	2	0	0	0	0		0	0	0	0
Irritability	2	(0.4)	1	1	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Local swelling	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Malaise	7	(1.5)	5	2	0	0	4	(0.8)	2	1	1	0	7	(2.6)	4	2	1	0
Mass	1	(0.2)	0	0	0	1	0		0	0	0	0	0		0	0	0	0
Nodule	2	(0.4)	2	0	0	0	1	(0.2)	1	0	0	0	1	(0.4)	1	0	0	0
Oedema	0		0	0	0	0	0		0	0	0	0	1	(0.4)	1	0	0	0
Oedema peripheral	15	(3.1)	14	1	0	0	9	(1.8)	4	4	1	0	6	(2.2)	3	3	0	0
Pain	5	(1.0)	4	1	0	0	9	(1.8)	6	3	0	0	4	(1.5)	2	2	0	0
Pitting oedema	1	(0.2)	1	0	0	0	0		0	0	0	0	0		0	0	0	0
Pyrexia	35	(7.3)	25	6	1	3	57	(11.7)	31	16	8	2	21	(7.7)	10	9	2	0
Thirst	0		0	0	0	0	2	(0.4)	1	1	0	0	0		0	0	0	0
Upper extremity mass	1	(0.2)	1	0	0	0	0		0	0	0	0	0		0	0	0	0

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Includes data up to 7 days after last dose of study drug.
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Maraviroc Summary of Clinical Safety
Incidence and Severity of Treatment-Emergent Adverse Events (All Causalities)
Phase 2b/3 Treatment Experienced Studies

Number of Subjects evaluable for adverse events	maraviroc QD (n=477)						maraviroc BID (n=487)						Placebo (n=271)					
			Severity Grade*						Severity Grade*						Severity Grade*			
	N	(%)	1	2	3	4	N	(%)	1	2	3	4	N	(%)	1	2	3	4
System Organ Class and MedDRA (v9.0) preferred term																		
HEPATOBILIARY DISORDERS	10	(2.1)	4	2	1	3	18	(3.7)	7	2	7	2	8	(3.0)	3	0	3	2
Cholecystitis	0		0	0	0	0	1	(0.2)	0	0	1	0	0		0	0	0	0
Cholecystitis acute	0		0	0	0	0	1	(0.2)	0	0	1	0	0		0	0	0	0
Cholelithiasis	1	(0.2)	0	1	0	0	3	(0.6)	1	2	0	0	1	(0.4)	0	0	1	0
Chronic hepatitis	0		0	0	0	0	0		0	0	0	0	1	(0.4)	1	0	0	0
Cytolytic hepatitis	0		0	0	0	0	0		0	0	0	0	1	(0.4)	0	0	1	0
Hepatic cirrhosis	0		0	0	0	0	2	(0.4)	0	0	1	1	0		0	0	0	0
Hepatic failure	1	(0.2)	0	0	0	1	0		0	0	0	0	0		0	0	0	0
Hepatitis toxic	0		0	0	0	0	0		0	0	0	0	1	(0.4)	0	0	0	1
Hepatomegaly	2	(0.4)	1	1	0	0	1	(0.2)	1	0	0	0	1	(0.4)	0	0	1	0
Hepatosplenomegaly	0		0	0	0	0	2	(0.4)	2	0	0	0	0		0	0	0	0
Hyperbilirubinaemia	3	(0.6)	0	0	1	2	4	(0.8)	0	0	4	0	2	(0.7)	1	0	0	1
Jaundice	5	(1.0)	5	0	0	0	3	(0.6)	3	0	0	0	1	(0.4)	1	0	0	0
Jaundice cholestatic	0		0	0	0	0	1	(0.2)	0	0	0	1	0		0	0	0	0
Portal vein thrombosis	0		0	0	0	0	1	(0.2)	0	0	0	1	0		0	0	0	0
IMMUNE SYSTEM DISORDERS	16	(3.4)	10	4	2	0	11	(2.3)	4	2	4	1	8	(3.0)	4	2	2	0
Allergy to arthropod bite	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Antiphospholipid syndrome	1	(0.2)	0	1	0	0	0		0	0	0	0	0		0	0	0	0
Drug hypersensitivity	3	(0.6)	0	2	1	0	3	(0.6)	0	1	2	0	1	(0.4)	0	0	1	0
Food allergy	1	(0.2)	1	0	0	0	0		0	0	0	0	1	(0.4)	1	0	0	0
Hypersensitivity	1	(0.2)	0	0	1	0	2	(0.4)	0	0	1	1	1	(0.4)	0	0	1	0
Immune reconstitution syndrome	0		0	0	0	0	2	(0.4)	1	0	1	0	0		0	0	0	0

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MedDRA (v9.0) coding dictionary applied.

Number of Subjects evaluable for adverse events	maraviroc QD (n=477)						maraviroc BID (n=487)						Placebo (n=271)					
			Severity Grade*						Severity Grade*						Severity Grade*			
	N	(%)	1	2	3	4	N	(%)	1	2	3	4	N	(%)	1	2	3	4
System Organ Class and MedDRA (v9.0) preferred term																		
Multiple allergies	1	(0.2)	1	0	0	0	0		0	0	0	0	0		0	0	0	0
Seasonal allergy	9	(1.9)	8	1	0	0	3	(0.6)	2	1	0	0	5	(1.8)	3	2	0	0
INFECTIONS AND INFESTATIONS	226	(47.4)	105	93	15	13	239	(49.1)	106	106	16	11	103	(38.0)	43	43	10	7
AIDS encephalopathy	1	(0.2)	0	1	0	0	0		0	0	0	0	0		0	0	0	0
Abscess	2	(0.4)	1	1	0	0	0		0	0	0	0	1	(0.4)	0	0	1	0
Abscess of eyelid	0		0	0	0	0	1	(0.2)	0	1	0	0	0		0	0	0	0
Acarodermatitis	1	(0.2)	0	1	0	0	1	(0.2)	0	1	0	0	0		0	0	0	0
Acquired immunodeficiency syndrome	1	(0.2)	0	0	0	1	0		0	0	0	0	0		0	0	0	0
Acute sinusitis	2	(0.4)	1	1	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Acute tonsillitis	1	(0.2)	1	0	0	0	0		0	0	0	0	0		0	0	0	0
Amoebic colitis	0		0	0	0	0	1	(0.2)	0	1	0	0	1	(0.4)	1	0	0	0
Anal chlamydia infection	0		0	0	0	0	1	(0.2)	0	1	0	0	0		0	0	0	0
Anal fistula infection	0		0	0	0	0	0		0	0	0	0	1	(0.4)	0	0	1	0
Appendicitis	0		0	0	0	0	1	(0.2)	0	0	1	0	0		0	0	0	0
Aspergillosis	1	(0.2)	0	0	0	1	1	(0.2)	0	1	0	0	0		0	0	0	0
Bacteraemia	0		0	0	0	0	1	(0.2)	0	1	0	0	0		0	0	0	0
Bacterial infection	0		0	0	0	0	0		0	0	0	0	1	(0.4)	1	0	0	0
Balanitis candida	1	(0.2)	1	0	0	0	0		0	0	0	0	0		0	0	0	0
Blister infected	2	(0.4)	2	0	0	0	0		0	0	0	0	0		0	0	0	0
Body tinea	2	(0.4)	2	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Bronchitis	24	(5.0)	13	11	0	0	27	(5.5)	14	13	0	0	8	(3.0)	4	4	0	0
Bronchitis acute	2	(0.4)	2	0	0	0	2	(0.4)	1	1	0	0	1	(0.4)	1	0	0	0
Bronchitis bacterial	1	(0.2)	1	0	0	0	0		0	0	0	0	0		0	0	0	0
Bronchopneumonia	0		0	0	0	0	0		0	0	0	0	1	(0.4)	1	0	0	0

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In this case, the reported severity is summarized. Missing baseline severities are imputed as grade 1.
Includes data up to 7 days after last dose of study drug.
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Table 3.4.2.5
Maraviroc Summary of Clinical Safety
Incidence and Severity of Treatment-Emergent Adverse Events (All Causalities)
Phase 2b/3 Treatment Experienced Studies

Number of Subjects evaluable for adverse events	maraviroc QD (n=477)						maraviroc BID (n=487)						Placebo (n=271)					
			Severity Grade*						Severity Grade*						Severity Grade*			
	N	(%)	1	2	3	4	N	(%)	1	2	3	4	N	(%)	1	2	3	4
System Organ Class and MedDRA (v9.0) preferred term																		
Campylobacter infection	1	(0.2)	0	0	1	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Candidiasis	4	(0.8)	3	1	0	0	6	(1.2)	3	3	0	0	2	(0.7)	1	0	0	1
Carbuncle	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Cavernous sinus thrombosis	1	(0.2)	0	0	0	1	0		0	0	0	0	0		0	0	0	0
Cellulitis	7	(1.5)	2	4	0	1	7	(1.4)	3	2	2	0	2	(0.7)	0	2	0	0
Cellulitis orbital	1	(0.2)	0	1	0	0	0		0	0	0	0	0		0	0	0	0
Cervicitis	1	(0.2)	1	0	0	0	0		0	0	0	0	0		0	0	0	0
Chronic sinusitis	0		0	0	0	0	0		0	0	0	0	1	(0.4)	0	1	0	0
Clostridial infection	0		0	0	0	0	0		0	0	0	0	1	(0.4)	0	1	0	0
Clostridium difficile colitis	1	(0.2)	0	0	1	0	0		0	0	0	0	0		0	0	0	0
Condyloma acuminatum	6	(1.3)	4	1	0	1	11	(2.3)	7	4	0	0	2	(0.7)	2	0	0	0
Cystitis	1	(0.2)	0	1	0	0	2	(0.4)	1	1	0	0	0		0	0	0	0
Cytomegalovirus chorioretinitis	3	(0.6)	0	1	2	0	0		0	0	0	0	0		0	0	0	0
Cytomegalovirus gastrointestinal infection	0		0	0	0	0	1	(0.2)	0	1	0	0	0		0	0	0	0
Cytomegalovirus infection	0		0	0	0	0	1	(0.2)	0	1	0	0	0		0	0	0	0
Diverticulitis	0		0	0	0	0	0		0	0	0	0	1	(0.4)	0	0	1	0
Ear infection	2	(0.4)	2	0	0	0	6	(1.2)	1	4	1	0	1	(0.4)	1	0	0	0
Endocarditis	0		0	0	0	0	1	(0.2)	0	0	0	1	0		0	0	0	0
Erysipelas	1	(0.2)	0	1	0	0	0		0	0	0	0	1	(0.4)	1	0	0	0
Eye infection	2	(0.4)	2	0	0	0	1	(0.2)	0	1	0	0	0		0	0	0	0
Eyelid infection	0		0	0	0	0	2	(0.4)	0	2	0	0	0		0	0	0	0
Folliculitis	8	(1.7)	5	3	0	0	14	(2.9)	8	6	0	0	5	(1.8)	4	1	0	0
Fungal infection	2	(0.4)	1	1	0	0	1	(0.2)	0	0	0	1	0		0	0	0	0
Fungal rash	1	(0.2)	1	0	0	0	0		0	0	0	0	0		0	0	0	0
Fungal skin infection	2	(0.4)	2	0	0	0	4	(0.8)	3	1	0	0	0		0	0	0	0
Furuncle	2	(0.4)	1	1	0	0	1	(0.2)	1	0	0	0	2	(0.7)	1	1	0	0

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In this case, the reported severity is summarized. Missing baseline severities are imputed as grade 1.
Includes data up to 7 days after last dose of study drug.
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Number of Subjects evaluable for adverse events	maraviroc QD (n=477)						maraviroc BID (n=487)						Placebo (n=271)					
			Severity Grade*						Severity Grade*						Severity Grade*			
	N	(%)	1	2	3	4	N	(%)	1	2	3	4	N	(%)	1	2	3	4
System Organ Class and MedDRA (v9.0) preferred term																		
Gangrene	1	(0.2)	0	1	0	0	0		0	0	0	0	0		0	0	0	0
Gastric infection	1	(0.2)	0	1	0	0	0		0	0	0	0	0		0	0	0	0
Gastritis viral	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Gastroenteritis	7	(1.5)	1	4	2	0	2	(0.4)	0	2	0	0	2	(0.7)	0	1	1	0
Gastroenteritis bacterial	1	(0.2)	0	1	0	0	0		0	0	0	0	0		0	0	0	0
Gastroenteritis cryptosporidial	0		0	0	0	0	0		0	0	0	0	1	(0.4)	0	0	1	0
Gastroenteritis viral	3	(0.6)	3	0	0	0	3	(0.6)	1	1	1	0	0		0	0	0	0
Gastrointestinal infection	1	(0.2)	1	0	0	0	1	(0.2)	0	1	0	0	1	(0.4)	0	1	0	0
Genitourinary chlamydia infection	0		0	0	0	0	0		0	0	0	0	1	(0.4)	0	1	0	0
Genitourinary tract infection	0		0	0	0	0	1	(0.2)	0	0	0	1	0		0	0	0	0
Giardiasis	1	(0.2)	0	1	0	0	2	(0.4)	0	2	0	0	0		0	0	0	0
Gonorrhoea	2	(0.4)	1	1	0	0	0		0	0	0	0	0		0	0	0	0
Groin abscess	0		0	0	0	0	0		0	0	0	0	1	(0.4)	0	1	0	0
HIV wasting syndrome	1	(0.2)	0	1	0	0	0		0	0	0	0	0		0	0	0	0
Helicobacter gastritis	1	(0.2)	0	1	0	0	0		0	0	0	0	0		0	0	0	0
Hepatitis B	0		0	0	0	0	0		0	0	0	0	1	(0.4)	0	0	1	0
Hepatitis C	2	(0.4)	1	1	0	0	0		0	0	0	0	0		0	0	0	0
Herpes simplex	17	(3.6)	8	7	2	0	29	(6.0)	19	10	0	0	7	(2.6)	3	4	0	0
Herpes virus infection	5	(1.0)	5	0	0	0	3	(0.6)	1	1	1	0	2	(0.7)	2	0	0	0
Herpes zoster	6	(1.3)	2	4	0	0	8	(1.6)	2	6	0	0	5	(2.2)	1	4	1	0
Histoplasmosis	1	(0.2)	0	1	0	0	0		0	0	0	0	0		0	0	0	0
Hordeolum	2	(0.4)	2	0	0	0	0		0	0	0	0	0		0	0	0	0
Human ehrlichiosis	0		0	0	0	0	1	(0.2)	0	1	0	0	0		0	0	0	0
Incision site infection	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Infected sebaceous cyst	0		0	0	0	0	0		0	0	0	0	1	(0.4)	1	0	0	0
Infected skin ulcer	0		0	0	0	0	0		0	0	0	0	1	(0.4)	0	1	0	0

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MedDRA (v9.0) coding dictionary applied.

Maraviroc Summary of Clinical Safety
Incidence and Severity of Treatment-Emergent Adverse Events (All Causalities)
Phase 2b/3 Treatment Experienced Studies

Number of Subjects evaluable for adverse events	maraviroc QD (n=477)						maraviroc BID (n=487)						Placebo (n=271)					
			Severity Grade*						Severity Grade*						Severity Grade*			
	N	(%)	1	2	3	4	N	(%)	1	2	3	4	N	(%)	1	2	3	4
System Organ Class and MedDRA (v9.0) preferred term																		
Infective myositis	0		0	0	0	0	1	(0.2)	0	0	0	1	0		0	0	0	0
Influenza	14	(2.9)	8	6	0	0	8	(1.6)	5	3	0	0	1	(0.4)	0	1	0	0
Injection site abscess	2	(0.4)	0	2	0	0	0		0	0	0	0	0		0	0	0	0
Injection site infection	2	(0.4)	2	0	0	0	0		0	0	0	0	0		0	0	0	0
Klebsiella sepsis	1	(0.2)	0	0	0	1	0		0	0	0	0	0		0	0	0	0
Laryngitis	0		0	0	0	0	1	(0.2)	0	1	0	0	0		0	0	0	0
Laryngopharyngitis	1	(0.2)	0	1	0	0	0		0	0	0	0	1	(0.4)	1	0	0	0
Lobar pneumonia	1	(0.2)	1	0	0	0	1	(0.2)	0	1	0	0	3	(1.1)	0	0	2	1
Localised infection	2	(0.4)	1	1	0	0	2	(0.4)	0	2	0	0	1	(0.4)	1	0	0	0
Lower respiratory tract infection	5	(1.0)	3	2	0	0	2	(0.4)	1	1	0	0	1	(0.4)	0	1	0	0
Lymph gland infection	0		0	0	0	0	1	(0.2)	0	1	0	0	0		0	0	0	0
Lymphangitis	2	(0.4)	1	0	1	0	0		0	0	0	0	0		0	0	0	0
Malaria	1	(0.2)	0	1	0	0	0		0	0	0	0	0		0	0	0	0
Mastitis	0		0	0	0	0	1	(0.2)	0	1	0	0	0		0	0	0	0
Meningitis viral	0		0	0	0	0	2	(0.4)	0	1	0	1	0		0	0	0	0
Molluscum contagiosum	2	(0.4)	2	0	0	0	1	(0.2)	1	0	0	0	1	(0.4)	1	0	0	0
Mycobacterial infection	0		0	0	0	0	1	(0.2)	0	0	1	0	0		0	0	0	0
Mycobacterium avium complex infection	1	(0.2)	0	1	0	0	2	(0.4)	0	1	0	1	3	(1.1)	1	1	0	1
Mycoplasma infection	0		0	0	0	0	1	(0.2)	0	0	1	0	0		0	0	0	0
Nail candida	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Nasopharyngitis	35	(7.3)	28	7	0	0	31	(6.4)	21	10	0	0	10	(3.7)	7	3	0	0
Neurosyphilis	0		0	0	0	0	1	(0.2)	0	1	0	0	0		0	0	0	0
Oesophageal candidiasis	12	(2.5)	1	8	1	2	4	(0.8)	1	0	0	3	2	(0.7)	0	1	1	0
Onychomycosis	4	(0.8)	2	2	0	0	7	(1.4)	4	3	0	0	1	(0.4)	0	1	0	0
Oral candidiasis	14	(2.9)	7	6	1	0	13	(2.7)	9	4	0	0	7	(2.6)	3	4	0	0
Oral fungal infection	1	(0.2)	0	1	0	0	0		0	0	0	0	1	(0.4)	1	0	0	0

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Maraviroc Summary of Clinical Safety
Incidence and Severity of Treatment-Emergent Adverse Events (All Causalities)
Phase 2b/3 Treatment Experienced Studies

Number of Subjects evaluable for adverse events	maraviroc QD (n=477)						maraviroc BID (n=487)						Placebo (n=271)					
			Severity Grade*						Severity Grade*						Severity Grade*			
	N	(%)	1	2	3	4	N	(%)	1	2	3	4	N	(%)	1	2	3	4
System Organ Class and MedDRA (v9.0) preferred term																		
Oral hairy leukoplakia	1	(0.2)	1	0	0	0	0		0	0	0	0	0		0	0	0	0
Oral infection	1	(0.2)	0	1	0	0	0		0	0	0	0	0		0	0	0	0
Oropharyngeal candidiasis	2	(0.4)	2	0	0	0	0		0	0	0	0	1	(0.4)	0	1	0	0
Osteomyelitis	1	(0.2)	0	1	0	0	0		0	0	0	0	0		0	0	0	0
Otitis externa	0		0	0	0	0	2	(0.4)	2	0	0	0	3	(1.1)	1	2	0	0
Otitis media	1	(0.2)	0	1	0	0	6	(1.2)	5	1	0	0	2	(0.7)	2	0	0	0
Papilloma viral infection	0		0	0	0	0	3	(0.6)	3	0	0	0	2	(0.7)	2	0	0	0
Paronychia	0		0	0	0	0	1	(0.2)	0	1	0	0	1	(0.4)	1	0	0	0
Parotitis	0		0	0	0	0	1	(0.2)	0	1	0	0	0		0	0	0	0
Perianal abscess	1	(0.2)	0	1	0	0	0		0	0	0	0	0		0	0	0	0
Perirectal abscess	0		0	0	0	0	1	(0.2)	0	1	0	0	0		0	0	0	0
Pharyngeal candidiasis	1	(0.2)	1	0	0	0	0		0	0	0	0	0		0	0	0	0
Pharyngitis	5	(1.0)	3	1	1	0	8	(1.6)	3	5	0	0	2	(0.7)	1	1	0	0
Pharyngitis streptococcal	0		0	0	0	0	0		0	0	0	0	1	(0.4)	1	0	0	0
Pneumococcal sepsis	0		0	0	0	0	1	(0.2)	0	0	1	0	0		0	0	0	0
Pneumocystis jiroveci pneumonia	3	(0.6)	0	0	1	2	3	(0.6)	0	1	0	2	0		0	0	0	0
Pneumonia	13	(2.7)	0	7	3	3	6	(1.2)	2	2	0	2	9	(3.3)	2	3	1	3
Pneumonia bacterial	1	(0.2)	0	0	0	1	2	(0.4)	1	1	0	0	1	(0.4)	0	0	0	1
Postoperative wound infection	0		0	0	0	0	2	(0.4)	1	1	0	0	0		0	0	0	0
Proctitis herpes	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Progressive multifocal leukoencephalopathy	0		0	0	0	0	1	(0.2)	0	0	1	0	0		0	0	0	0
Pyelonephritis	3	(0.6)	1	2	0	0	1	(0.2)	0	0	1	0	1	(0.4)	1	0	0	0
Pyothorax	0		0	0	0	0	0		0	0	0	0	1	(0.4)	0	0	1	0
Rash pustular	1	(0.2)	0	1	0	0	1	(0.2)	1	0	0	0	1	(0.4)	0	1	0	0
Rectal abscess	0		0	0	0	0	1	(0.2)	0	0	1	0	0		0	0	0	0
Respiratory moniliasis	0		0	0	0	0	1	(0.2)	0	1	0	0	0		0	0	0	0

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Number of Subjects evaluable for adverse events	maraviroc QD (n=477)						maraviroc BID (n=487)						Placebo (n=271)					
			Severity Grade*						Severity Grade*						Severity Grade*			
	N	(%)	1	2	3	4	N	(%)	1	2	3	4	N	(%)	1	2	3	4
System Organ Class and MedDRA (v9.0) preferred term																		
Respiratory tract infection	4	(0.8)	3	1	0	0	4	(0.8)	3	1	0	0	2	(0.7)	1	0	0	1
Rhinitis	9	(1.9)	7	2	0	0	4	(0.8)	3	1	0	0	2	(0.7)	1	0	1	0
Secondary syphilis	0		0	0	0	0	1	(0.2)	0	0	1	0	0		0	0	0	0
Sepsis	0		0	0	0	0	0		0	0	0	0	1	(0.4)	0	0	0	1
Septic shock	1	(0.2)	0	0	0	1	0		0	0	0	0	0		0	0	0	0
Shigella infection	0		0	0	0	0	0		0	0	0	0	1	(0.4)	0	1	0	0
Sinobronchitis	0		0	0	0	0	1	(0.2)	0	1	0	0	0		0	0	0	0
Sinusitis	17	(3.6)	8	7	1	1	26	(5.3)	11	15	0	0	10	(3.7)	5	5	0	0
Skin infection	0		0	0	0	0	1	(0.2)	0	0	1	0	1	(0.4)	1	0	0	0
Staphylococcal abscess	1	(0.2)	1	0	0	0	1	(0.2)	0	0	1	0	0		0	0	0	0
Staphylococcal infection	4	(0.8)	3	1	0	0	5	(1.0)	1	4	0	0	2	(0.7)	0	1	0	1
Subcutaneous abscess	4	(0.8)	0	4	0	0	2	(0.4)	1	1	0	0	2	(0.7)	1	1	0	0
Syphilis	2	(0.4)	1	1	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Tinea cruris	4	(0.8)	2	2	0	0	2	(0.4)	2	0	0	0	1	(0.4)	0	1	0	0
Tinea infection	0		0	0	0	0	0		0	0	0	0	1	(0.4)	1	0	0	0
Tinea pedis	4	(0.8)	4	0	0	0	3	(0.6)	0	3	0	0	1	(0.4)	1	0	0	0
Tonsillitis	1	(0.2)	1	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Tooth abscess	3	(0.6)	1	1	1	0	0		0	0	0	0	3	(1.1)	1	2	0	0
Tooth infection	2	(0.4)	1	1	0	0	0		0	0	0	0	4	(1.5)	1	3	0	0
Upper respiratory tract infection	41	(8.6)	27	14	0	0	48	(9.9)	29	18	1	0	15	(5.5)	13	2	0	0
Urethritis	0		0	0	0	0	1	(0.2)	0	1	0	0	1	(0.4)	0	1	0	0
Urethritis gonococcal	1	(0.2)	1	0	0	0	0		0	0	0	0	0		0	0	0	0
Urinary tract infection	9	(1.9)	4	4	1	0	3	(0.6)	2	1	0	0	3	(1.1)	2	1	0	0
Vaginal candidiasis	2	(0.4)	2	0	0	0	0		0	0	0	0	0		0	0	0	0
Vaginitis bacterial	1	(0.2)	0	1	0	0	0		0	0	0	0	0		0	0	0	0
Viral infection	1	(0.2)	0	1	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0

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In this case, the reported severity is summarized. Missing baseline severities are imputed as grade 1.
Includes data up to 7 days after last dose of study drug.
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Number of Subjects evaluable for adverse events	maraviroc QD (n=477)						maraviroc BID (n=487)						Placebo (n=271)					
			Severity Grade*						Severity Grade*						Severity Grade*			
	N	(%)	1	2	3	4	N	(%)	1	2	3	4	N	(%)	1	2	3	4
System Organ Class and MedDRA (v9.0) preferred term																		
Viral upper respiratory tract infection	2	(0.4)	2	0	0	0	3	(0.6)	3	0	0	0	1	(0.4)	0	1	0	0
Vulvitis	1	(0.2)	0	1	0	0	0		0	0	0	0	0		0	0	0	0
Vulvovaginal mycotic infection	0		0	0	0	0	0		0	0	0	0	1	(0.4)	0	1	0	0
Wound infection	1	(0.2)	1	0	0	0	0		0	0	0	0	0		0	0	0	0
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	35	(7.3)	17	17	1	0	35	(7.2)	22	8	5	0	17	(6.3)	8	7	2	0
Animal bite	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Ankle fracture	1	(0.2)	0	1	0	0	0		0	0	0	0	0		0	0	0	0
Arthropod bite	0		0	0	0	0	2	(0.4)	2	0	0	0	1	(0.4)	1	0	0	0
Back injury	0		0	0	0	0	2	(0.4)	0	2	0	0	1	(0.4)	1	0	0	0
Bite	1	(0.2)	0	1	0	0	0		0	0	0	0	0		0	0	0	0
Burns first degree	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Burns second degree	1	(0.2)	0	1	0	0	0		0	0	0	0	0		0	0	0	0
Contusion	5	(1.0)	4	1	0	0	1	(0.2)	1	0	0	0	1	(0.4)	0	1	0	0
Corneal abrasion	1	(0.2)	0	1	0	0	0		0	0	0	0	0		0	0	0	0
Ear injury	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Epicondylitis	2	(0.4)	2	0	0	0	2	(0.4)	1	1	0	0	1	(0.4)	1	0	0	0
Excoriation	1	(0.2)	0	1	0	0	0		0	0	0	0	2	(0.7)	1	1	0	0
Facial bones fracture	1	(0.2)	0	0	1	0	0		0	0	0	0	0		0	0	0	0
Fall	2	(0.4)	0	2	0	0	3	(0.6)	2	0	1	0	1	(0.4)	0	1	0	0
Foot fracture	2	(0.4)	0	2	0	0	3	(0.6)	1	1	1	0	0		0	0	0	0
Haemothorax	0		0	0	0	0	0		0	0	0	0	1	(0.4)	0	0	1	0
Hand fracture	0		0	0	0	0	2	(0.4)	2	0	0	0	0		0	0	0	0
Heat exhaustion	0		0	0	0	0	1	(0.2)	0	0	1	0	0		0	0	0	0
Heat stroke	1	(0.2)	1	0	0	0	0		0	0	0	0	0		0	0	0	0

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In this case, the reported severity is summarized. Missing baseline severities are imputed as grade 1.
Includes data up to 7 days after last dose of study drug.
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Number of Subjects evaluable for adverse events	maraviroc QD (n=477)						maraviroc BID (n=487)						Placebo (n=271)					
			Severity Grade*						Severity Grade*						Severity Grade*			
	N	(%)	1	2	3	4	N	(%)	1	2	3	4	N	(%)	1	2	3	4
System Organ Class and MedDRA (v9.0) preferred term																		
Injury corneal	0		0	0	0	0	0		0	0	0	0	1	(0.4)	0	1	0	0
Joint injury	2	(0.4)	1	1	0	0	0		0	0	0	0	0		0	0	0	0
Joint sprain	3	(0.6)	2	1	0	0	3	(0.6)	3	0	0	0	0		0	0	0	0
Laceration	1	(0.2)	0	1	0	0	0		0	0	0	0	0		0	0	0	0
Muscle injury	0		0	0	0	0	2	(0.4)	2	0	0	0	1	(0.4)	1	0	0	0
Muscle strain	2	(0.4)	1	1	0	0	0		0	0	0	0	1	(0.4)	1	0	0	0
Neck injury	0		0	0	0	0	1	(0.2)	0	1	0	0	0		0	0	0	0
Open wound	1	(0.2)	1	0	0	0	0		0	0	0	0	0		0	0	0	0
Overdose	0		0	0	0	0	0		0	0	0	0	1	(0.4)	0	0	1	0
Post procedural complication	1	(0.2)	0	1	0	0	0		0	0	0	0	0		0	0	0	0
Post-traumatic pain	1	(0.2)	1	0	0	0	0		0	0	0	0	0		0	0	0	0
Procedural pain	1	(0.2)	1	0	0	0	1	(0.2)	0	0	1	0	2	(0.7)	1	1	0	0
Radiation skin injury	1	(0.2)	0	1	0	0	0		0	0	0	0	0		0	0	0	0
Rib fracture	1	(0.2)	1	0	0	0	5	(1.0)	1	3	1	0	0		0	0	0	0
Skeletal injury	1	(0.2)	1	0	0	0	0		0	0	0	0	0		0	0	0	0
Skin laceration	2	(0.4)	1	0	1	0	3	(0.6)	3	0	0	0	1	(0.4)	0	1	0	0
Spinal fracture	0		0	0	0	0	0		0	0	0	0	1	(0.4)	1	0	0	0
Sternal fracture	0		0	0	0	0	1	(0.2)	0	0	1	0	0		0	0	0	0
Stress fracture	0		0	0	0	0	2	(0.4)	1	1	0	0	0		0	0	0	0
Sunburn	0		0	0	0	0	1	(0.2)	1	0	0	0	1	(0.4)	1	0	0	0
Tendon rupture	0		0	0	0	0	0		0	0	0	0	1	(0.4)	0	1	0	0
Venom poisoning	1	(0.2)	1	0	0	0	0		0	0	0	0	0		0	0	0	0
Whiplash injury	1	(0.2)	0	1	0	0	0		0	0	0	0	0		0	0	0	0
Wound	0		0	0	0	0	1	(0.2)	1	0	0	0	1	(0.4)	0	1	0	0
INVESTIGATIONS	82	(17.2)	33	18	24	7	90	(18.5)	29	28	18	15	33	(12.2)	10	12	8	3

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MedDRA (v9.0) coding dictionary applied.

Number of Subjects evaluable for adverse events	maraviroc QD (n=477)						maraviroc BID (n=487)						Placebo (n=271)					
			Severity Grade*						Severity Grade*						Severity Grade*			
	N	(%)	1	2	3	4	N	(%)	1	2	3	4	N	(%)	1	2	3	4
System Organ Class and MedDRA (v9.0) preferred term																		
Alanine aminotransferase increased	7	(1.5)	0	1	5	1	10	(2.1)	1	3	3	3	2	(0.7)	0	1	1	0
Aspartate aminotransferase	0		0	0	0	0	1	(0.2)	0	0	0	1	0		0	0	0	0
Aspartate aminotransferase increased	8	(1.7)	0	2	6	0	15	(3.1)	2	2	6	5	2	(0.7)	0	0	2	0
Aspiration biopsy	0		0	0	0	0	1	(0.2)	0	1	0	0	0		0	0	0	0
Aspiration bursa	0		0	0	0	0	1	(0.2)	0	1	0	0	0		0	0	0	0
Blast cells present	1	(0.2)	1	0	0	0	0		0	0	0	0	0		0	0	0	0
Bleeding time prolonged	1	(0.2)	1	0	0	0	0		0	0	0	0	0		0	0	0	0
Blood alkaline phosphatase increased	2	(0.4)	1	0	1	0	0		0	0	0	0	0		0	0	0	0
Blood amylase	1	(0.2)	0	0	0	1	1	(0.2)	0	0	1	0	0		0	0	0	0
Blood amylase increased	4	(0.8)	1	1	2	0	2	(0.4)	0	0	1	1	2	(0.7)	1	0	1	0
Blood bilirubin	1	(0.2)	0	0	1	0	0		0	0	0	0	0		0	0	0	0
Blood bilirubin increased	8	(1.7)	1	4	2	1	4	(0.8)	1	1	2	0	1	(0.4)	0	0	1	0
Blood cholesterol increased	2	(0.4)	1	1	0	0	2	(0.4)	0	2	0	0	0		0	0	0	0
Blood creatine increased	1	(0.2)	0	1	0	0	1	(0.2)	0	1	0	0	1	(0.4)	0	1	0	0
Blood creatine phosphokinase increased	5	(1.0)	3	2	0	0	10	(2.1)	2	2	3	3	2	(0.7)	0	1	0	1
Blood creatinine increased	6	(1.3)	3	2	1	0	6	(1.2)	4	2	0	0	1	(0.4)	0	1	0	0
Blood glucose	1	(0.2)	0	0	1	0	0		0	0	0	0	0		0	0	0	0
Blood glucose increased	4	(0.8)	2	0	2	0	2	(0.4)	1	1	0	0	2	(0.7)	2	0	0	0
Blood iron decreased	0		0	0	0	0	1	(0.2)	0	1	0	0	0		0	0	0	0
Blood lactate dehydrogenase increased	0		0	0	0	0	3	(0.6)	1	1	0	1	1	(0.4)	1	0	0	0
Blood lactic acid increased	0		0	0	0	0	0		0	0	0	0	1	(0.4)	0	1	0	0
Blood potassium decreased	0		0	0	0	0	2	(0.4)	2	0	0	0	1	(0.4)	1	0	0	0
Blood potassium increased	0		0	0	0	0	1	(0.2)	0	1	0	0	0		0	0	0	0
Blood pressure diastolic increased	0		0	0	0	0	0		0	0	0	0	1	(0.4)	1	0	0	0
Blood pressure increased	3	(0.6)	2	0	1	0	1	(0.2)	1	0	0	0	0		0	0	0	0

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MedDRA (v9.0) coding dictionary applied.

Maraviroc Summary of Clinical Safety
Incidence and Severity of Treatment-Emergent Adverse Events (All Causalities)
Phase 2b/3 Treatment Experienced Studies

Number of Subjects evaluable for adverse events	maraviroc QD (n=477)						maraviroc BID (n=487)						Placebo (n=271)					
			Severity Grade*						Severity Grade*						Severity Grade*			
	N	(%)	1	2	3	4	N	(%)	1	2	3	4	N	(%)	1	2	3	4
System Organ Class and MedDRA (v9.0) preferred term																		
Blood sodium increased	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Blood testosterone decreased	1	(0.2)	0	1	0	0	0		0	0	0	0	0		0	0	0	0
Blood thyroid stimulating hormone increased	0		0	0	0	0	0		0	0	0	0	1	(0.4)	0	1	0	0
Blood triglycerides abnormal	1	(0.2)	0	0	0	1	0		0	0	0	0	0		0	0	0	0
Blood triglycerides increased	1	(0.2)	0	0	1	0	8	(1.6)	1	4	2	1	1	(0.4)	0	0	1	0
Blood urea increased	3	(0.6)	1	2	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Blood uric acid increased	0		0	0	0	0	2	(0.4)	1	1	0	0	2	(0.7)	1	1	0	0
Blood urine present	1	(0.2)	1	0	0	0	0		0	0	0	0	0		0	0	0	0
Body temperature	1	(0.2)	1	0	0	0	0		0	0	0	0	0		0	0	0	0
Body temperature increased	1	(0.2)	1	0	0	0	2	(0.4)	1	1	0	0	0		0	0	0	0
Breath sounds abnormal	0		0	0	0	0	0		0	0	0	0	1	(0.4)	0	1	0	0
Cardiac murmur	1	(0.2)	0	1	0	0	0		0	0	0	0	0		0	0	0	0
Crystal urine	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Cytomegalovirus antibody positive	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Electrocardiogram QT prolonged	0		0	0	0	0	1	(0.2)	0	1	0	0	0		0	0	0	0
Gamma-glutamyltransferase	0		0	0	0	0	2	(0.4)	0	0	2	0	0		0	0	0	0
Gamma-glutamyltransferase increased	6	(1.3)	1	0	1	4	6	(1.2)	0	2	2	2	3	(1.1)	0	0	2	1
Haematocrit decreased	1	(0.2)	1	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Haemoglobin decreased	2	(0.4)	2	0	0	0	1	(0.2)	0	0	1	0	1	(0.4)	0	1	0	0
Heart rate increased	1	(0.2)	1	0	0	0	3	(0.6)	3	0	0	0	1	(0.4)	0	1	0	0
Hepatic enzyme increased	0		0	0	0	0	3	(0.6)	1	1	1	0	0		0	0	0	0
International normalised ratio increased	1	(0.2)	0	0	1	0	0		0	0	0	0	0		0	0	0	0
Investigation	1	(0.2)	0	1	0	0	0		0	0	0	0	0		0	0	0	0
Lipase	0		0	0	0	0	1	(0.2)	0	0	1	0	0		0	0	0	0
Lipase increased	3	(0.6)	0	0	2	1	3	(0.6)	1	0	1	1	2	(0.7)	0	1	1	0
Lipids increased	0		0	0	0	0	1	(0.2)	0	1	0	0	0		0	0	0	0

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Maraviroc Summary of Clinical Safety
Incidence and Severity of Treatment-Emergent Adverse Events (All Causalities)
Phase 2b/3 Treatment Experienced Studies

Number of Subjects evaluable for adverse events	maraviroc QD (n=477)						maraviroc BID (n=487)						Placebo (n=271)					
			Severity Grade*						Severity Grade*						Severity Grade*			
	N	(%)	1	2	3	4	N	(%)	1	2	3	4	N	(%)	1	2	3	4
System Organ Class and MedDRA (v9.0) preferred term																		
Liver function test abnormal	3	(0.6)	1	0	2	0	2	(0.4)	0	0	1	1	2	(0.7)	0	0	1	1
Neutrophil count decreased	1	(0.2)	0	0	1	0	2	(0.4)	1	0	0	1	0		0	0	0	0
Neutrophil count increased	1	(0.2)	0	0	1	0	1	(0.2)	0	0	0	1	0		0	0	0	0
Neutrophil hypersegmented morphology present	1	(0.2)	1	0	0	0	0		0	0	0	0	0		0	0	0	0
Platelet count decreased	0		0	0	0	0	1	(0.2)	0	1	0	0	2	(0.7)	0	1	1	0
Prostate examination abnormal	2	(0.4)	1	1	0	0	0		0	0	0	0	0		0	0	0	0
Prostatic specific antigen increased	1	(0.2)	0	1	0	0	0		0	0	0	0	0		0	0	0	0
Protein total increased	0		0	0	0	0	0		0	0	0	0	1	(0.4)	1	0	0	0
Protein urine	2	(0.4)	1	1	0	0	1	(0.2)	0	1	0	0	0		0	0	0	0
Syphilis test positive	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Thyroxine free decreased	0		0	0	0	0	0		0	0	0	0	2	(0.7)	1	1	0	0
Transaminases increased	2	(0.4)	0	1	1	0	1	(0.2)	0	0	0	1	0		0	0	0	0
Tuberculin test positive	0		0	0	0	0	0		0	0	0	0	1	(0.4)	0	1	0	0
Urine output decreased	1	(0.2)	0	1	0	0	0		0	0	0	0	0		0	0	0	0
Urine output increased	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Viral load increased	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Viral test	0		0	0	0	0	2	(0.4)	2	0	0	0	0		0	0	0	0
Weight decreased	19	(4.0)	14	5	0	0	15	(3.1)	7	8	0	0	5	(1.8)	4	1	0	0
Weight increased	6	(1.3)	6	0	0	0	3	(0.6)	2	1	0	0	0		0	0	0	0
White blood cell count decreased	0		0	0	0	0	1	(0.2)	0	0	1	0	1	(0.4)	1	0	0	0
METABOLISM AND NUTRITION DISORDERS	52	(10.9)	25	22	3	2	61	(12.5)	27	26	5	3	26	(9.6)	13	6	4	3
Alcohol intolerance	1	(0.2)	1	0	0	0	0		0	0	0	0	0		0	0	0	0
Anorexia	17	(3.6)	8	8	1	0	18	(3.7)	10	8	0	0	9	(3.3)	6	1	1	1
Cachexia	2	(0.4)	1	1	0	0	1	(0.2)	0	0	1	0	0		0	0	0	0

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Number of Subjects evaluable for adverse events	maraviroc QD (n=477)						maraviroc BID (n=487)						Placebo (n=271)					
			Severity Grade*						Severity Grade*						Severity Grade*			
	N	(%)	1	2	3	4	N	(%)	1	2	3	4	N	(%)	1	2	3	4
System Organ Class and MedDRA (v9.0) preferred term																		
Decreased appetite	10	(2.1)	6	4	0	0	16	(3.3)	10	6	0	0	5	(1.8)	4	1	0	0
Dehydration	2	(0.4)	0	2	0	0	6	(1.2)	0	2	3	1	4	(1.5)	2	1	0	1
Diabetes mellitus	1	(0.2)	0	1	0	0	1	(0.2)	0	1	0	0	0		0	0	0	0
Diabetes mellitus inadequate control	0		0	0	0	0	0		0	0	0	0	1	(0.4)	0	0	1	0
Diabetes mellitus non-insulin-dependent	1	(0.2)	0	0	0	1	0		0	0	0	0	1	(0.4)	0	0	1	0
Facial wasting	0		0	0	0	0	0		0	0	0	0	1	(0.4)	0	1	0	0
Fluid retention	1	(0.2)	1	0	0	0	0		0	0	0	0	0		0	0	0	0
Food craving	0		0	0	0	0	1	(0.2)	0	1	0	0	0		0	0	0	0
Gout	2	(0.4)	1	1	0	0	5	(1.0)	3	1	0	1	2	(0.7)	1	1	0	0
Hyperamylasaemia	1	(0.2)	1	0	0	0	0		0	0	0	0	0		0	0	0	0
Hypercholesterolaemia	0		0	0	0	0	1	(0.2)	0	0	0	1	1	(0.4)	1	0	0	0
Hypercreatininaemia	1	(0.2)	0	1	0	0	0		0	0	0	0	0		0	0	0	0
Hyperglycaemia	2	(0.4)	0	1	1	0	4	(0.8)	0	4	0	0	2	(0.7)	1	0	1	0
Hyperkalaemia	0		0	0	0	0	1	(0.2)	0	1	0	0	0		0	0	0	0
Hyperlipidaemia	3	(0.6)	2	0	1	0	1	(0.2)	0	1	0	0	2	(0.7)	0	0	0	2
Hypertriglyceridaemia	1	(0.2)	0	1	0	0	6	(1.2)	1	4	0	1	0		0	0	0	0
Hypervitaminosis	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Hypocalcaemia	0		0	0	0	0	1	(0.2)	0	0	1	0	1	(0.4)	0	1	0	0
Hypoglycaemia	3	(0.6)	1	1	0	1	0		0	0	0	0	0		0	0	0	0
Hypokalaemia	3	(0.6)	0	2	1	0	1	(0.2)	0	1	0	0	1	(0.4)	1	0	0	0
Hyponatraemia	0		0	0	0	0	1	(0.2)	0	0	1	0	0		0	0	0	0
Hypovolaemia	1	(0.2)	0	1	0	0	0		0	0	0	0	0		0	0	0	0
Increased appetite	3	(0.6)	3	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Insulin resistant diabetes	0		0	0	0	0	1	(0.2)	0	1	0	0	0		0	0	0	0
Iron deficiency	1	(0.2)	1	0	0	0	1	(0.2)	1	0	0	0	1	(0.4)	1	0	0	0
Lactic acidosis	0		0	0	0	0	0		0	0	0	0	1	(0.4)	0	0	1	0

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In this case, the reported severity is summarized. Missing baseline severities are imputed as grade 1.
Includes data up to 7 days after last dose of study drug.
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Number of Subjects evaluable for adverse events	maraviroc QD (n=477)						maraviroc BID (n=487)						Placebo (n=271)					
			Severity Grade*						Severity Grade*						Severity Grade*			
	N	(%)	1	2	3	4	N	(%)	1	2	3	4	N	(%)	1	2	3	4
System Organ Class and MedDRA (v9.0) preferred term																		
Polydipsia	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Tetany	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Vitamin B12 deficiency	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Vitamin D deficiency	0		0	0	0	0	0		0	0	0	0	1	(0.4)	0	1	0	0
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	103	(21.6)	69	25	8	1	92	(18.9)	55	30	4	3	47	(17.3)	28	18	1	0
Arthralgia	18	(3.8)	12	6	0	0	25	(5.1)	17	7	0	1	7	(2.6)	6	1	0	0
Arthritis	4	(0.8)	2	2	0	0	1	(0.2)	0	1	0	0	0		0	0	0	0
Arthropathy	1	(0.2)	1	0	0	0	0		0	0	0	0	0		0	0	0	0
Back pain	27	(5.7)	19	6	2	0	23	(4.7)	15	6	2	0	8	(3.0)	3	5	0	0
Bone pain	0		0	0	0	0	2	(0.4)	2	0	0	0	1	(0.4)	1	0	0	0
Bursitis	0		0	0	0	0	3	(0.6)	2	1	0	0	3	(1.1)	1	2	0	0
Costochondritis	0		0	0	0	0	0		0	0	0	0	1	(0.4)	0	1	0	0
Flank pain	4	(0.8)	2	2	0	0	3	(0.6)	2	0	0	1	0		0	0	0	0
Ganglion	1	(0.2)	1	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Gouty arthritis	0		0	0	0	0	1	(0.2)	0	1	0	0	0		0	0	0	0
Groin pain	0		0	0	0	0	1	(0.2)	0	1	0	0	0		0	0	0	0
Intervertebral disc degeneration	2	(0.4)	1	0	1	0	0		0	0	0	0	0		0	0	0	0
Intervertebral disc disorder	1	(0.2)	1	0	0	0	0		0	0	0	0	0		0	0	0	0
Joint swelling	3	(0.6)	3	0	0	0	5	(1.0)	1	4	0	0	0		0	0	0	0
Monarthritis	2	(0.4)	2	0	0	0	0		0	0	0	0	1	(0.4)	0	1	0	0
Muscle atrophy	0		0	0	0	0	0		0	0	0	0	1	(0.4)	1	0	0	0
Muscle fatigue	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Muscle spasms	13	(2.7)	13	0	0	0	9	(1.8)	7	2	0	0	11	(4.1)	9	2	0	0
Muscle tightness	0		0	0	0	0	2	(0.4)	2	0	0	0	0		0	0	0	0

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Includes data up to 7 days after last dose of study drug.
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MedDRA (v9.0) coding dictionary applied.

Number of Subjects evaluable for adverse events	maraviroc QD (n=477)						maraviroc BID (n=487)						Placebo (n=271)					
			Severity Grade*						Severity Grade*						Severity Grade*			
	N	(%)	1	2	3	4	N	(%)	1	2	3	4	N	(%)	1	2	3	4
System Organ Class and MedDRA (v9.0) preferred term																		
Muscle twitching	2	(0.4)	2	0	0	0	0		0	0	0	0	0		0	0	0	0
Muscular weakness	2	(0.4)	1	0	1	0	1	(0.2)	1	0	0	0	3	(1.1)	3	0	0	0
Musculoskeletal chest pain	3	(0.6)	2	0	1	0	0		0	0	0	0	1	(0.4)	0	1	0	0
Musculoskeletal discomfort	1	(0.2)	0	1	0	0	0		0	0	0	0	0		0	0	0	0
Musculoskeletal pain	0		0	0	0	0	2	(0.4)	1	1	0	0	0		0	0	0	0
Musculoskeletal stiffness	3	(0.6)	2	1	0	0	3	(0.6)	2	1	0	0	3	(1.1)	1	2	0	0
Myalgia	22	(4.6)	16	4	2	0	14	(2.9)	9	5	0	0	2	(0.7)	2	0	0	0
Myopathy	0		0	0	0	0	1	(0.2)	1	0	0	0	1	(0.4)	1	0	0	0
Myositis	1	(0.2)	0	0	1	0	0		0	0	0	0	0		0	0	0	0
Neck pain	3	(0.6)	3	0	0	0	2	(0.4)	1	1	0	0	2	(0.7)	1	1	0	0
Osteoarthritis	3	(0.6)	2	1	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Osteonecrosis	0		0	0	0	0	2	(0.4)	1	0	1	0	0		0	0	0	0
Osteoporosis	1	(0.2)	0	1	0	0	2	(0.4)	1	1	0	0	1	(0.4)	0	1	0	0
Pain in extremity	13	(2.7)	9	2	1	1	12	(2.5)	7	5	0	0	6	(2.2)	3	2	1	0
Plantar fasciitis	1	(0.2)	1	0	0	0	0		0	0	0	0	1	(0.4)	0	1	0	0
Rhabdomyolysis	1	(0.2)	0	0	1	0	3	(0.6)	1	0	1	1	0		0	0	0	0
Rotator cuff syndrome	1	(0.2)	1	0	0	0	1	(0.2)	0	1	0	0	0		0	0	0	0
Shoulder pain	4	(0.8)	0	4	0	0	2	(0.4)	2	0	0	0	4	(1.5)	1	3	0	0
Spinal disorder	1	(0.2)	0	0	1	0	0		0	0	0	0	0		0	0	0	0
Synovial cyst	1	(0.2)	1	0	0	0	0		0	0	0	0	0		0	0	0	0
Tendon disorder	1	(0.2)	1	0	0	0	0		0	0	0	0	1	(0.4)	1	0	0	0
Tendonitis	2	(0.4)	2	0	0	0	0		0	0	0	0	0		0	0	0	0
Tenosynovitis	1	(0.2)	1	0	0	0	0		0	0	0	0	0		0	0	0	0
Vertebral column mass	1	(0.2)	0	1	0	0	0		0	0	0	0	0		0	0	0	0
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL																		

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MedDRA (v9.0) coding dictionary applied.

Number of Subjects evaluable for adverse events	maraviroc QD (n=477)						maraviroc BID (n=487)						Placebo (n=271)					
			Severity Grade*						Severity Grade*						Severity Grade*			
	N	(%)	1	2	3	4	N	(%)	1	2	3	4	N	(%)	1	2	3	4
System Organ Class and MedDRA (v9.0) preferred term																		
Abdominal neoplasm	0		0	0	0	0	1	(0.2)	0	1	0	0	1	(0.4)	1	0	0	0
Anal cancer	2	(0.4)	0	1	0	1	3	(0.6)	0	1	0	2	3	(1.1)	0	3	0	0
Anal cancer stage 0	1	(0.2)	0	0	1	0	0		0	0	0	0	0		0	0	0	0
Basal cell carcinoma	1	(0.2)	1	0	0	0	1	(0.2)	1	0	0	0	1	(0.4)	1	0	0	0
Benign neoplasm of orbit	1	(0.2)	1	0	0	0	0		0	0	0	0	0		0	0	0	0
Benign oesophageal neoplasm	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Bowen's disease	0		0	0	0	0	1	(0.2)	0	0	1	0	0		0	0	0	0
Bowenoid papulosis	0		0	0	0	0	1	(0.2)	0	0	1	0	0		0	0	0	0
Diffuse large B-cell lymphoma	0		0	0	0	0	0		0	0	0	0	1	(0.4)	0	0	0	1
Haemangioma	1	(0.2)	1	0	0	0	0		0	0	0	0	0		0	0	0	0
Haemangioma of liver	1	(0.2)	1	0	0	0	0		0	0	0	0	0		0	0	0	0
Kaposi's sarcoma	1	(0.2)	0	0	0	1	2	(0.4)	2	0	0	0	3	(1.1)	1	1	1	0
Lipoma	1	(0.2)	1	0	0	0	0		0	0	0	0	1	(0.4)	1	0	0	0
Lymphoma	2	(0.4)	0	1	0	1	1	(0.2)	0	0	0	1	1	(0.4)	0	0	1	0
Metastases to liver	1	(0.2)	0	1	0	0	0		0	0	0	0	0		0	0	0	0
Neoplasm	0		0	0	0	0	1	(0.2)	0	1	0	0	1	(0.4)	0	1	0	0
Oesophageal carcinoma	1	(0.2)	0	0	0	1	0		0	0	0	0	0		0	0	0	0
Seborrhoeic keratosis	1	(0.2)	1	0	0	0	2	(0.4)	1	1	0	0	0		0	0	0	0
Skin papilloma	11	(2.3)	10	1	0	0	9	(1.8)	7	2	0	0	3	(1.1)	1	2	0	0
Squamous cell carcinoma	1	(0.2)	0	1	0	0	0		0	0	0	0	1	(0.4)	0	0	1	0
Squamous cell carcinoma of skin	1	(0.2)	1	0	0	0	0		0	0	0	0	0		0	0	0	0
Sweat gland tumour	1	(0.2)	1	0	0	0	1	(0.2)	0	0	0	1	0		0	0	0	0
Testicular neoplasm	1	(0.2)	1	0	0	0	0		0	0	0	0	0		0	0	0	0
Tongue neoplasm malignant stage unspecified	0		0	0	0	0	1	(0.2)	0	0	1	0	0		0	0	0	0

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Maraviroc Summary of Clinical Safety
Incidence and Severity of Treatment-Emergent Adverse Events (All Causalities)
Phase 2b/3 Treatment Experienced Studies

Number of Subjects evaluable for adverse events	maraviroc QD (n=477)						maraviroc BID (n=487)						Placebo (n=271)					
			Severity Grade*						Severity Grade*						Severity Grade*			
	N	(%)	1	2	3	4	N	(%)	1	2	3	4	N	(%)	1	2	3	4
System Organ Class and MedDRA (v9.0) preferred term																		
NERVOUS SYSTEM DISORDERS	158	(33.1)	92	57	6	3	152	(31.2)	101	39	8	4	80	(29.5)	45	28	5	2
Ageusia	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Amnesia	2	(0.4)	2	0	0	0	3	(0.6)	3	0	0	0	1	(0.4)	0	1	0	0
Aphonia	0		0	0	0	0	0		0	0	0	0	1	(0.4)	1	0	0	0
Areflexia	3	(0.6)	3	0	0	0	2	(0.4)	2	0	0	0	0		0	0	0	0
Balance disorder	2	(0.4)	1	1	0	0	1	(0.2)	1	0	0	0	1	(0.4)	1	0	0	0
Burning sensation	3	(0.6)	2	1	0	0	0		0	0	0	0	0		0	0	0	0
Carpal tunnel syndrome	1	(0.2)	0	1	0	0	0		0	0	0	0	0		0	0	0	0
Central nervous system lesion	0		0	0	0	0	0		0	0	0	0	1	(0.4)	0	0	0	1
Cerebral haemorrhage	1	(0.2)	0	1	0	0	0		0	0	0	0	0		0	0	0	0
Cerebrovascular accident	1	(0.2)	0	0	0	1	1	(0.2)	0	0	0	1	0		0	0	0	0
Convulsion	3	(0.6)	0	1	1	1	1	(0.2)	0	0	0	1	0		0	0	0	0
Depressed level of consciousness	1	(0.2)	1	0	0	0	0		0	0	0	0	0		0	0	0	0
Disturbance in attention	3	(0.6)	2	1	0	0	3	(0.6)	2	1	0	0	3	(1.1)	3	0	0	0
Dizziness	45	(9.4)	40	5	0	0	38	(7.8)	29	8	1	0	17	(6.3)	11	6	0	0
Dizziness postural	6	(1.3)	6	0	0	0	2	(0.4)	1	1	0	0	2	(0.7)	2	0	0	0
Dysaesthesia	1	(0.2)	0	1	0	0	0		0	0	0	0	0		0	0	0	0
Dysarthria	0		0	0	0	0	0		0	0	0	0	1	(0.4)	1	0	0	0
Dysgeusia	3	(0.6)	1	2	0	0	12	(2.5)	11	1	0	0	4	(1.5)	3	1	0	0
Dyskinesia	0		0	0	0	0	0		0	0	0	0	1	(0.4)	1	0	0	0
Encephalitis	0		0	0	0	0	0		0	0	0	0	1	(0.4)	0	0	0	1
Epilepsy	1	(0.2)	0	1	0	0	2	(0.4)	0	0	2	0	0		0	0	0	0
Facial palsy	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Headache	73	(15.3)	49	20	3	1	60	(12.3)	50	10	0	0	38	(14.0)	23	13	2	0

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Number of Subjects evaluable for adverse events	maraviroc QD (n=477)						maraviroc BID (n=487)						Placebo (n=271)					
			Severity Grade*						Severity Grade*						Severity Grade*			
	N	(%)	1	2	3	4	N	(%)	1	2	3	4	N	(%)	1	2	3	4
System Organ Class and MedDRA (v9.0) preferred term																		
Hyperaesthesia	6	(1.3)	4	2	0	0	0		0	0	0	0	0		0	0	0	0
Hypersomnia	0		0	0	0	0	1	(0.2)	0	1	0	0	0		0	0	0	0
Hypoaesthesia	11	(2.3)	8	3	0	0	14	(2.9)	12	2	0	0	2	(0.7)	1	0	1	0
IIIrd nerve disorder	0		0	0	0	0	0		0	0	0	0	1	(0.4)	0	1	0	0
Lethargy	5	(1.0)	2	3	0	0	4	(0.8)	3	0	1	0	5	(1.8)	3	2	0	0
Loss of consciousness	0		0	0	0	0	1	(0.2)	0	1	0	0	0		0	0	0	0
Memory impairment	2	(0.4)	1	0	1	0	0		0	0	0	0	2	(0.7)	1	1	0	0
Mental impairment	1	(0.2)	1	0	0	0	0		0	0	0	0	0		0	0	0	0
Migraine	4	(0.8)	0	4	0	0	2	(0.4)	0	2	0	0	1	(0.4)	0	1	0	0
Movement disorder	1	(0.2)	1	0	0	0	0		0	0	0	0	0		0	0	0	0
Nervous system disorder	1	(0.2)	0	1	0	0	0		0	0	0	0	1	(0.4)	1	0	0	0
Neuralgia	1	(0.2)	0	1	0	0	2	(0.4)	0	2	0	0	0		0	0	0	0
Neuritis	1	(0.2)	1	0	0	0	0		0	0	0	0	0		0	0	0	0
Neuropathy	4	(0.8)	2	2	0	0	4	(0.8)	1	2	1	0	2	(0.7)	1	1	0	0
Neuropathy peripheral	10	(2.1)	4	5	1	0	10	(2.1)	7	2	1	0	4	(1.5)	2	2	0	0
Paraesthesia	13	(2.7)	12	1	0	0	11	(2.3)	10	1	0	0	7	(2.6)	5	1	1	0
Parkinsonism	0		0	0	0	0	1	(0.2)	0	1	0	0	0		0	0	0	0
Petit mal epilepsy	1	(0.2)	0	1	0	0	0		0	0	0	0	0		0	0	0	0
Polyneuropathy	2	(0.4)	2	0	0	0	1	(0.2)	1	0	0	0	1	(0.4)	0	1	0	0
Poor quality sleep	3	(0.6)	2	1	0	0	0		0	0	0	0	0		0	0	0	0
Psychomotor hyperactivity	1	(0.2)	1	0	0	0	3	(0.6)	2	1	0	0	0		0	0	0	0
Radicular pain	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Radiculopathy	0		0	0	0	0	1	(0.2)	0	1	0	0	0		0	0	0	0
Restless legs syndrome	2	(0.4)	2	0	0	0	2	(0.4)	2	0	0	0	0		0	0	0	0
Sciatica	1	(0.2)	0	1	0	0	2	(0.4)	0	2	0	0	1	(0.4)	1	0	0	0
Sedation	0		0	0	0	0	2	(0.4)	1	0	0	1	1	(0.4)	0	1	0	0

* If the same subject in a given treatment had more than one occurrence in the same preferred term event category, only the most severe occurrence is taken. Subjects are counted only once per treatment in each row. For the TESS algorithm any missing severities have been imputed as grade 4 unless the subject experienced another occurrence of the same event in a given treatment for which severity was recorded.
In this case, the reported severity is summarized. Missing baseline severities are imputed as grade 1.
Includes data up to 7 days after last dose of study drug.
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Number of Subjects evaluable for adverse events	maraviroc QD (n=477)						maraviroc BID (n=487)						Placebo (n=271)					
			Severity Grade*						Severity Grade*						Severity Grade*			
	N	(%)	1	2	3	4	N	(%)	1	2	3	4	N	(%)	1	2	3	4
System Organ Class and MedDRA (v9.0) preferred term																		
Sensory disturbance	0		0	0	0	0	1	(0.2)	0	0	1	0	1	(0.4)	1	0	0	0
Sinus headache	2	(0.4)	0	2	0	0	3	(0.6)	3	0	0	0	0		0	0	0	0
Somnolence	8	(1.7)	7	0	1	0	8	(1.6)	7	1	0	0	0		0	0	0	0
Speech disorder	0		0	0	0	0	1	(0.2)	1	0	0	0	1	(0.4)	0	0	1	0
Syncope	2	(0.4)	1	1	0	0	5	(1.0)	1	3	0	1	2	(0.7)	1	0	1	0
Transient ischaemic attack	0		0	0	0	0	0		0	0	0	0	3	(1.1)	0	1	2	0
Tremor	6	(1.3)	6	0	0	0	6	(1.2)	4	0	2	0	0		0	0	0	0
Trigeminal neuralgia	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Visual field defect	0		0	0	0	0	0		0	0	0	0	1	(0.4)	0	1	0	0
Vocal cord paralysis	1	(0.2)	0	1	0	0	0		0	0	0	0	0		0	0	0	0
PREGNANCY, PUERPERIUM AND PERINATAL CONDITIONS	2	(0.4)	2	0	0	0	0		0	0	0	0	0		0	0	0	0
Pregnancy	2	(0.4)	2	0	0	0	0		0	0	0	0	0		0	0	0	0
PSYCHIATRIC DISORDERS	77	(16.1)	42	31	4	0	77	(15.8)	49	25	3	0	35	(12.9)	20	11	3	1
Abnormal dreams	9	(1.9)	5	3	1	0	4	(0.8)	1	3	0	0	3	(1.1)	0	3	0	0
Affective disorder	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Aggression	0		0	0	0	0	0		0	0	0	0	1	(0.4)	1	0	0	0
Agitation	0		0	0	0	0	1	(0.2)	0	0	1	0	1	(0.4)	1	0	0	0
Alcoholism	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Anxiety	11	(2.3)	6	4	1	0	13	(2.7)	6	6	1	0	6	(2.2)	6	0	0	0
Apathy	1	(0.2)	1	0	0	0	0		0	0	0	0	0		0	0	0	0
Attention deficit/hyperactivity disorder	2	(0.4)	2	0	0	0	0		0	0	0	0	0		0	0	0	0
Confusional state	1	(0.2)	0	1	0	0	1	(0.2)	1	0	0	0	1	(0.4)	0	0	1	0

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In this case, the reported severity is summarized. Missing baseline severities are imputed as grade 1.
Includes data up to 7 days after last dose of study drug.
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Number of Subjects evaluable for adverse events	maraviroc QD (n=477)						maraviroc BID (n=487)						Placebo (n=271)					
			Severity Grade*						Severity Grade*						Severity Grade*			
	N	(%)	1	2	3	4	N	(%)	1	2	3	4	N	(%)	1	2	3	4
System Organ Class and MedDRA (v9.0) preferred term																		
Cyclothymic disorder	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Depressed mood	1	(0.2)	1	0	0	0	1	(0.2)	0	1	0	0	0		0	0	0	0
Depression	16	(3.4)	6	9	1	0	15	(3.1)	5	9	1	0	9	(3.3)	1	5	2	1
Disorientation	2	(0.4)	1	1	0	0	2	(0.4)	2	0	0	0	0		0	0	0	0
Dissociation	0		0	0	0	0	1	(0.2)	0	1	0	0	0		0	0	0	0
Dysthymic disorder	0		0	0	0	0	1	(0.2)	0	1	0	0	0		0	0	0	0
Euphoric mood	1	(0.2)	1	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Excitability	0		0	0	0	0	2	(0.4)	1	1	0	0	0		0	0	0	0
Hallucination	2	(0.4)	1	1	0	0	0		0	0	0	0	0		0	0	0	0
Hallucination, auditory	1	(0.2)	1	0	0	0	0		0	0	0	0	0		0	0	0	0
Initial insomnia	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Insomnia	28	(5.9)	17	10	1	0	33	(6.8)	27	6	0	0	11	(4.1)	8	3	0	0
Libido decreased	4	(0.8)	1	3	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Loss of libido	1	(0.2)	0	1	0	0	0		0	0	0	0	0		0	0	0	0
Mental status changes	1	(0.2)	1	0	0	0	1	(0.2)	0	1	0	0	0		0	0	0	0
Mood altered	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Mood swings	1	(0.2)	1	0	0	0	2	(0.4)	1	1	0	0	0		0	0	0	0
Nervousness	2	(0.4)	2	0	0	0	0		0	0	0	0	0		0	0	0	0
Nightmare	4	(0.8)	3	1	0	0	2	(0.4)	0	2	0	0	1	(0.4)	1	0	0	0
Panic attack	1	(0.2)	0	1	0	0	0		0	0	0	0	0		0	0	0	0
Restlessness	1	(0.2)	1	0	0	0	0		0	0	0	0	0		0	0	0	0
Sleep disorder	9	(1.9)	7	2	0	0	6	(1.2)	5	1	0	0	5	(1.8)	5	0	0	0
Stress	1	(0.2)	1	0	0	0	0		0	0	0	0	1	(0.4)	1	0	0	0
Suicidal ideation	0		0	0	0	0	1	(0.2)	1	0	0	0	1	(0.4)	0	0	1	0
RENAL AND URINARY DISORDERS	39	(8.2)	24	11	2	2	47	(9.7)	27	17	2	1	15	(5.5)	9	5	0	1

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In this case, the reported severity is summarized. Missing baseline severities are imputed as grade 1.
Includes data up to 7 days after last dose of study drug.
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Number of Subjects evaluable for adverse events	maraviroc QD (n=477)						maraviroc BID (n=487)						Placebo (n=271)					
			Severity Grade*						Severity Grade*						Severity Grade*			
	N	(%)	1	2	3	4	N	(%)	1	2	3	4	N	(%)	1	2	3	4
System Organ Class and MedDRA (v9.0) preferred term																		
Bladder pain	1	(0.2)	1	0	0	0	0		0	0	0	0	0		0	0	0	0
Chromaturia	2	(0.4)	2	0	0	0	3	(0.6)	2	1	0	0	0		0	0	0	0
Dysuria	6	(1.3)	6	0	0	0	11	(2.3)	9	2	0	0	2	(0.7)	2	0	0	0
Haematuria	4	(0.8)	3	1	0	0	2	(0.4)	2	0	0	0	2	(0.7)	1	1	0	0
Micturition urgency	0		0	0	0	0	1	(0.2)	0	0	1	0	1	(0.4)	1	0	0	0
Nephrolithiasis	8	(1.7)	2	3	1	2	3	(0.6)	0	1	1	1	2	(0.7)	0	2	0	0
Nocturia	6	(1.3)	4	2	0	0	8	(1.6)	5	3	0	0	1	(0.4)	1	0	0	0
Oliguria	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Pollakiuria	4	(0.8)	4	0	0	0	7	(1.4)	3	4	0	0	2	(0.7)	2	0	0	0
Polyuria	0		0	0	0	0	3	(0.6)	2	1	0	0	2	(0.7)	2	0	0	0
Proteinuria	2	(0.4)	1	1	0	0	2	(0.4)	2	0	0	0	0		0	0	0	0
Renal colic	2	(0.4)	0	1	0	1	1	(0.2)	0	0	1	0	0		0	0	0	0
Renal failure	2	(0.4)	0	1	1	0	5	(1.0)	2	3	0	0	4	(1.5)	2	2	0	0
Renal failure acute	1	(0.2)	0	1	0	0	1	(0.2)	0	1	0	0	1	(0.4)	0	0	0	1
Renal impairment	1	(0.2)	1	0	0	0	1	(0.2)	0	1	0	0	0		0	0	0	0
Renal pain	1	(0.2)	1	0	0	0	1	(0.2)	0	1	0	0	0		0	0	0	0
Stress incontinence	0		0	0	0	0	0		0	0	0	0	1	(0.4)	0	1	0	0
Urinary hesitation	1	(0.2)	1	0	0	0	0		0	0	0	0	0		0	0	0	0
Urinary incontinence	3	(0.6)	1	2	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Urinary retention	0		0	0	0	0	1	(0.2)	0	1	0	0	0		0	0	0	0
Urine abnormality	1	(0.2)	1	0	0	0	0		0	0	0	0	0		0	0	0	0
Urine odour abnormal	1	(0.2)	0	1	0	0	1	(0.2)	0	1	0	0	0		0	0	0	0
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	22	(4.6)	13	8	1	0	27	(5.5)	18	8	1	0	10	(3.7)	8	2	0	0

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In this case, the reported severity is summarized. Missing baseline severities are imputed as grade 1.
Includes data up to 7 days after last dose of study drug.
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Table 3.4.2.5
Maraviroc Summary of Clinical Safety
Incidence and Severity of Treatment-Emergent Adverse Events (All Causalities)
Phase 2b/3 Treatment Experienced Studies

Number of Subjects evaluable for adverse events	maraviroc QD (n=477)						maraviroc BID (n=487)						Placebo (n=271)					
			Severity Grade*						Severity Grade*						Severity Grade*			
	N	(%)	1	2	3	4	N	(%)	1	2	3	4	N	(%)	1	2	3	4
System Organ Class and MedDRA (v9.0) preferred term																		
Amenorrhoea	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Balanitis	2	(0.4)	1	1	0	0	0		0	0	0	0	0		0	0	0	0
Benign prostatic hyperplasia	4	(0.8)	1	3	0	0	2	(0.4)	1	1	0	0	0		0	0	0	0
Breast atrophy	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Breast mass	0		0	0	0	0	2	(0.4)	2	0	0	0	1	(0.4)	0	1	0	0
Breast pain	1	(0.2)	1	0	0	0	0		0	0	0	0	0		0	0	0	0
Breast tenderness	1	(0.2)	1	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Cervical dysplasia	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Endometrial hyperplasia	0		0	0	0	0	0		0	0	0	0	1	(0.4)	1	0	0	0
Epididymitis	1	(0.2)	1	0	0	0	2	(0.4)	1	1	0	0	1	(0.4)	0	1	0	0
Erectile dysfunction	6	(1.3)	4	1	1	0	5	(1.0)	3	2	0	0	3	(1.1)	3	0	0	0
Genital erythema	1	(0.2)	1	0	0	0	0		0	0	0	0	0		0	0	0	0
Genital lesion	0		0	0	0	0	2	(0.4)	2	0	0	0	0		0	0	0	0
Genital pain female	1	(0.2)	1	0	0	0	0		0	0	0	0	0		0	0	0	0
Genital pruritus female	0		0	0	0	0	0		0	0	0	0	1	(0.4)	1	0	0	0
Genital pruritus male	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Genital rash	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Haematospermia	0		0	0	0	0	1	(0.2)	0	1	0	0	0		0	0	0	0
Hypertrophy breast	1	(0.2)	0	1	0	0	0		0	0	0	0	0		0	0	0	0
Metrorrhagia	0		0	0	0	0	1	(0.2)	0	0	1	0	0		0	0	0	0
Nipple disorder	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Oedema genital	1	(0.2)	1	0	0	0	0		0	0	0	0	0		0	0	0	0
Ovulation pain	1	(0.2)	1	0	0	0	0		0	0	0	0	0		0	0	0	0
Pelvic pain	1	(0.2)	1	0	0	0	1	(0.2)	1	0	0	0	1	(0.4)	1	0	0	0
Penile discharge	0		0	0	0	0	0		0	0	0	0	1	(0.4)	1	0	0	0
Prostatitis	2	(0.4)	2	0	0	0	4	(0.8)	4	0	0	0	1	(0.4)	1	0	0	0

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Includes data up to 7 days after last dose of study drug.
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Number of Subjects evaluable for adverse events	maraviroc QD (n=477)						maraviroc BID (n=487)						Placebo (n=271)					
			Severity Grade*						Severity Grade*						Severity Grade*			
	N	(%)	1	2	3	4	N	(%)	1	2	3	4	N	(%)	1	2	3	4
System Organ Class and MedDRA (v9.0) preferred term																		
Pruritus genital	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Scrotal mass	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Scrotal pain	0		0	0	0	0	1	(0.2)	0	1	0	0	0		0	0	0	0
Scrotal swelling	0		0	0	0	0	1	(0.2)	0	1	0	0	0		0	0	0	0
Scrotal ulcer	0		0	0	0	0	0		0	0	0	0	1	(0.4)	1	0	0	0
Semen discolouration	1	(0.2)	1	0	0	0	0		0	0	0	0	0		0	0	0	0
Sexual dysfunction	0		0	0	0	0	1	(0.2)	0	1	0	0	0		0	0	0	0
Testicular atrophy	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Testicular disorder	1	(0.2)	0	1	0	0	0		0	0	0	0	0		0	0	0	0
Testicular pain	1	(0.2)	0	1	0	0	0		0	0	0	0	0		0	0	0	0
Vaginal disorder	0		0	0	0	0	1	(0.2)	0	1	0	0	0		0	0	0	0
Vaginal erythema	1	(0.2)	0	1	0	0	0		0	0	0	0	0		0	0	0	0
Vaginal swelling	1	(0.2)	0	1	0	0	0		0	0	0	0	0		0	0	0	0
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	115	(24.1)	77	34	2	2	118	(24.2)	80	30	5	3	42	(15.5)	29	10	0	3
Acute respiratory failure	0		0	0	0	0	0		0	0	0	0	1	(0.4)	0	0	0	1
Allergic sinusitis	1	(0.2)	1	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Asthma	6	(1.3)	2	4	0	0	4	(0.8)	1	3	0	0	0		0	0	0	0
Atelectasis	2	(0.4)	2	0	0	0	1	(0.2)	0	1	0	0	0		0	0	0	0
Bronchial disorder	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Bronchial hyperactivity	0		0	0	0	0	0		0	0	0	0	1	(0.4)	1	0	0	0
Bronchospasm	1	(0.2)	1	0	0	0	1	(0.2)	1	0	0	0	1	(0.4)	0	1	0	0
Chronic obstructive pulmonary disease	0		0	0	0	0	2	(0.4)	1	0	0	1	2	(0.7)	0	1	0	1
Cough	42	(8.8)	32	9	0	1	52	(10.7)	37	14	1	0	14	(5.2)	11	3	0	0
Dysphonia	4	(0.8)	4	0	0	0	3	(0.6)	3	0	0	0	1	(0.4)	1	0	0	0

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MedDRA (v9.0) coding dictionary applied.

Number of Subjects evaluable for adverse events	maraviroc QD (n=477)						maraviroc BID (n=487)						Placebo (n=271)					
			Severity Grade*						Severity Grade*						Severity Grade*			
	N	(%)	1	2	3	4	N	(%)	1	2	3	4	N	(%)	1	2	3	4
System Organ Class and MedDRA (v9.0) preferred term																		
Dyspnoea	14	(2.9)	8	4	1	1	12	(2.5)	8	2	2	0	4	(1.5)	2	2	0	0
Dyspnoea exacerbated	0		0	0	0	0	1	(0.2)	0	1	0	0	1	(0.4)	0	0	0	1
Dyspnoea exertional	3	(0.6)	2	1	0	0	2	(0.4)	0	2	0	0	1	(0.4)	0	1	0	0
Emphysema	1	(0.2)	0	1	0	0	2	(0.4)	1	0	1	0	0		0	0	0	0
Epistaxis	2	(0.4)	1	1	0	0	3	(0.6)	3	0	0	0	2	(0.7)	2	0	0	0
Haemoptysis	0		0	0	0	0	2	(0.4)	2	0	0	0	0		0	0	0	0
Hiccups	3	(0.6)	2	1	0	0	0		0	0	0	0	3	(1.1)	2	1	0	0
Hypoxia	1	(0.2)	0	1	0	0	0		0	0	0	0	0		0	0	0	0
Lung disorder	0		0	0	0	0	1	(0.2)	0	0	1	0	0		0	0	0	0
Lung infiltration	2	(0.4)	0	1	1	0	0		0	0	0	0	0		0	0	0	0
Nasal congestion	12	(2.5)	11	1	0	0	12	(2.5)	9	2	1	0	6	(2.2)	6	0	0	0
Nasal dryness	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Nasal septum deviation	0		0	0	0	0	1	(0.2)	0	1	0	0	0		0	0	0	0
Nasal ulcer	1	(0.2)	1	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Paranasal sinus hypersecretion	1	(0.2)	0	1	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Pharyngeal erythema	1	(0.2)	0	1	0	0	1	(0.2)	1	0	0	0	1	(0.4)	1	0	0	0
Pharyngeal ulceration	0		0	0	0	0	0		0	0	0	0	1	(0.4)	1	0	0	0
Pharyngolaryngeal pain	19	(4.0)	16	3	0	0	13	(2.7)	12	1	0	0	7	(2.6)	7	0	0	0
Pharynx discomfort	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Pleural effusion	0		0	0	0	0	0		0	0	0	0	1	(0.4)	0	0	0	1
Pleurisy	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Pleuritic pain	2	(0.4)	0	2	0	0	0		0	0	0	0	0		0	0	0	0
Pneumonitis	0		0	0	0	0	1	(0.2)	0	0	0	1	0		0	0	0	0
Postnasal drip	2	(0.4)	2	0	0	0	3	(0.6)	3	0	0	0	1	(0.4)	1	0	0	0
Productive cough	6	(1.3)	5	1	0	0	6	(1.2)	3	3	0	0	0		0	0	0	0
Pulmonary congestion	0		0	0	0	0	1	(0.2)	0	1	0	0	0		0	0	0	0

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In this case, the reported severity is summarized. Missing baseline severities are imputed as grade 1.
Includes data up to 7 days after last dose of study drug.
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Maraviroc Summary of Clinical Safety
Incidence and Severity of Treatment-Emergent Adverse Events (All Causalities)
Phase 2b/3 Treatment Experienced Studies

Number of Subjects evaluable for adverse events	maraviroc QD (n=477)						maraviroc BID (n=487)						Placebo (n=271)					
			Severity Grade*						Severity Grade*						Severity Grade*			
	N	(%)	1	2	3	4	N	(%)	1	2	3	4	N	(%)	1	2	3	4
System Organ Class and MedDRA (v9.0) preferred term																		
Pulmonary embolism	0		0	0	0	0	1	(0.2)	0	0	0	1	0		0	0	0	0
Pulmonary hypertension	0		0	0	0	0	1	(0.2)	0	1	0	0	0		0	0	0	0
Rales	0		0	0	0	0	2	(0.4)	2	0	0	0	1	(0.4)	1	0	0	0
Respiratory disorder	2	(0.4)	1	1	0	0	1	(0.2)	0	1	0	0	0		0	0	0	0
Respiratory distress	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Respiratory failure	2	(0.4)	0	1	0	1	0		0	0	0	0	0		0	0	0	0
Respiratory tract congestion	3	(0.6)	1	2	0	0	7	(1.4)	5	2	0	0	3	(1.1)	2	1	0	0
Rhinitis allergic	4	(0.8)	3	1	0	0	2	(0.4)	2	0	0	0	0		0	0	0	0
Rhinitis seasonal	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Rhinorrhoea	7	(1.5)	7	0	0	0	11	(2.3)	9	2	0	0	0		0	0	0	0
Rhonchi	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Sinus congestion	6	(1.3)	6	0	0	0	8	(1.6)	7	1	0	0	2	(0.7)	1	1	0	0
Sleep apnoea syndrome	0		0	0	0	0	0		0	0	0	0	1	(0.4)	1	0	0	0
Sneezing	3	(0.6)	3	0	0	0	2	(0.4)	1	1	0	0	0		0	0	0	0
Sputum discoloured	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Throat irritation	0		0	0	0	0	1	(0.2)	0	1	0	0	1	(0.4)	1	0	0	0
Throat tightness	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Upper respiratory tract congestion	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Vocal cord polyp	0		0	0	0	0	1	(0.2)	0	1	0	0	0		0	0	0	0
Wheezing	1	(0.2)	1	0	0	0	3	(0.6)	2	1	0	0	0		0	0	0	0
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	115	(24.1)	72	33	9	1	137	(28.1)	92	37	7	1	54	(19.9)	37	15	2	0
Acne	4	(0.8)	4	0	0	0	5	(1.0)	5	0	0	0	0		0	0	0	0
Actinic keratosis	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Alopecia	2	(0.4)	1	0	1	0	6	(1.2)	5	1	0	0	0		0	0	0	0

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In this case, the reported severity is summarized. Missing baseline severities are imputed as grade 1.
Includes data up to 7 days after last dose of study drug.
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Table 3.4.2.5
Maraviroc Summary of Clinical Safety
Incidence and Severity of Treatment-Emergent Adverse Events (All Causalities)
Phase 2b/3 Treatment Experienced Studies

Number of Subjects evaluable for adverse events	maraviroc QD (n=477)						maraviroc BID (n=487)						Placebo (n=271)					
			Severity Grade*						Severity Grade*						Severity Grade*			
	N	(%)	1	2	3	4	N	(%)	1	2	3	4	N	(%)	1	2	3	4
System Organ Class and MedDRA (v9.0) preferred term																		
Blister	1	(0.2)	1	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Cold sweat	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Comedone	0		0	0	0	0	1	(0.2)	0	1	0	0	0		0	0	0	0
Dermal cyst	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Dermatitis	3	(0.6)	2	1	0	0	4	(0.8)	4	0	0	0	2	(0.7)	2	0	0	0
Dermatitis acneiform	0		0	0	0	0	0		0	0	0	0	1	(0.4)	1	0	0	0
Dermatitis contact	2	(0.4)	2	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Dermatitis exfoliative	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Drug eruption	2	(0.4)	0	1	1	0	2	(0.4)	1	1	0	0	0		0	0	0	0
Dry skin	7	(1.5)	6	1	0	0	9	(1.8)	8	1	0	0	3	(1.1)	3	0	0	0
Ecchymosis	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Eczema	0		0	0	0	0	4	(0.8)	4	0	0	0	3	(1.1)	2	1	0	0
Erythema	7	(1.5)	7	0	0	0	6	(1.2)	5	1	0	0	2	(0.7)	2	0	0	0
Exfoliative rash	2	(0.4)	2	0	0	0	0		0	0	0	0	1	(0.4)	1	0	0	0
Fat atrophy	0		0	0	0	0	2	(0.4)	1	0	1	0	1	(0.4)	1	0	0	0
Hand dermatitis	1	(0.2)	1	0	0	0	0		0	0	0	0	1	(0.4)	1	0	0	0
Heat rash	0		0	0	0	0	1	(0.2)	0	1	0	0	0		0	0	0	0
Hidradenitis	0		0	0	0	0	0		0	0	0	0	1	(0.4)	1	0	0	0
Hyperhidrosis	5	(1.0)	3	2	0	0	3	(0.6)	2	1	0	0	2	(0.7)	2	0	0	0
Hyperkeratosis	1	(0.2)	0	1	0	0	2	(0.4)	1	1	0	0	0		0	0	0	0
Hypertrichosis	1	(0.2)	1	0	0	0	0		0	0	0	0	0		0	0	0	0
Hypoaesthesia facial	1	(0.2)	1	0	0	0	0		0	0	0	0	1	(0.4)	1	0	0	0
Ingrowing nail	0		0	0	0	0	1	(0.2)	0	1	0	0	0		0	0	0	0
Lichen planus	1	(0.2)	0	1	0	0	0		0	0	0	0	0		0	0	0	0
Lipoatrophy	3	(0.6)	2	0	0	1	1	(0.2)	1	0	0	0	0		0	0	0	0
Lipodystrophy acquired	3	(0.6)	2	1	0	0	4	(0.8)	2	2	0	0	1	(0.4)	0	1	0	0

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In this case, the reported severity is summarized. Missing baseline severities are imputed as grade 1.
Includes data up to 7 days after last dose of study drug.
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Table 3.4.2.5
Maraviroc Summary of Clinical Safety
Incidence and Severity of Treatment-Emergent Adverse Events (All Causalities)
Phase 2b/3 Treatment Experienced Studies

Number of Subjects evaluable for adverse events	maraviroc QD (n=477)						maraviroc BID (n=487)						Placebo (n=271)					
			Severity Grade*						Severity Grade*						Severity Grade*			
	N	(%)	1	2	3	4	N	(%)	1	2	3	4	N	(%)	1	2	3	4
System Organ Class and MedDRA (v9.0) preferred term																		
Lipohypertrophy	4	(0.8)	2	1	1	0	6	(1.2)	5	1	0	0	0		0	0	0	0
Nail discolouration	0		0	0	0	0	1	(0.2)	1	0	0	0	1	(0.4)	0	1	0	0
Nail disorder	1	(0.2)	0	1	0	0	1	(0.2)	1	0	0	0	1	(0.4)	1	0	0	0
Night sweats	15	(3.1)	12	2	1	0	17	(3.5)	14	2	1	0	7	(2.6)	5	1	1	0
Onycholysis	1	(0.2)	0	1	0	0	0		0	0	0	0	0		0	0	0	0
Photosensitivity reaction	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Prurigo	1	(0.2)	1	0	0	0	0		0	0	0	0	0		0	0	0	0
Pruritus	12	(2.5)	9	2	1	0	16	(3.3)	12	3	1	0	7	(2.6)	5	2	0	0
Pruritus generalised	3	(0.6)	2	1	0	0	0		0	0	0	0	0		0	0	0	0
Psoriasis	2	(0.4)	1	1	0	0	1	(0.2)	0	1	0	0	2	(0.7)	0	2	0	0
Purpura	1	(0.2)	0	1	0	0	0		0	0	0	0	0		0	0	0	0
Rash	31	(6.5)	18	11	2	0	40	(8.2)	26	11	2	1	14	(5.2)	12	2	0	0
Rash erythematous	3	(0.6)	2	1	0	0	2	(0.4)	1	1	0	0	1	(0.4)	1	0	0	0
Rash generalised	2	(0.4)	1	0	1	0	6	(1.2)	2	3	1	0	0		0	0	0	0
Rash macular	0		0	0	0	0	1	(0.2)	1	0	0	0	1	(0.4)	0	1	0	0
Rash maculo-papular	2	(0.4)	0	2	0	0	2	(0.4)	1	1	0	0	1	(0.4)	1	0	0	0
Rash papular	6	(1.3)	6	0	0	0	6	(1.2)	5	1	0	0	2	(0.7)	2	0	0	0
Rash pruritic	3	(0.6)	1	2	0	0	4	(0.8)	1	3	0	0	1	(0.4)	1	0	0	0
Rosacea	0		0	0	0	0	0		0	0	0	0	2	(0.7)	0	2	0	0
Scar	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Seborrhoeic dermatitis	5	(1.0)	3	2	0	0	3	(0.6)	2	1	0	0	1	(0.4)	1	0	0	0
Skin discolouration	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Skin exfoliation	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Skin hyperpigmentation	2	(0.4)	2	0	0	0	0		0	0	0	0	0		0	0	0	0
Skin irritation	0		0	0	0	0	1	(0.2)	0	0	1	0	0		0	0	0	0
Skin lesion	4	(0.8)	4	0	0	0	6	(1.2)	3	3	0	0	4	(1.5)	4	0	0	0

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Includes data up to 7 days after last dose of study drug.
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Table 3.4.2.5
Maraviroc Summary of Clinical Safety
Incidence and Severity of Treatment-Emergent Adverse Events (All Causalities)
Phase 2b/3 Treatment Experienced Studies

Number of Subjects evaluable for adverse events	maraviroc QD (n=477)						maraviroc BID (n=487)						Placebo (n=271)					
			Severity Grade*						Severity Grade*						Severity Grade*			
	N	(%)	1	2	3	4	N	(%)	1	2	3	4	N	(%)	1	2	3	4
System Organ Class and MedDRA (v9.0) preferred term																		
Skin nodule	2	(0.4)	1	1	0	0	0		0	0	0	0	2	(0.7)	1	1	0	0
Skin odour abnormal	0		0	0	0	0	0		0	0	0	0	1	(0.4)	1	0	0	0
Skin reaction	2	(0.4)	0	1	1	0	2	(0.4)	1	1	0	0	1	(0.4)	1	0	0	0
Skin swelling	1	(0.2)	1	0	0	0	0		0	0	0	0	0		0	0	0	0
Stasis dermatitis	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Subcutaneous nodule	1	(0.2)	1	0	0	0	3	(0.6)	3	0	0	0	2	(0.7)	1	1	0	0
Swelling face	0		0	0	0	0	1	(0.2)	1	0	0	0	2	(0.7)	0	2	0	0
Telangiectasia	1	(0.2)	1	0	0	0	0		0	0	0	0	0		0	0	0	0
Urticaria	3	(0.6)	2	1	0	0	1	(0.2)	1	0	0	0	2	(0.7)	0	1	1	0
Xeroderma	1	(0.2)	1	0	0	0	0		0	0	0	0	0		0	0	0	0
SOCIAL CIRCUMSTANCES	1	(0.2)	0	0	1	0	1	(0.2)	1	0	0	0	1	(0.4)	1	0	0	0
Drug abuser	1	(0.2)	0	0	1	0	0		0	0	0	0	0		0	0	0	0
Exposure to communicable disease	0		0	0	0	0	0		0	0	0	0	1	(0.4)	1	0	0	0
Stress at work	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
SURGICAL AND MEDICAL PROCEDURES	11	(2.3)	8	2	1	0	9	(1.8)	4	2	2	1	3	(1.1)	1	1	1	0
Abscess drainage	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Anorectal operation	1	(0.2)	1	0	0	0	0		0	0	0	0	0		0	0	0	0
Arterial bypass operation	0		0	0	0	0	1	(0.2)	0	0	0	1	0		0	0	0	0
Cataract operation	0		0	0	0	0	0		0	0	0	0	1	(0.4)	0	0	1	0
Central nervous system stimulation	1	(0.2)	1	0	0	0	0		0	0	0	0	0		0	0	0	0
Endodontic procedure	0		0	0	0	0	0		0	0	0	0	1	(0.4)	1	0	0	0
Foot operation	0		0	0	0	0	1	(0.2)	0	1	0	0	0		0	0	0	0

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MedDRA (v9.0) coding dictionary applied.

Number of Subjects evaluable for adverse events	maraviroc QD (n=477)						maraviroc BID (n=487)						Placebo (n=271)					
			Severity Grade*						Severity Grade*						Severity Grade*			
	N	(%)	1	2	3	4	N	(%)	1	2	3	4	N	(%)	1	2	3	4
System Organ Class and MedDRA (v9.0) preferred term																		
Hip surgery	0		0	0	0	0	1	(0.2)	0	0	1	0	0		0	0	0	0
Limb operation	0		0	0	0	0	1	(0.2)	0	0	1	0	0		0	0	0	0
Nasal sinus drainage	1	(0.2)	0	1	0	0	0		0	0	0	0	0		0	0	0	0
Rectal lesion excision	0		0	0	0	0	1	(0.2)	0	1	0	0	0		0	0	0	0
Sinus operation	5	(1.0)	5	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Skin neoplasm excision	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Stent placement	0		0	0	0	0	0		0	0	0	0	1	(0.4)	0	1	0	0
Suture insertion	1	(0.2)	0	1	0	0	0		0	0	0	0	0		0	0	0	0
Toe operation	1	(0.2)	0	0	1	0	0		0	0	0	0	0		0	0	0	0
Tooth extraction	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Wart excision	1	(0.2)	1	0	0	0	0		0	0	0	0	0		0	0	0	0
VASCULAR DISORDERS	23	(4.8)	13	8	2	0	31	(6.4)	17	10	3	1	9	(3.3)	4	3	1	1
Aortic arteriosclerosis	0		0	0	0	0	0		0	0	0	0	1	(0.4)	0	0	1	0
Arterial occlusive disease	0		0	0	0	0	1	(0.2)	0	0	1	0	0		0	0	0	0
Circulatory collapse	1	(0.2)	1	0	0	0	0		0	0	0	0	0		0	0	0	0
Flushing	2	(0.4)	2	0	0	0	3	(0.6)	3	0	0	0	0		0	0	0	0
Haematoma	1	(0.2)	1	0	0	0	2	(0.4)	1	0	0	1	0		0	0	0	0
Hot flush	1	(0.2)	1	0	0	0	5	(1.0)	4	1	0	0	1	(0.4)	1	0	0	0
Hypertension	8	(1.7)	3	5	0	0	13	(2.7)	7	6	0	0	4	(1.5)	1	3	0	0
Hypotension	5	(1.0)	2	1	2	0	1	(0.2)	0	1	0	0	1	(0.4)	0	0	0	1
Iliac artery stenosis	0		0	0	0	0	0		0	0	0	0	1	(0.4)	0	0	1	0
Intermittent claudication	1	(0.2)	1	0	0	0	0		0	0	0	0	0		0	0	0	0
Orthostatic hypotension	2	(0.4)	0	2	0	0	2	(0.4)	0	1	1	0	1	(0.4)	1	0	0	0
Pallor	0		0	0	0	0	0		0	0	0	0	1	(0.4)	1	0	0	0

* If the same subject in a given treatment had more than one occurrence in the same preferred term event category, only the most severe occurrence is taken. Subjects are counted only once per treatment in each row. For the TESS algorithm any missing severities have been imputed as grade 4 unless the subject experienced another occurrence of the same event in a given treatment for which severity was recorded.
In this case, the reported severity is summarized. Missing baseline severities are imputed as grade 1.
Includes data up to 7 days after last dose of study drug.
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Maraviroc Summary of Clinical Safety
Incidence and Severity of Treatment-Emergent Adverse Events (All Causalities)
Phase 2b/3 Treatment Experienced Studies

Number of Subjects evaluable for adverse events	maraviroc QD (n=477)						maraviroc BID (n=487)						Placebo (n=271)					
			Severity Grade*						Severity Grade*						Severity Grade*			
	N	(%)	1	2	3	4	N	(%)	1	2	3	4	N	(%)	1	2	3	4
System Organ Class and MedDRA (v9.0) preferred term																		
Peripheral embolism	0		0	0	0	0	1	(0.2)	0	0	1	0	0		0	0	0	0
Phlebitis	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Raynaud's phenomenon	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Thrombophlebitis	0		0	0	0	0	0		0	0	0	0	1	(0.4)	1	0	0	0
Varicose vein	1	(0.2)	1	0	0	0	1	(0.2)	0	1	0	0	0		0	0	0	0
Vasculitis	1	(0.2)	1	0	0	0	0		0	0	0	0	0		0	0	0	0
Venous thrombosis	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Total preferred term events	2346		1457	686	141	62	2407		1452	715	160	80	1130		638	372	83	37

* If the same subject in a given treatment had more than one occurrence in the same preferred term event category, only the most severe occurrence is taken. Subjects are counted only once per treatment in each row. For the TESS algorithm any missing severities have been imputed as grade 4 unless the subject experienced another occurrence of the same event in a given treatment for which severity was recorded.
In this case, the reported severity is summarized. Missing baseline severities are imputed as grade 1.
Includes data up to 7 days after last dose of study drug.
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Table 3.4.3.1

Maraviroc Summary of Clinical Safety
Treatment-Emergent Adverse Events (All Causalities)
Phase 3 Treatment Experienced CCR5 Tropic Studies

	maraviroc QD		maraviroc BID		Placebo	
	n	(%)	n	(%)	n	(%)
Number (%) of subjects:						
Subjects evaluable for adverse events	414		426		209	
Number of adverse events	2080		2160		884	
Subjects with adverse events	366	(88.4)	383	(89.9)	175	(83.7)
Subjects with serious adverse events	58	(14.0)	67	(15.7)	34	(16.3)
Subjects with grade 3 adverse events	77	(18.6)	92	(21.6)	43	(20.6)
Subjects with grade 4 adverse events	33	(8.0)	42	(9.9)	13	(6.2)
Subjects discontinued due to adverse events	20	(4.8)	17	(4.0)	8	(3.8)
Subjects with dose reduced or temporary discontinuation due to adverse events	20	(4.8)	28	(6.6)	13	(6.2)

Includes data up to 7 days after last dose of study drug.
Except for the Number of Adverse Events subjects are counted only once per treatment in each row.
Serious Adverse Events - according to the investigator's assessment.
For the grade 3/grade 4 rows, if the same subject in a given treatment had more than one occurrence in the same preferred term event category, only the most severe (grade 4) occurrence is taken. If the same subject had two different preferred term events, one classified as grade 3, one as grade 4, they will be present in both rows.
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Table 3.4.3.2
Maraviroc Summary of Clinical Safety
Treatment-Emergent Adverse Events by System Organ Class (All Causalities)
Phase 3 Treatment Experienced CCR5 Tropic Studies

	maraviroc QD		maraviroc BID		Placebo	
	n	(%)	n	(%)	n	(%)
Number (%) of Subjects:						
Evaluable for adverse events	414		426		209	
With adverse events	366	(88.4)	383	(89.9)	175	(83.7)
Discontinued due to adverse events	20	(4.8)	17	(4.0)	8	(3.8)
Number (%) of Subjects with Adverse Events by System Organ Class:						
Being queried	1	(0.2)	0		0	
Blood and lymphatic system disorders	22	(5.3)	31	(7.3)	18	(8.6)
Cardiac disorders	12	(2.9)	8	(1.9)	3	(1.4)
Ear and labyrinth disorders	13	(3.1)	17	(4.0)	8	(3.8)
Endocrine disorders	8	(1.9)	5	(1.2)	2	(1.0)
Eye disorders	34	(8.2)	42	(9.9)	16	(7.7)
Gastrointestinal disorders	199	(48.1)	208	(48.8)	106	(50.7)
General disorders and administration site conditions	137	(33.1)	157	(36.9)	79	(37.8)
Hepatobiliary disorders	9	(2.2)	17	(4.0)	7	(3.3)
Immune system disorders	14	(3.4)	9	(2.1)	7	(3.3)
Infections and infestations	198	(47.8)	214	(50.2)	80	(38.3)
Injury, poisoning and procedural complications	34	(8.2)	32	(7.5)	12	(5.7)
Investigations	74	(17.9)	85	(20.0)	26	(12.4)
Metabolism and nutrition disorders	47	(11.4)	51	(12.0)	24	(11.5)
Musculoskeletal and connective tissue disorders	93	(22.5)	82	(19.2)	38	(18.2)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	26	(6.3)	20	(4.7)	14	(6.7)
Nervous system disorders	136	(32.9)	135	(31.7)	63	(30.1)
Pregnancy, puerperium and perinatal conditions	2	(0.5)	0		0	
Psychiatric disorders	68	(16.4)	68	(16.0)	27	(12.9)
Renal and urinary disorders	36	(8.7)	45	(10.6)	12	(5.7)
Reproductive system and breast disorders	18	(4.3)	24	(5.6)	7	(3.3)
Respiratory, thoracic and mediastinal disorders	103	(24.9)	107	(25.1)	29	(13.9)
Skin and subcutaneous tissue disorders	104	(25.1)	115	(27.0)	38	(18.2)
Social circumstances	1	(0.2)	0		1	(0.5)
Surgical and medical procedures	9	(2.2)	9	(2.1)	3	(1.4)
Vascular disorders	22	(5.3)	31	(7.3)	7	(3.3)

Subjects are only counted once per treatment for each row.
Includes data up to 7 days after last dose of study drug.
MedDRA (v9.0) coding dictionary applied.

Number of Subjects evaluable for adverse events	maraviroc QD (n=414)						maraviroc BID (n=426)						Placebo (n=209)					
			Severity Grade*						Severity Grade*						Severity Grade*			
	N	(%)	1	2	3	4	N	(%)	1	2	3	4	N	(%)	1	2	3	4
System Organ Class and MedDRA (v9.0) preferred term																		
BEING QUERIED	1	(0.2)	0	0	1	0	0		0	0	0	0	0		0	0	0	0
WORSENING OF CANDIDIASIS	1	(0.2)	0	0	1	0	0		0	0	0	0	0		0	0	0	0
BLOOD AND LYMPHATIC SYSTEM DISORDERS	22	(5.3)	12	5	2	3	31	(7.3)	9	9	8	5	18	(8.6)	6	7	4	1
Anaemia	9	(2.2)	4	2	1	2	12	(2.8)	3	6	2	1	6	(2.9)	3	3	0	0
Bone marrow failure	1	(0.2)	0	1	0	0	0		0	0	0	0	0		0	0	0	0
Coagulopathy	1	(0.2)	1	0	0	0	0		0	0	0	0	0		0	0	0	0
Febrile neutropenia	0		0	0	0	0	1	(0.2)	0	1	0	0	1	(0.5)	0	0	0	1
Haemoglobinaemia	0		0	0	0	0	0		0	0	0	0	1	(0.5)	1	0	0	0
Haemolytic anaemia	0		0	0	0	0	1	(0.2)	0	0	0	1	0		0	0	0	0
Iron deficiency anaemia	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Leukopenia	0		0	0	0	0	1	(0.2)	0	1	0	0	2	(1.0)	0	2	0	0
Lymph node pain	1	(0.2)	1	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Lymphadenopathy	7	(1.7)	5	2	0	0	8	(1.9)	5	3	0	0	6	(2.9)	3	2	1	0
Neutropenia	3	(0.7)	1	0	1	1	8	(1.9)	0	0	5	3	4	(1.9)	0	1	3	0
Pancytopenia	1	(0.2)	0	1	0	0	2	(0.5)	0	0	2	0	0		0	0	0	0
Splenomegaly	0		0	0	0	0	1	(0.2)	0	0	0	1	1	(0.5)	0	0	1	0
Thrombocytopenia	0		0	0	0	0	0		0	0	0	0	1	(0.5)	0	0	1	0
CARDIAC DISORDERS	12	(2.9)	6	1	3	2	8	(1.9)	2	3	2	1	3	(1.4)	0	1	2	0
Acute myocardial infarction	1	(0.2)	0	0	1	0	0		0	0	0	0	0		0	0	0	0
Angina pectoris	2	(0.5)	2	0	0	0	1	(0.2)	0	0	1	0	0		0	0	0	0

* If the same subject in a given treatment had more than one occurrence in the same preferred term event category, only the most severe occurrence is taken. Subjects are counted only once per treatment in each row. For the TESS algorithm any missing severities have been imputed as grade 4 unless the subject experienced another occurrence of the same event in a given treatment for which severity was recorded.
In this case, the reported severity is summarized. Missing baseline severities are imputed as grade 1.
Includes data up to 7 days after last dose of study drug.
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Number of Subjects evaluable for adverse events	maraviroc QD (n=414)						maraviroc BID (n=426)						Placebo (n=209)					
			Severity Grade*						Severity Grade*						Severity Grade*			
	N	(%)	1	2	3	4	N	(%)	1	2	3	4	N	(%)	1	2	3	4
System Organ Class and MedDRA (v9.0) preferred term																		
Angina unstable	1	(0.2)	0	0	1	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Aortic valve disease	0		0	0	0	0	0		0	0	0	0	1	(0.5)	0	0	1	0
Arrhythmia	0		0	0	0	0	1	(0.2)	0	0	0	1	0		0	0	0	0
Atrioventricular block first degree	1	(0.2)	1	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Bradycardia	0		0	0	0	0	2	(0.5)	0	2	0	0	0		0	0	0	0
Cardiac failure acute	1	(0.2)	0	0	0	1	0		0	0	0	0	0		0	0	0	0
Coronary artery disease	2	(0.5)	0	1	1	0	0		0	0	0	0	0		0	0	0	0
Coronary artery occlusion	2	(0.5)	0	1	1	0	0		0	0	0	0	0		0	0	0	0
Myocardial infarction	1	(0.2)	0	0	0	1	0		0	0	0	0	0		0	0	0	0
Myocardial ischaemia	0		0	0	0	0	2	(0.5)	1	0	1	0	0		0	0	0	0
Palpitations	1	(0.2)	1	0	0	0	1	(0.2)	1	0	0	0	1	(0.5)	0	1	0	0
Prinzmetal angina	0		0	0	0	0	1	(0.2)	0	1	0	0	0		0	0	0	0
Sinus bradycardia	1	(0.2)	1	0	0	0	0		0	0	0	0	0		0	0	0	0
Supraventricular tachyarrhythmia	0		0	0	0	0	0		0	0	0	0	1	(0.5)	0	0	1	0
Tachycardia	1	(0.2)	1	0	0	0	2	(0.5)	1	1	0	0	0		0	0	0	0
EAR AND LABYRINTH DISORDERS	13	(3.1)	10	2	1	0	17	(4.0)	10	6	1	0	8	(3.8)	3	4	0	1
Cerumen impaction	0		0	0	0	0	2	(0.5)	1	1	0	0	0		0	0	0	0
Deafness	1	(0.2)	1	0	0	0	0		0	0	0	0	1	(0.5)	0	0	0	1
Ear congestion	0		0	0	0	0	2	(0.5)	1	1	0	0	1	(0.5)	0	1	0	0
Ear discomfort	0		0	0	0	0	2	(0.5)	1	1	0	0	0		0	0	0	0
Ear disorder	0		0	0	0	0	0		0	0	0	0	1	(0.5)	0	1	0	0
Ear haemorrhage	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Ear pain	2	(0.5)	1	1	0	0	2	(0.5)	2	0	0	0	0		0	0	0	0
Hyperacusis	1	(0.2)	1	0	0	0	0		0	0	0	0	0		0	0	0	0

* If the same subject in a given treatment had more than one occurrence in the same preferred term event category, only the most severe occurrence is taken. Subjects are counted only once per treatment in each row. For the TESS algorithm any missing severities have been imputed as grade 4 unless the subject experienced another occurrence of the same event in a given treatment for which severity was recorded.
In this case, the reported severity is summarized. Missing baseline severities are imputed as grade 1.
Includes data up to 7 days after last dose of study drug.
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Number of Subjects evaluable for adverse events	maraviroc QD (n=414)						maraviroc BID (n=426)						Placebo (n=209)					
			Severity Grade*						Severity Grade*						Severity Grade*			
	N	(%)	1	2	3	4	N	(%)	1	2	3	4	N	(%)	1	2	3	4
System Organ Class and MedDRA (v9.0) preferred term																		
Motion sickness	0		0	0	0	0	1	(0.2)	0	1	0	0	0		0	0	0	0
Otorrhoea	1	(0.2)	1	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Tinnitus	2	(0.5)	2	0	0	0	2	(0.5)	1	1	0	0	2	(1.0)	0	2	0	0
Tympanic membrane hyperaemia	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Vertigo	6	(1.4)	4	1	1	0	4	(0.9)	2	1	1	0	3	(1.4)	3	0	0	0
Vertigo positional	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
ENDOCRINE DISORDERS	8	(1.9)	4	4	0	0	5	(1.2)	2	3	0	0	2	(1.0)	0	2	0	0
Adrenal insufficiency	1	(0.2)	0	1	0	0	0		0	0	0	0	0		0	0	0	0
Adrenal mass	1	(0.2)	1	0	0	0	0		0	0	0	0	0		0	0	0	0
Basedow's disease	1	(0.2)	1	0	0	0	0		0	0	0	0	0		0	0	0	0
Hyperparathyroidism	0		0	0	0	0	0		0	0	0	0	1	(0.5)	0	1	0	0
Hypogonadism	2	(0.5)	1	1	0	0	4	(0.9)	2	2	0	0	0		0	0	0	0
Hypothyroidism	3	(0.7)	1	2	0	0	1	(0.2)	0	1	0	0	1	(0.5)	0	1	0	0
EYE DISORDERS	34	(8.2)	24	8	1	1	42	(9.9)	30	10	1	1	16	(7.7)	11	5	0	0
Amblyopia	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Blepharitis	1	(0.2)	1	0	0	0	0		0	0	0	0	2	(1.0)	1	1	0	0
Blindness unilateral	0		0	0	0	0	1	(0.2)	0	0	0	1	0		0	0	0	0
Cataract	1	(0.2)	1	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Chalazion	0		0	0	0	0	0		0	0	0	0	1	(0.5)	1	0	0	0
Conjunctival irritation	1	(0.2)	1	0	0	0	0		0	0	0	0	0		0	0	0	0
Conjunctivitis	5	(1.2)	3	2	0	0	8	(1.9)	6	2	0	0	3	(1.4)	1	2	0	0
Conjunctivitis allergic	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0

* If the same subject in a given treatment had more than one occurrence in the same preferred term event category, only the most severe occurrence is taken.
Subjects are counted only once per treatment in each row. For the TESS algorithm any missing severities have been imputed as grade 4 unless the subject experienced another occurrence of the same event in a given treatment for which severity was recorded.
In this case, the reported severity is summarized. Missing baseline severities are imputed as grade 1.
Includes data up to 7 days after last dose of study drug.
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Maraviroc Summary of Clinical Safety
Incidence and Severity of Treatment-Emergent Adverse Events (All Causalities)
Phase 3 Treatment Experienced CCR5 Tropic Studies

Number of Subjects evaluable for adverse events	maraviroc QD (n=414)						maraviroc BID (n=426)						Placebo (n=209)					
			Severity Grade*						Severity Grade*						Severity Grade*			
	N	(%)	1	2	3	4	N	(%)	1	2	3	4	N	(%)	1	2	3	4
System Organ Class and MedDRA (v9.0) preferred term																		
Dacryoadenitis acquired	1	(0.2)	1	0	0	0	0		0	0	0	0	0		0	0	0	0
Dacryostenosis acquired	0		0	0	0	0	0		0	0	0	0	1	(0.5)	1	0	0	0
Diplopia	0		0	0	0	0	2	(0.5)	1	0	1	0	1	(0.5)	0	1	0	0
Dry eye	0		0	0	0	0	7	(1.6)	3	4	0	0	1	(0.5)	1	0	0	0
Erythema of eyelid	1	(0.2)	1	0	0	0	0		0	0	0	0	0		0	0	0	0
Exophthalmos	1	(0.2)	0	0	1	0	0		0	0	0	0	0		0	0	0	0
Eye allergy	0		0	0	0	0	1	(0.2)	0	1	0	0	0		0	0	0	0
Eye discharge	0		0	0	0	0	0		0	0	0	0	1	(0.5)	1	0	0	0
Eye disorder	1	(0.2)	1	0	0	0	0		0	0	0	0	0		0	0	0	0
Eye irritation	2	(0.5)	2	0	0	0	5	(1.2)	5	0	0	0	0		0	0	0	0
Eye oedema	1	(0.2)	1	0	0	0	0		0	0	0	0	0		0	0	0	0
Eye pain	1	(0.2)	0	1	0	0	3	(0.7)	3	0	0	0	0		0	0	0	0
Eye pruritus	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Eyelid disorder	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Eyelid oedema	2	(0.5)	2	0	0	0	0		0	0	0	0	0		0	0	0	0
Eyelid ptosis	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Glaucoma	1	(0.2)	0	1	0	0	0		0	0	0	0	0		0	0	0	0
Halo vision	0		0	0	0	0	0		0	0	0	0	1	(0.5)	1	0	0	0
Keratoconjunctivitis sicca	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Lacrimation increased	2	(0.5)	2	0	0	0	0		0	0	0	0	0		0	0	0	0
Ocular hyperaemia	3	(0.7)	2	1	0	0	1	(0.2)	1	0	0	0	1	(0.5)	0	1	0	0
Ocular icterus	2	(0.5)	2	0	0	0	2	(0.5)	1	1	0	0	0		0	0	0	0
Photophobia	1	(0.2)	1	0	0	0	0		0	0	0	0	0		0	0	0	0
Presbyopia	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Punctate keratitis	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Retinal tear	1	(0.2)	0	1	0	0	0		0	0	0	0	0		0	0	0	0

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In this case, the reported severity is summarized. Missing baseline severities are imputed as grade 1.
Includes data up to 7 days after last dose of study drug.
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Number of Subjects evaluable for adverse events	maraviroc QD (n=414)						maraviroc BID (n=426)						Placebo (n=209)					
			Severity Grade*						Severity Grade*						Severity Grade*			
	N	(%)	1	2	3	4	N	(%)	1	2	3	4	N	(%)	1	2	3	4
System Organ Class and MedDRA (v9.0) preferred term																		
Scleritis	1	(0.2)	1	0	0	0	0		0	0	0	0	0		0	0	0	0
Strabismus	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Vision blurred	6	(1.4)	5	1	0	0	4	(0.9)	4	0	0	0	4	(1.9)	4	0	0	0
Visual acuity reduced	2	(0.5)	1	1	0	0	1	(0.2)	0	0	1	0	1	(0.5)	1	0	0	0
Visual disturbance	5	(1.2)	3	1	0	1	1	(0.2)	0	1	0	0	1	(0.5)	1	0	0	0
Vitreous floaters	2	(0.5)	2	0	0	0	2	(0.5)	1	1	0	0	0		0	0	0	0
Vitritis	0		0	0	0	0	1	(0.2)	0	1	0	0	0		0	0	0	0
Xerophthalmia	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
GASTROINTESTINAL DISORDERS	199	(48.1)	109	77	10	3	208	(48.8)	119	73	13	3	106	(50.7)	52	46	7	1
Abdominal discomfort	1	(0.2)	1	0	0	0	5	(1.2)	3	2	0	0	2	(1.0)	0	1	1	0
Abdominal distension	14	(3.4)	10	3	1	0	10	(2.3)	9	1	0	0	6	(2.9)	3	3	0	0
Abdominal pain	18	(4.3)	8	9	1	0	19	(4.5)	11	6	2	0	7	(3.3)	2	3	2	0
Abdominal pain lower	3	(0.7)	3	0	0	0	2	(0.5)	2	0	0	0	1	(0.5)	1	0	0	0
Abdominal pain upper	20	(4.8)	14	5	1	0	14	(3.3)	8	4	1	1	7	(3.3)	6	1	0	0
Abdominal rigidity	0		0	0	0	0	0		0	0	0	0	1	(0.5)	0	0	1	0
Abdominal tenderness	2	(0.5)	2	0	0	0	1	(0.2)	0	1	0	0	2	(1.0)	2	0	0	0
Abnormal faeces	0		0	0	0	0	2	(0.5)	2	0	0	0	0		0	0	0	0
Anal fistula	1	(0.2)	0	1	0	0	0		0	0	0	0	0		0	0	0	0
Anal inflammation	0		0	0	0	0	0		0	0	0	0	1	(0.5)	0	1	0	0
Anal ulcer	1	(0.2)	1	0	0	0	0		0	0	0	0	1	(0.5)	1	0	0	0
Anogenital dysplasia	1	(0.2)	0	1	0	0	0		0	0	0	0	1	(0.5)	0	1	0	0
Aphthous stomatitis	7	(1.7)	5	2	0	0	5	(1.2)	4	1	0	0	1	(0.5)	1	0	0	0
Ascites	0		0	0	0	0	1	(0.2)	0	0	0	1	0		0	0	0	0
Bowel sounds abnormal	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0

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In this case, the reported severity is summarized. Missing baseline severities are imputed as grade 1.
Includes data up to 7 days after last dose of study drug.
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Number of Subjects evaluable for adverse events	maraviroc QD (n=414)						maraviroc BID (n=426)						Placebo (n=209)					
			Severity Grade*						Severity Grade*						Severity Grade*			
	N	(%)	1	2	3	4	N	(%)	1	2	3	4	N	(%)	1	2	3	4
System Organ Class and MedDRA (v9.0) preferred term																		
Chapped lips	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Cheilitis	2	(0.5)	2	0	0	0	0		0	0	0	0	1	(0.5)	1	0	0	0
Colitis	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Constipation	19	(4.6)	13	5	1	0	23	(5.4)	17	5	1	0	6	(2.9)	4	2	0	0
Diarrhoea	94	(22.7)	52	38	3	1	89	(20.9)	56	31	2	0	45	(21.5)	26	19	0	0
Diarrhoea haemorrhagic	1	(0.2)	0	0	0	1	0		0	0	0	0	0		0	0	0	0
Diverticulum intestinal	0		0	0	0	0	0		0	0	0	0	1	(0.5)	1	0	0	0
Diverticulum intestinal haemorrhagic	1	(0.2)	0	0	0	1	0		0	0	0	0	0		0	0	0	0
Dry mouth	3	(0.7)	2	1	0	0	5	(1.2)	3	2	0	0	3	(1.4)	3	0	0	0
Dyspepsia	10	(2.4)	8	2	0	0	11	(2.6)	6	5	0	0	5	(2.4)	2	3	0	0
Dysphagia	3	(0.7)	1	1	1	0	3	(0.7)	1	1	0	1	1	(0.5)	0	0	1	0
Enteritis	1	(0.2)	1	0	0	0	0		0	0	0	0	1	(0.5)	0	1	0	0
Eructation	2	(0.5)	1	1	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Faecal incontinence	1	(0.2)	0	1	0	0	0		0	0	0	0	0		0	0	0	0
Faeces discoloured	0		0	0	0	0	1	(0.2)	0	1	0	0	0		0	0	0	0
Faeces pale	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Flatulence	14	(3.4)	12	2	0	0	16	(3.8)	13	3	0	0	9	(4.3)	7	2	0	0
Food poisoning	0		0	0	0	0	0		0	0	0	0	1	(0.5)	1	0	0	0
Gastritis	5	(1.2)	2	3	0	0	2	(0.5)	1	1	0	0	0		0	0	0	0
Gastrointestinal disorder	0		0	0	0	0	1	(0.2)	0	1	0	0	0		0	0	0	0
Gastrointestinal pain	0		0	0	0	0	1	(0.2)	1	0	0	0	1	(0.5)	1	0	0	0
Gastrooesophageal reflux disease	5	(1.2)	3	2	0	0	6	(1.4)	6	0	0	0	2	(1.0)	1	1	0	0
Gingival bleeding	0		0	0	0	0	0		0	0	0	0	1	(0.5)	1	0	0	0
Gingival pain	0		0	0	0	0	1	(0.2)	0	1	0	0	0		0	0	0	0
Gingivitis	4	(1.0)	1	3	0	0	4	(0.9)	4	0	0	0	2	(1.0)	1	1	0	0
Glossitis	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0

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Includes data up to 7 days after last dose of study drug.
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Number of Subjects evaluable for adverse events	maraviroc QD (n=414)						maraviroc BID (n=426)						Placebo (n=209)					
			Severity Grade*						Severity Grade*						Severity Grade*			
	N	(%)	1	2	3	4	N	(%)	1	2	3	4	N	(%)	1	2	3	4
System Organ Class and MedDRA (v9.0) preferred term																		
Glossodynia	1	(0.2)	0	1	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Haematochezia	3	(0.7)	1	1	1	0	0		0	0	0	0	1	(0.5)	1	0	0	0
Haemorrhoids	6	(1.4)	3	3	0	0	4	(0.9)	2	2	0	0	0		0	0	0	0
Hiatus hernia	1	(0.2)	1	0	0	0	0		0	0	0	0	0		0	0	0	0
Hypoaesthesia oral	5	(1.2)	4	1	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Inguinal hernia	0		0	0	0	0	0		0	0	0	0	1	(0.5)	1	0	0	0
Intestinal spasm	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Lip blister	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Lip dry	0		0	0	0	0	0		0	0	0	0	1	(0.5)	0	1	0	0
Melaena	0		0	0	0	0	0		0	0	0	0	1	(0.5)	0	1	0	0
Mesenteric artery stenosis	0		0	0	0	0	0		0	0	0	0	1	(0.5)	0	1	0	0
Mouth ulceration	1	(0.2)	1	0	0	0	7	(1.6)	6	1	0	0	2	(1.0)	2	0	0	0
Nausea	75	(18.1)	51	18	6	0	73	(17.1)	49	20	3	1	39	(18.7)	24	14	1	0
Odynophagia	1	(0.2)	0	1	0	0	1	(0.2)	0	0	0	1	0		0	0	0	0
Oesophagitis	0		0	0	0	0	1	(0.2)	1	0	0	0	1	(0.5)	1	0	0	0
Oral pain	1	(0.2)	0	1	0	0	0		0	0	0	0	0		0	0	0	0
Oral soft tissue disorder	1	(0.2)	1	0	0	0	3	(0.7)	3	0	0	0	1	(0.5)	1	0	0	0
Painful defaecation	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Pancreatitis	1	(0.2)	1	0	0	0	1	(0.2)	0	1	0	0	2	(1.0)	0	1	0	1
Paraesthesia oral	5	(1.2)	5	0	0	0	3	(0.7)	3	0	0	0	1	(0.5)	1	0	0	0
Parotid duct cyst	0		0	0	0	0	0		0	0	0	0	1	(0.5)	1	0	0	0
Parotid duct obstruction	1	(0.2)	0	1	0	0	0		0	0	0	0	0		0	0	0	0
Parotid gland enlargement	1	(0.2)	0	1	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Perianal erythema	0		0	0	0	0	0		0	0	0	0	1	(0.5)	1	0	0	0
Proctalgia	2	(0.5)	2	0	0	0	2	(0.5)	1	1	0	0	1	(0.5)	0	1	0	0
Rectal haemorrhage	2	(0.5)	0	2	0	0	0		0	0	0	0	1	(0.5)	1	0	0	0

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Includes data up to 7 days after last dose of study drug.
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Number of Subjects evaluable for adverse events	maraviroc QD (n=414)						maraviroc BID (n=426)						Placebo (n=209)					
			Severity Grade*						Severity Grade*						Severity Grade*			
	N	(%)	1	2	3	4	N	(%)	1	2	3	4	N	(%)	1	2	3	4
System Organ Class and MedDRA (v9.0) preferred term																		
Rectal ulcer	1	(0.2)	0	0	0	1	1	(0.2)	0	0	1	0	0		0	0	0	0
Retching	0		0	0	0	0	1	(0.2)	1	0	0	0	1	(0.5)	0	1	0	0
Sensitivity of teeth	0		0	0	0	0	2	(0.5)	2	0	0	0	1	(0.5)	1	0	0	0
Small intestinal obstruction	0		0	0	0	0	1	(0.2)	0	0	1	0	0		0	0	0	0
Stomach discomfort	1	(0.2)	1	0	0	0	1	(0.2)	1	0	0	0	1	(0.5)	1	0	0	0
Tongue black hairy	0		0	0	0	0	0		0	0	0	0	1	(0.5)	1	0	0	0
Tongue coated	0		0	0	0	0	0		0	0	0	0	1	(0.5)	0	1	0	0
Tongue disorder	1	(0.2)	1	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Tongue ulceration	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Tooth disorder	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Toothache	1	(0.2)	0	1	0	0	4	(0.9)	1	3	0	0	3	(1.4)	0	3	0	0
Umbilical hernia	1	(0.2)	1	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Varices oesophageal	0		0	0	0	0	1	(0.2)	0	0	0	1	0		0	0	0	0
Vomiting	38	(9.2)	22	11	4	1	31	(7.3)	22	6	3	0	20	(9.6)	13	6	1	0
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	137	(33.1)	91	35	10	1	157	(36.9)	95	42	19	1	79	(37.8)	39	32	7	1
Adverse drug reaction	2	(0.5)	0	1	1	0	0		0	0	0	0	0		0	0	0	0
Asthenia	16	(3.9)	11	3	2	0	11	(2.6)	4	4	3	0	5	(2.4)	1	3	0	1
Axillary pain	1	(0.2)	1	0	0	0	0		0	0	0	0	0		0	0	0	0
Catheter related complication	0		0	0	0	0	0		0	0	0	0	1	(0.5)	1	0	0	0
Chest discomfort	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Chest pain	8	(1.9)	2	2	4	0	6	(1.4)	2	3	1	0	2	(1.0)	0	0	2	0
Chills	5	(1.2)	5	0	0	0	5	(1.2)	4	0	1	0	3	(1.4)	2	1	0	0
Condition aggravated	1	(0.2)	1	0	0	0	0		0	0	0	0	0		0	0	0	0

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MedDRA (v9.0) coding dictionary applied.

Number of Subjects evaluable for adverse events	maraviroc QD (n=414)						maraviroc BID (n=426)						Placebo (n=209)					
			Severity Grade*						Severity Grade*						Severity Grade*			
	N	(%)	1	2	3	4	N	(%)	1	2	3	4	N	(%)	1	2	3	4
System Organ Class and MedDRA (v9.0) preferred term																		
Cyst	1	(0.2)	1	0	0	0	0		0	0	0	0	0		0	0	0	0
Drug intolerance	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Fat tissue increased	4	(1.0)	2	2	0	0	4	(0.9)	3	1	0	0	0		0	0	0	0
Fatigue	45	(10.9)	32	10	3	0	54	(12.7)	35	15	4	0	31	(14.8)	17	13	1	0
Feeling abnormal	1	(0.2)	1	0	0	0	1	(0.2)	1	0	0	0	1	(0.5)	1	0	0	0
Feeling cold	0		0	0	0	0	1	(0.2)	0	1	0	0	0		0	0	0	0
Feeling drunk	0		0	0	0	0	1	(0.2)	1	0	0	0	1	(0.5)	1	0	0	0
Feeling hot	0		0	0	0	0	3	(0.7)	3	0	0	0	1	(0.5)	1	0	0	0
Gait disturbance	1	(0.2)	1	0	0	0	0		0	0	0	0	0		0	0	0	0
General physical health deterioration	0		0	0	0	0	1	(0.2)	0	1	0	0	0		0	0	0	0
Generalised oedema	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Hernia pain	1	(0.2)	1	0	0	0	0		0	0	0	0	0		0	0	0	0
Hunger	1	(0.2)	1	0	0	0	0		0	0	0	0	0		0	0	0	0
Hyperthermia	0		0	0	0	0	1	(0.2)	0	1	0	0	0		0	0	0	0
Hypothermia	0		0	0	0	0	1	(0.2)	1	0	0	0	1	(0.5)	0	0	1	0
Impaired healing	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Induration	3	(0.7)	2	1	0	0	1	(0.2)	0	1	0	0	2	(1.0)	1	1	0	0
Inflammation	1	(0.2)	1	0	0	0	2	(0.5)	1	1	0	0	0		0	0	0	0
Influenza like illness	4	(1.0)	3	1	0	0	1	(0.2)	1	0	0	0	1	(0.5)	1	0	0	0
Infusion site reaction	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Injection site erythema	2	(0.5)	1	1	0	0	3	(0.7)	1	2	0	0	0		0	0	0	0
Injection site haemorrhage	1	(0.2)	0	1	0	0	0		0	0	0	0	0		0	0	0	0
Injection site induration	1	(0.2)	1	0	0	0	6	(1.4)	4	2	0	0	0		0	0	0	0
Injection site inflammation	0		0	0	0	0	0		0	0	0	0	1	(0.5)	0	0	1	0
Injection site mass	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Injection site nodule	4	(1.0)	4	0	0	0	2	(0.5)	2	0	0	0	1	(0.5)	0	1	0	0

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MedDRA (v9.0) coding dictionary applied.

Number of Subjects evaluable for adverse events	maraviroc QD (n=414)						maraviroc BID (n=426)						Placebo (n=209)					
			Severity Grade*						Severity Grade*						Severity Grade*			
	N	(%)	1	2	3	4	N	(%)	1	2	3	4	N	(%)	1	2	3	4
System Organ Class and MedDRA (v9.0) preferred term																		
Injection site pain	1	(0.2)	1	0	0	0	4	(0.9)	2	1	1	0	2	(1.0)	1	1	0	0
Injection site pruritus	0		0	0	0	0	0		0	0	0	0	1	(0.5)	0	1	0	0
Injection site reaction	28	(6.8)	18	9	1	0	31	(7.3)	25	5	1	0	18	(8.6)	11	7	0	0
Injection site swelling	1	(0.2)	0	1	0	0	1	(0.2)	0	1	0	0	0		0	0	0	0
Injection site urticaria	0		0	0	0	0	2	(0.5)	2	0	0	0	0		0	0	0	0
Irritability	2	(0.5)	1	1	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Local swelling	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Malaise	6	(1.4)	4	2	0	0	3	(0.7)	1	1	1	0	6	(2.9)	3	2	1	0
Nodule	2	(0.5)	2	0	0	0	1	(0.2)	1	0	0	0	1	(0.5)	1	0	0	0
Oedema	0		0	0	0	0	0		0	0	0	0	1	(0.5)	1	0	0	0
Oedema peripheral	14	(3.4)	13	1	0	0	9	(2.1)	4	4	1	0	6	(2.9)	3	3	0	0
Pain	5	(1.2)	4	1	0	0	9	(2.1)	6	3	0	0	4	(1.9)	2	2	0	0
Pitting oedema	1	(0.2)	1	0	0	0	0		0	0	0	0	0		0	0	0	0
Pyrexia	30	(7.2)	23	6	0	1	51	(12.0)	29	13	8	1	17	(8.1)	8	7	2	0
Thirst	0		0	0	0	0	2	(0.5)	1	1	0	0	0		0	0	0	0
Upper extremity mass	1	(0.2)	1	0	0	0	0		0	0	0	0	0		0	0	0	0
HEPATOBILIARY DISORDERS	9	(2.2)	4	2	0	3	17	(4.0)	6	2	7	2	7	(3.3)	2	0	3	2
Cholecystitis	0		0	0	0	0	1	(0.2)	0	0	1	0	0		0	0	0	0
Cholecystitis acute	0		0	0	0	0	1	(0.2)	0	0	1	0	0		0	0	0	0
Cholelithiasis	1	(0.2)	0	1	0	0	3	(0.7)	1	2	0	0	1	(0.5)	0	0	1	0
Cytolytic hepatitis	0		0	0	0	0	0		0	0	0	0	1	(0.5)	0	0	1	0
Hepatic cirrhosis	0		0	0	0	0	2	(0.5)	0	0	1	1	0		0	0	0	0
Hepatic failure	1	(0.2)	0	0	0	1	0		0	0	0	0	0		0	0	0	0
Hepatitis toxic	0		0	0	0	0	0		0	0	0	0	1	(0.5)	0	0	0	1

* If the same subject in a given treatment had more than one occurrence in the same preferred term event category, only the most severe occurrence is taken. Subjects are counted only once per treatment in each row. For the TESS algorithm any missing severities have been imputed as grade 4 unless the subject experienced another occurrence of the same event in a given treatment for which severity was recorded.
In this case, the reported severity is summarized. Missing baseline severities are imputed as grade 1.
Includes data up to 7 days after last dose of study drug.
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Number of Subjects evaluable for adverse events	maraviroc QD (n=414)						maraviroc BID (n=426)						Placebo (n=209)					
			Severity Grade*						Severity Grade*						Severity Grade*			
	N	(%)	1	2	3	4	N	(%)	1	2	3	4	N	(%)	1	2	3	4
System Organ Class and MedDRA (v9.0) preferred term																		
Hepatomegaly	2	(0.5)	1	1	0	0	1	(0.2)	1	0	0	0	1	(0.5)	0	0	1	0
Hepatosplenomegaly	0		0	0	0	0	2	(0.5)	2	0	0	0	0		0	0	0	0
Hyperbilirubinaemia	2	(0.5)	0	0	0	2	4	(0.9)	0	0	4	0	2	(1.0)	1	0	0	1
Jaundice	5	(1.2)	5	0	0	0	2	(0.5)	2	0	0	0	1	(0.5)	1	0	0	0
Jaundice cholestatic	0		0	0	0	0	1	(0.2)	0	0	0	1	0		0	0	0	0
Portal vein thrombosis	0		0	0	0	0	1	(0.2)	0	0	0	1	0		0	0	0	0
IMMUNE SYSTEM DISORDERS	14	(3.4)	9	3	2	0	9	(2.1)	4	1	4	0	7	(3.3)	4	2	1	0
Allergy to arthropod bite	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Antiphospholipid syndrome	1	(0.2)	0	1	0	0	0		0	0	0	0	0		0	0	0	0
Drug hypersensitivity	2	(0.5)	0	1	1	0	2	(0.5)	0	0	2	0	1	(0.5)	0	0	1	0
Food allergy	1	(0.2)	1	0	0	0	0		0	0	0	0	1	(0.5)	1	0	0	0
Hypersensitivity	1	(0.2)	0	0	1	0	1	(0.2)	0	0	1	0	0		0	0	0	0
Immune reconstitution syndrome	0		0	0	0	0	2	(0.5)	1	0	1	0	0		0	0	0	0
Multiple allergies	1	(0.2)	1	0	0	0	0		0	0	0	0	0		0	0	0	0
Seasonal allergy	8	(1.9)	7	1	0	0	3	(0.7)	2	1	0	0	5	(2.4)	3	2	0	0
INFECTIONS AND INFESTATIONS	198	(47.8)	94	81	13	10	214	(50.2)	99	92	15	8	80	(38.3)	33	35	7	5
AIDS encephalopathy	1	(0.2)	0	1	0	0	0		0	0	0	0	0		0	0	0	0
Abscess	2	(0.5)	1	1	0	0	0		0	0	0	0	0		0	0	0	0
Abscess of eyelid	0		0	0	0	0	1	(0.2)	0	1	0	0	0		0	0	0	0
Acarodermatitis	0		0	0	0	0	1	(0.2)	0	1	0	0	0		0	0	0	0
Acute sinusitis	1	(0.2)	0	1	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Acute tonsillitis	1	(0.2)	1	0	0	0	0		0	0	0	0	0		0	0	0	0

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In this case, the reported severity is summarized. Missing baseline severities are imputed as grade 1.
Includes data up to 7 days after last dose of study drug.
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Number of Subjects evaluable for adverse events	maraviroc QD (n=414)						maraviroc BID (n=426)						Placebo (n=209)					
			Severity Grade*						Severity Grade*						Severity Grade*			
	N	(%)	1	2	3	4	N	(%)	1	2	3	4	N	(%)	1	2	3	4
System Organ Class and MedDRA (v9.0) preferred term																		
Amoebic colitis	0		0	0	0	0	1	(0.2)	0	1	0	0	1	(0.5)	1	0	0	0
Anal chlamydia infection	0		0	0	0	0	1	(0.2)	0	1	0	0	0		0	0	0	0
Anal fistula infection	0		0	0	0	0	0		0	0	0	0	1	(0.5)	0	0	1	0
Appendicitis	0		0	0	0	0	1	(0.2)	0	0	1	0	0		0	0	0	0
Aspergillosis	1	(0.2)	0	0	0	1	1	(0.2)	0	1	0	0	0		0	0	0	0
Bacteraemia	0		0	0	0	0	1	(0.2)	0	1	0	0	0		0	0	0	0
Balanitis candida	1	(0.2)	1	0	0	0	0		0	0	0	0	0		0	0	0	0
Blister infected	2	(0.5)	2	0	0	0	0		0	0	0	0	0		0	0	0	0
Body tinea	2	(0.5)	2	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Bronchitis	23	(5.6)	13	10	0	0	23	(5.4)	14	9	0	0	8	(3.8)	4	4	0	0
Bronchitis acute	2	(0.5)	2	0	0	0	2	(0.5)	1	1	0	0	1	(0.5)	1	0	0	0
Bronchitis bacterial	1	(0.2)	1	0	0	0	0		0	0	0	0	0		0	0	0	0
Bronchopneumonia	0		0	0	0	0	0		0	0	0	0	1	(0.5)	1	0	0	0
Campylobacter infection	1	(0.2)	0	0	1	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Candidiasis	4	(1.0)	3	1	0	0	5	(1.2)	3	2	0	0	1	(0.5)	1	0	0	0
Carbuncle	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Cavernous sinus thrombosis	1	(0.2)	0	0	0	1	0		0	0	0	0	0		0	0	0	0
Cellulitis	7	(1.7)	2	4	0	1	5	(1.2)	2	1	2	0	2	(1.0)	0	2	0	0
Cellulitis orbital	1	(0.2)	0	1	0	0	0		0	0	0	0	0		0	0	0	0
Cervicitis	1	(0.2)	1	0	0	0	0		0	0	0	0	0		0	0	0	0
Clostridial infection	0		0	0	0	0	0		0	0	0	0	1	(0.5)	0	1	0	0
Clostridium difficile colitis	1	(0.2)	0	0	1	0	0		0	0	0	0	0		0	0	0	0
Condyloma acuminatum	6	(1.4)	4	1	0	1	9	(2.1)	5	4	0	0	2	(1.0)	2	0	0	0
Cystitis	1	(0.2)	0	1	0	0	2	(0.5)	1	1	0	0	0		0	0	0	0
Cytomegalovirus chorioretinitis	2	(0.5)	0	1	1	0	0		0	0	0	0	0		0	0	0	0
Cytomegalovirus gastrointestinal infection	0		0	0	0	0	1	(0.2)	0	1	0	0	0		0	0	0	0

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In this case, the reported severity is summarized. Missing baseline severities are imputed as grade 1.
Includes data up to 7 days after last dose of study drug.
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Number of Subjects evaluable for adverse events	maraviroc QD (n=414)						maraviroc BID (n=426)						Placebo (n=209)					
			Severity Grade*						Severity Grade*						Severity Grade*			
	N	(%)	1	2	3	4	N	(%)	1	2	3	4	N	(%)	1	2	3	4
System Organ Class and MedDRA (v9.0) preferred term																		
Cytomegalovirus infection	0		0	0	0	0	1	(0.2)	0	1	0	0	0		0	0	0	0
Diverticulitis	0		0	0	0	0	0		0	0	0	0	1	(0.5)	0	0	1	0
Ear infection	2	(0.5)	2	0	0	0	6	(1.4)	1	4	1	0	1	(0.5)	1	0	0	0
Endocarditis	0		0	0	0	0	1	(0.2)	0	0	0	1	0		0	0	0	0
Erysipelas	1	(0.2)	0	1	0	0	0		0	0	0	0	0		0	0	0	0
Eye infection	2	(0.5)	2	0	0	0	1	(0.2)	0	1	0	0	0		0	0	0	0
Eyelid infection	0		0	0	0	0	2	(0.5)	0	2	0	0	0		0	0	0	0
Folliculitis	7	(1.7)	4	3	0	0	14	(3.3)	8	6	0	0	4	(1.9)	3	1	0	0
Fungal infection	2	(0.5)	1	1	0	0	1	(0.2)	0	0	0	1	0		0	0	0	0
Fungal rash	1	(0.2)	1	0	0	0	0		0	0	0	0	0		0	0	0	0
Fungal skin infection	1	(0.2)	1	0	0	0	4	(0.9)	3	1	0	0	0		0	0	0	0
Furuncle	1	(0.2)	1	0	0	0	0		0	0	0	0	1	(0.5)	1	0	0	0
Gangrene	1	(0.2)	0	1	0	0	0		0	0	0	0	0		0	0	0	0
Gastric infection	1	(0.2)	0	1	0	0	0		0	0	0	0	0		0	0	0	0
Gastritis viral	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Gastroenteritis	6	(1.4)	1	3	2	0	2	(0.5)	0	2	0	0	2	(1.0)	0	1	1	0
Gastroenteritis bacterial	1	(0.2)	0	1	0	0	0		0	0	0	0	0		0	0	0	0
Gastroenteritis cryptosporidial	0		0	0	0	0	0		0	0	0	0	1	(0.5)	0	0	1	0
Gastroenteritis viral	3	(0.7)	3	0	0	0	2	(0.5)	1	0	1	0	0		0	0	0	0
Gastrointestinal infection	1	(0.2)	1	0	0	0	1	(0.2)	0	1	0	0	1	(0.5)	0	1	0	0
Genitourinary chlamydia infection	0		0	0	0	0	0		0	0	0	0	1	(0.5)	0	1	0	0
Genitourinary tract infection	0		0	0	0	0	1	(0.2)	0	0	0	1	0		0	0	0	0
Giardiasis	1	(0.2)	0	1	0	0	1	(0.2)	0	1	0	0	0		0	0	0	0
Gonorrhoea	1	(0.2)	0	1	0	0	0		0	0	0	0	0		0	0	0	0
Groin abscess	0		0	0	0	0	0		0	0	0	0	1	(0.5)	0	1	0	0
HIV wasting syndrome	1	(0.2)	0	1	0	0	0		0	0	0	0	0		0	0	0	0

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MedDRA (v9.0) coding dictionary applied.

Maraviroc Summary of Clinical Safety
Incidence and Severity of Treatment-Emergent Adverse Events (All Causalities)
Phase 3 Treatment Experienced CCR5 Tropic Studies

Number of Subjects evaluable for adverse events	maraviroc QD (n=414)						maraviroc BID (n=426)						Placebo (n=209)					
			Severity Grade*						Severity Grade*						Severity Grade*			
	N	(%)	1	2	3	4	N	(%)	1	2	3	4	N	(%)	1	2	3	4
System Organ Class and MedDRA (v9.0) preferred term																		
Helicobacter gastritis	1	(0.2)	0	1	0	0	0		0	0	0	0	0		0	0	0	0
Hepatitis C	2	(0.5)	1	1	0	0	0		0	0	0	0	0		0	0	0	0
Herpes simplex	14	(3.4)	7	5	2	0	26	(6.1)	17	9	0	0	6	(2.9)	2	4	0	0
Herpes virus infection	4	(1.0)	4	0	0	0	2	(0.5)	0	1	1	0	2	(1.0)	2	0	0	0
Herpes zoster	6	(1.4)	2	4	0	0	7	(1.6)	2	5	0	0	3	(1.4)	0	2	1	0
Hordeolum	2	(0.5)	2	0	0	0	0		0	0	0	0	0		0	0	0	0
Incision site infection	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Infected sebaceous cyst	0		0	0	0	0	0		0	0	0	0	1	(0.5)	1	0	0	0
Infected skin ulcer	0		0	0	0	0	0		0	0	0	0	1	(0.5)	0	1	0	0
Infective myositis	0		0	0	0	0	1	(0.2)	0	0	0	1	0		0	0	0	0
Influenza	14	(3.4)	8	6	0	0	6	(1.4)	4	2	0	0	0		0	0	0	0
Injection site abscess	2	(0.5)	0	2	0	0	0		0	0	0	0	0		0	0	0	0
Injection site infection	1	(0.2)	1	0	0	0	0		0	0	0	0	0		0	0	0	0
Klebsiella sepsis	1	(0.2)	0	0	0	1	0		0	0	0	0	0		0	0	0	0
Laryngitis	0		0	0	0	0	1	(0.2)	0	1	0	0	0		0	0	0	0
Laryngopharyngitis	1	(0.2)	0	1	0	0	0		0	0	0	0	1	(0.5)	1	0	0	0
Lobar pneumonia	1	(0.2)	1	0	0	0	1	(0.2)	0	1	0	0	2	(1.0)	0	0	1	1
Localised infection	2	(0.5)	1	1	0	0	2	(0.5)	0	2	0	0	1	(0.5)	1	0	0	0
Lower respiratory tract infection	4	(1.0)	2	2	0	0	2	(0.5)	1	1	0	0	1	(0.5)	0	1	0	0
Lymph gland infection	0		0	0	0	0	1	(0.2)	0	1	0	0	0		0	0	0	0
Lymphangitis	2	(0.5)	1	0	1	0	0		0	0	0	0	0		0	0	0	0
Malaria	1	(0.2)	0	1	0	0	0		0	0	0	0	0		0	0	0	0
Mastitis	0		0	0	0	0	1	(0.2)	0	1	0	0	0		0	0	0	0
Meningitis viral	0		0	0	0	0	2	(0.5)	0	1	0	1	0		0	0	0	0
Molluscum contagiosum	2	(0.5)	2	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Mycobacterial infection	0		0	0	0	0	1	(0.2)	0	0	1	0	0		0	0	0	0

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Includes data up to 7 days after last dose of study drug.
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Number of Subjects evaluable for adverse events	maraviroc QD (n=414)						maraviroc BID (n=426)						Placebo (n=209)					
			Severity Grade*						Severity Grade*						Severity Grade*			
	N	(%)	1	2	3	4	N	(%)	1	2	3	4	N	(%)	1	2	3	4
System Organ Class and MedDRA (v9.0) preferred term																		
Mycobacterium avium complex infection	0		0	0	0	0	2	(0.5)	0	1	0	1	3	(1.4)	1	1	0	1
Mycoplasma infection	0		0	0	0	0	1	(0.2)	0	0	1	0	0		0	0	0	0
Nail candida	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Nasopharyngitis	30	(7.2)	25	5	0	0	30	(7.0)	20	10	0	0	9	(4.3)	6	3	0	0
Neurosyphilis	0		0	0	0	0	1	(0.2)	0	1	0	0	0		0	0	0	0
Oesophageal candidiasis	12	(2.9)	1	8	1	2	2	(0.5)	1	0	0	1	2	(1.0)	0	1	1	0
Onychomycosis	4	(1.0)	2	2	0	0	6	(1.4)	3	3	0	0	1	(0.5)	0	1	0	0
Oral candidiasis	13	(3.1)	6	6	1	0	10	(2.3)	6	4	0	0	7	(3.3)	3	4	0	0
Oral fungal infection	1	(0.2)	0	1	0	0	0		0	0	0	0	1	(0.5)	1	0	0	0
Oral hairy leukoplakia	1	(0.2)	1	0	0	0	0		0	0	0	0	0		0	0	0	0
Oral infection	1	(0.2)	0	1	0	0	0		0	0	0	0	0		0	0	0	0
Oropharyngeal candidiasis	2	(0.5)	2	0	0	0	0		0	0	0	0	1	(0.5)	0	1	0	0
Osteomyelitis	1	(0.2)	0	1	0	0	0		0	0	0	0	0		0	0	0	0
Otitis externa	0		0	0	0	0	2	(0.5)	2	0	0	0	2	(1.0)	1	1	0	0
Otitis media	1	(0.2)	0	1	0	0	6	(1.4)	5	1	0	0	1	(0.5)	1	0	0	0
Papilloma viral infection	0		0	0	0	0	3	(0.7)	3	0	0	0	2	(1.0)	2	0	0	0
Paronychia	0		0	0	0	0	1	(0.2)	0	1	0	0	1	(0.5)	1	0	0	0
Parotitis	0		0	0	0	0	1	(0.2)	0	1	0	0	0		0	0	0	0
Perianal abscess	1	(0.2)	0	1	0	0	0		0	0	0	0	0		0	0	0	0
Perirectal abscess	0		0	0	0	0	1	(0.2)	0	1	0	0	0		0	0	0	0
Pharyngeal candidiasis	1	(0.2)	1	0	0	0	0		0	0	0	0	0		0	0	0	0
Pharyngitis	4	(1.0)	2	1	1	0	6	(1.4)	3	3	0	0	2	(1.0)	1	1	0	0
Pneumococcal sepsis	0		0	0	0	0	1	(0.2)	0	0	1	0	0		0	0	0	0
Pneumocystis jiroveci pneumonia	0		0	0	0	0	2	(0.5)	0	1	0	1	0		0	0	0	0
Pneumonia	11	(2.7)	0	6	3	2	6	(1.4)	2	2	0	2	7	(3.3)	2	2	1	2
Pneumonia bacterial	1	(0.2)	0	0	0	1	2	(0.5)	1	1	0	0	1	(0.5)	0	0	0	1

* If the same subject in a given treatment had more than one occurrence in the same preferred term event category, only the most severe occurrence is taken. Subjects are counted only once per treatment in each row. For the TESS algorithm any missing severities have been imputed as grade 4 unless the subject experienced another occurrence of the same event in a given treatment for which severity was recorded.
In this case, the reported severity is summarized. Missing baseline severities are imputed as grade 1.
Includes data up to 7 days after last dose of study drug.
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Number of Subjects evaluable for adverse events	maraviroc QD (n=414)						maraviroc BID (n=426)						Placebo (n=209)					
			Severity Grade*						Severity Grade*						Severity Grade*			
	N	(%)	1	2	3	4	N	(%)	1	2	3	4	N	(%)	1	2	3	4
System Organ Class and MedDRA (v9.0) preferred term																		
Postoperative wound infection	0		0	0	0	0	2	(0.5)	1	1	0	0	0		0	0	0	0
Proctitis herpes	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Progressive multifocal leukoencephalopathy	0		0	0	0	0	1	(0.2)	0	0	1	0	0		0	0	0	0
Pyelonephritis	3	(0.7)	1	2	0	0	1	(0.2)	0	0	1	0	1	(0.5)	1	0	0	0
Pyothorax	0		0	0	0	0	0		0	0	0	0	1	(0.5)	0	0	1	0
Rash pustular	1	(0.2)	0	1	0	0	1	(0.2)	1	0	0	0	1	(0.5)	0	1	0	0
Rectal abscess	0		0	0	0	0	1	(0.2)	0	0	1	0	0		0	0	0	0
Respiratory tract infection	4	(1.0)	3	1	0	0	3	(0.7)	2	1	0	0	2	(1.0)	1	0	0	1
Rhinitis	9	(2.2)	7	2	0	0	4	(0.9)	3	1	0	0	2	(1.0)	1	0	1	0
Secondary syphilis	0		0	0	0	0	1	(0.2)	0	0	1	0	0		0	0	0	0
Sepsis	0		0	0	0	0	0		0	0	0	0	1	(0.5)	0	0	0	1
Septic shock	1	(0.2)	0	0	0	1	0		0	0	0	0	0		0	0	0	0
Shigella infection	0		0	0	0	0	0		0	0	0	0	1	(0.5)	0	1	0	0
Sinobronchitis	0		0	0	0	0	1	(0.2)	0	1	0	0	0		0	0	0	0
Sinusitis	15	(3.6)	7	6	1	1	25	(5.9)	11	14	0	0	7	(3.3)	4	3	0	0
Skin infection	0		0	0	0	0	1	(0.2)	0	0	1	0	0		0	0	0	0
Staphylococcal abscess	1	(0.2)	1	0	0	0	0		0	0	0	0	0		0	0	0	0
Staphylococcal infection	4	(1.0)	3	1	0	0	3	(0.7)	0	3	0	0	1	(0.5)	0	1	0	0
Subcutaneous abscess	3	(0.7)	0	3	0	0	2	(0.5)	1	1	0	0	2	(1.0)	1	1	0	0
Syphilis	2	(0.5)	1	1	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Tinea cruris	4	(1.0)	2	2	0	0	2	(0.5)	2	0	0	0	1	(0.5)	0	1	0	0
Tinea pedis	4	(1.0)	4	0	0	0	2	(0.5)	0	2	0	0	1	(0.5)	1	0	0	0
Tonsillitis	1	(0.2)	1	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Tooth abscess	2	(0.5)	1	0	1	0	0		0	0	0	0	2	(1.0)	0	2	0	0
Tooth infection	2	(0.5)	1	1	0	0	0		0	0	0	0	2	(1.0)	0	2	0	0
Upper respiratory tract infection	38	(9.2)	24	14	0	0	44	(10.3)	26	17	1	0	11	(5.3)	9	2	0	0

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In this case, the reported severity is summarized. Missing baseline severities are imputed as grade 1.
Includes data up to 7 days after last dose of study drug.
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Number of Subjects evaluable for adverse events	maraviroc QD (n=414)						maraviroc BID (n=426)						Placebo (n=209)					
			Severity Grade*						Severity Grade*						Severity Grade*			
	N	(%)	1	2	3	4	N	(%)	1	2	3	4	N	(%)	1	2	3	4
System Organ Class and MedDRA (v9.0) preferred term																		
Urethritis	0		0	0	0	0	1	(0.2)	0	1	0	0	1	(0.5)	0	1	0	0
Urethritis gonococcal	1	(0.2)	1	0	0	0	0		0	0	0	0	0		0	0	0	0
Urinary tract infection	6	(1.4)	2	3	1	0	3	(0.7)	2	1	0	0	2	(1.0)	2	0	0	0
Vaginal candidiasis	2	(0.5)	2	0	0	0	0		0	0	0	0	0		0	0	0	0
Vaginitis bacterial	1	(0.2)	0	1	0	0	0		0	0	0	0	0		0	0	0	0
Viral infection	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Viral upper respiratory tract infection	2	(0.5)	2	0	0	0	3	(0.7)	3	0	0	0	1	(0.5)	0	1	0	0
Vulvitis	1	(0.2)	0	1	0	0	0		0	0	0	0	0		0	0	0	0
Vulvovaginal mycotic infection	0		0	0	0	0	0		0	0	0	0	1	(0.5)	0	1	0	0
Wound infection	1	(0.2)	1	0	0	0	0		0	0	0	0	0		0	0	0	0
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	34	(8.2)	16	17	1	0	32	(7.5)	19	8	5	0	12	(5.7)	6	5	1	0
Animal bite	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Ankle fracture	1	(0.2)	0	1	0	0	0		0	0	0	0	0		0	0	0	0
Arthropod bite	0		0	0	0	0	1	(0.2)	1	0	0	0	1	(0.5)	1	0	0	0
Back injury	0		0	0	0	0	2	(0.5)	0	2	0	0	1	(0.5)	1	0	0	0
Bite	1	(0.2)	0	1	0	0	0		0	0	0	0	0		0	0	0	0
Burns first degree	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Burns second degree	1	(0.2)	0	1	0	0	0		0	0	0	0	0		0	0	0	0
Contusion	5	(1.2)	4	1	0	0	1	(0.2)	1	0	0	0	1	(0.5)	0	1	0	0
Corneal abrasion	1	(0.2)	0	1	0	0	0		0	0	0	0	0		0	0	0	0
Ear injury	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Epicondylitis	2	(0.5)	2	0	0	0	1	(0.2)	0	1	0	0	1	(0.5)	1	0	0	0
Excoriation	1	(0.2)	0	1	0	0	0		0	0	0	0	1	(0.5)	0	1	0	0
Facial bones fracture	1	(0.2)	0	0	1	0	0		0	0	0	0	0		0	0	0	0

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In this case, the reported severity is summarized. Missing baseline severities are imputed as grade 1.
Includes data up to 7 days after last dose of study drug.
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Table 3.4.3.3
Maraviroc Summary of Clinical Safety
Incidence and Severity of Treatment-Emergent Adverse Events (All Causalities)
Phase 3 Treatment Experienced CCR5 Tropic Studies

Number of Subjects evaluable for adverse events	maraviroc QD (n=414)						maraviroc BID (n=426)						Placebo (n=209)					
			Severity Grade*						Severity Grade*						Severity Grade*			
	N	(%)	1	2	3	4	N	(%)	1	2	3	4	N	(%)	1	2	3	4
System Organ Class and MedDRA (v9.0) preferred term																		
Fall	2	(0.5)	0	2	0	0	3	(0.7)	2	0	1	0	1	(0.5)	0	1	0	0
Foot fracture	2	(0.5)	0	2	0	0	3	(0.7)	1	1	1	0	0		0	0	0	0
Hand fracture	0		0	0	0	0	2	(0.5)	2	0	0	0	0		0	0	0	0
Heat exhaustion	0		0	0	0	0	1	(0.2)	0	0	1	0	0		0	0	0	0
Heat stroke	1	(0.2)	1	0	0	0	0		0	0	0	0	0		0	0	0	0
Injury corneal	0		0	0	0	0	0		0	0	0	0	1	(0.5)	0	1	0	0
Joint injury	2	(0.5)	1	1	0	0	0		0	0	0	0	0		0	0	0	0
Joint sprain	3	(0.7)	2	1	0	0	2	(0.5)	2	0	0	0	0		0	0	0	0
Laceration	1	(0.2)	0	1	0	0	0		0	0	0	0	0		0	0	0	0
Muscle injury	0		0	0	0	0	2	(0.5)	2	0	0	0	0		0	0	0	0
Muscle strain	2	(0.5)	1	1	0	0	0		0	0	0	0	1	(0.5)	1	0	0	0
Neck injury	0		0	0	0	0	1	(0.2)	0	1	0	0	0		0	0	0	0
Open wound	1	(0.2)	1	0	0	0	0		0	0	0	0	0		0	0	0	0
Overdose	0		0	0	0	0	0		0	0	0	0	1	(0.5)	0	0	1	0
Post procedural complication	1	(0.2)	0	1	0	0	0		0	0	0	0	0		0	0	0	0
Post-traumatic pain	1	(0.2)	1	0	0	0	0		0	0	0	0	0		0	0	0	0
Procedural pain	1	(0.2)	1	0	0	0	1	(0.2)	0	0	1	0	1	(0.5)	1	0	0	0
Radiation skin injury	1	(0.2)	0	1	0	0	0		0	0	0	0	0		0	0	0	0
Rib fracture	1	(0.2)	1	0	0	0	5	(1.2)	1	3	1	0	0		0	0	0	0
Skeletal injury	1	(0.2)	1	0	0	0	0		0	0	0	0	0		0	0	0	0
Skin laceration	2	(0.5)	1	0	1	0	3	(0.7)	3	0	0	0	1	(0.5)	0	1	0	0
Spinal fracture	0		0	0	0	0	0		0	0	0	0	1	(0.5)	1	0	0	0
Sternal fracture	0		0	0	0	0	1	(0.2)	0	0	1	0	0		0	0	0	0
Stress fracture	0		0	0	0	0	2	(0.5)	1	1	0	0	0		0	0	0	0
Sunburn	0		0	0	0	0	1	(0.2)	1	0	0	0	1	(0.5)	1	0	0	0
Tendon rupture	0		0	0	0	0	0		0	0	0	0	1	(0.5)	0	1	0	0

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In this case, the reported severity is summarized. Missing baseline severities are imputed as grade 1.
Includes data up to 7 days after last dose of study drug.
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Maraviroc Summary of Clinical Safety
Incidence and Severity of Treatment-Emergent Adverse Events (All Causalities)
Phase 3 Treatment Experienced CCR5 Tropic Studies

Number of Subjects evaluable for adverse events	maraviroc QD (n=414)						maraviroc BID (n=426)						Placebo (n=209)					
			Severity Grade*						Severity Grade*						Severity Grade*			
	N	(%)	1	2	3	4	N	(%)	1	2	3	4	N	(%)	1	2	3	4
System Organ Class and MedDRA (v9.0) preferred term																		
Whiplash injury	1	(0.2)	0	1	0	0	0		0	0	0	0	0		0	0	0	0
Wound	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
INVESTIGATIONS	74	(17.9)	28	16	23	7	85	(20.0)	27	26	17	15	26	(12.4)	8	9	6	3
Alanine aminotransferase increased	7	(1.7)	0	1	5	1	10	(2.3)	1	3	3	3	1	(0.5)	0	1	0	0
Aspartate aminotransferase	0		0	0	0	0	1	(0.2)	0	0	0	1	0		0	0	0	0
Aspartate aminotransferase increased	7	(1.7)	0	1	6	0	15	(3.5)	2	2	6	5	1	(0.5)	0	0	1	0
Aspiration biopsy	0		0	0	0	0	1	(0.2)	0	1	0	0	0		0	0	0	0
Aspiration bursa	0		0	0	0	0	1	(0.2)	0	1	0	0	0		0	0	0	0
Blast cells present	1	(0.2)	1	0	0	0	0		0	0	0	0	0		0	0	0	0
Bleeding time prolonged	1	(0.2)	1	0	0	0	0		0	0	0	0	0		0	0	0	0
Blood alkaline phosphatase increased	2	(0.5)	1	0	1	0	0		0	0	0	0	0		0	0	0	0
Blood amylase	1	(0.2)	0	0	0	1	1	(0.2)	0	0	1	0	0		0	0	0	0
Blood amylase increased	4	(1.0)	1	1	2	0	2	(0.5)	0	0	1	1	2	(1.0)	1	0	1	0
Blood bilirubin	1	(0.2)	0	0	1	0	0		0	0	0	0	0		0	0	0	0
Blood bilirubin increased	8	(1.9)	1	4	2	1	4	(0.9)	1	1	2	0	1	(0.5)	0	0	1	0
Blood cholesterol increased	2	(0.5)	1	1	0	0	2	(0.5)	0	2	0	0	0		0	0	0	0
Blood creatine increased	1	(0.2)	0	1	0	0	1	(0.2)	0	1	0	0	1	(0.5)	0	1	0	0
Blood creatine phosphokinase increased	5	(1.2)	3	2	0	0	9	(2.1)	2	2	2	3	1	(0.5)	0	0	0	1
Blood creatinine increased	5	(1.2)	3	1	1	0	6	(1.4)	4	2	0	0	1	(0.5)	0	1	0	0
Blood glucose	1	(0.2)	0	0	1	0	0		0	0	0	0	0		0	0	0	0
Blood glucose increased	4	(1.0)	2	0	2	0	2	(0.5)	1	1	0	0	1	(0.5)	1	0	0	0
Blood iron decreased	0		0	0	0	0	1	(0.2)	0	1	0	0	0		0	0	0	0
Blood lactate dehydrogenase increased	0		0	0	0	0	3	(0.7)	1	1	0	1	1	(0.5)	1	0	0	0
Blood lactic acid increased	0		0	0	0	0	0		0	0	0	0	1	(0.5)	0	1	0	0

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Includes data up to 7 days after last dose of study drug.
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Number of Subjects evaluable for adverse events	maraviroc QD (n=414)						maraviroc BID (n=426)						Placebo (n=209)					
			Severity Grade*						Severity Grade*						Severity Grade*			
	N	(%)	1	2	3	4	N	(%)	1	2	3	4	N	(%)	1	2	3	4
System Organ Class and MedDRA (v9.0) preferred term																		
Blood potassium decreased	0		0	0	0	0	2	(0.5)	2	0	0	0	1	(0.5)	1	0	0	0
Blood potassium increased	0		0	0	0	0	1	(0.2)	0	1	0	0	0		0	0	0	0
Blood pressure diastolic increased	0		0	0	0	0	0		0	0	0	0	1	(0.5)	1	0	0	0
Blood pressure increased	3	(0.7)	2	0	1	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Blood sodium increased	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Blood testosterone decreased	1	(0.2)	0	1	0	0	0		0	0	0	0	0		0	0	0	0
Blood thyroid stimulating hormone increased	0		0	0	0	0	0		0	0	0	0	1	(0.5)	0	1	0	0
Blood triglycerides abnormal	1	(0.2)	0	0	0	1	0		0	0	0	0	0		0	0	0	0
Blood triglycerides increased	1	(0.2)	0	0	1	0	8	(1.9)	1	4	2	1	1	(0.5)	0	0	1	0
Blood urea increased	3	(0.7)	1	2	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Blood uric acid increased	0		0	0	0	0	2	(0.5)	1	1	0	0	2	(1.0)	1	1	0	0
Blood urine present	1	(0.2)	1	0	0	0	0		0	0	0	0	0		0	0	0	0
Body temperature increased	1	(0.2)	1	0	0	0	2	(0.5)	1	1	0	0	0		0	0	0	0
Breath sounds abnormal	0		0	0	0	0	0		0	0	0	0	1	(0.5)	0	1	0	0
Cardiac murmur	1	(0.2)	0	1	0	0	0		0	0	0	0	0		0	0	0	0
Crystal urine	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Cytomegalovirus antibody positive	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Electrocardiogram QT prolonged	0		0	0	0	0	1	(0.2)	0	1	0	0	0		0	0	0	0
Gamma-glutamyltransferase	0		0	0	0	0	2	(0.5)	0	0	2	0	0		0	0	0	0
Gamma-glutamyltransferase increased	6	(1.4)	1	0	1	4	6	(1.4)	0	2	2	2	3	(1.4)	0	0	2	1
Haematocrit decreased	1	(0.2)	1	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Haemoglobin decreased	2	(0.5)	2	0	0	0	1	(0.2)	0	0	1	0	1	(0.5)	0	1	0	0
Heart rate increased	0		0	0	0	0	2	(0.5)	2	0	0	0	0		0	0	0	0
Hepatic enzyme increased	0		0	0	0	0	3	(0.7)	1	1	1	0	0		0	0	0	0
International normalised ratio increased	1	(0.2)	0	0	1	0	0		0	0	0	0	0		0	0	0	0
Lipase	0		0	0	0	0	1	(0.2)	0	0	1	0	0		0	0	0	0

* If the same subject in a given treatment had more than one occurrence in the same preferred term event category, only the most severe occurrence is taken. Subjects are counted only once per treatment in each row. For the TESS algorithm any missing severities have been imputed as grade 4 unless the subject experienced another occurrence of the same event in a given treatment for which severity was recorded.
In this case, the reported severity is summarized. Missing baseline severities are imputed as grade 1.
Includes data up to 7 days after last dose of study drug.
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Table 3.4.3.3
Maraviroc Summary of Clinical Safety
Incidence and Severity of Treatment-Emergent Adverse Events (All Causalities)
Phase 3 Treatment Experienced CCR5 Tropic Studies

Number of Subjects evaluable for adverse events	maraviroc QD (n=414)						maraviroc BID (n=426)						Placebo (n=209)					
			Severity Grade*						Severity Grade*						Severity Grade*			
	N	(%)	1	2	3	4	N	(%)	1	2	3	4	N	(%)	1	2	3	4
System Organ Class and MedDRA (v9.0) preferred term																		
Lipase increased	3	(0.7)	0	0	2	1	2	(0.5)	0	0	1	1	1	(0.5)	0	1	0	0
Lipids increased	0		0	0	0	0	1	(0.2)	0	1	0	0	0		0	0	0	0
Liver function test abnormal	2	(0.5)	1	0	1	0	2	(0.5)	0	0	1	1	2	(1.0)	0	0	1	1
Neutrophil count decreased	1	(0.2)	0	0	1	0	2	(0.5)	1	0	0	1	0		0	0	0	0
Neutrophil count increased	1	(0.2)	0	0	1	0	1	(0.2)	0	0	0	1	0		0	0	0	0
Neutrophil hypersegmented morphology present	1	(0.2)	1	0	0	0	0		0	0	0	0	0		0	0	0	0
Platelet count decreased	0		0	0	0	0	1	(0.2)	0	1	0	0	2	(1.0)	0	1	1	0
Prostate examination abnormal	2	(0.5)	1	1	0	0	0		0	0	0	0	0		0	0	0	0
Prostatic specific antigen increased	1	(0.2)	0	1	0	0	0		0	0	0	0	0		0	0	0	0
Protein total increased	0		0	0	0	0	0		0	0	0	0	1	(0.5)	1	0	0	0
Protein urine	2	(0.5)	1	1	0	0	1	(0.2)	0	1	0	0	0		0	0	0	0
Syphilis test positive	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Thyroxine free decreased	0		0	0	0	0	0		0	0	0	0	2	(1.0)	1	1	0	0
Transaminases increased	2	(0.5)	0	1	1	0	1	(0.2)	0	0	0	1	0		0	0	0	0
Urine output decreased	1	(0.2)	0	1	0	0	0		0	0	0	0	0		0	0	0	0
Urine output increased	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Viral load increased	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Viral test	0		0	0	0	0	2	(0.5)	2	0	0	0	0		0	0	0	0
Weight decreased	17	(4.1)	13	4	0	0	13	(3.1)	7	6	0	0	4	(1.9)	3	1	0	0
Weight increased	4	(1.0)	4	0	0	0	3	(0.7)	2	1	0	0	0		0	0	0	0
White blood cell count decreased	0		0	0	0	0	1	(0.2)	0	0	1	0	1	(0.5)	1	0	0	0
METABOLISM AND NUTRITION DISORDERS	47	(11.4)	23	21	3	0	51	(12.0)	24	21	5	1	24	(11.5)	13	5	4	2
Alcohol intolerance	1	(0.2)	1	0	0	0	0		0	0	0	0	0		0	0	0	0
Anorexia	17	(4.1)	8	8	1	0	16	(3.8)	9	7	0	0	8	(3.8)	6	1	1	0

* If the same subject in a given treatment had more than one occurrence in the same preferred term event category, only the most severe occurrence is taken. Subjects are counted only once per treatment in each row. For the TESS algorithm any missing severities have been imputed as grade 4 unless the subject experienced another occurrence of the same event in a given treatment for which severity was recorded.
In this case, the reported severity is summarized. Missing baseline severities are imputed as grade 1.
Includes data up to 7 days after last dose of study drug.
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Number of Subjects evaluable for adverse events	maraviroc QD (n=414)						maraviroc BID (n=426)						Placebo (n=209)					
			Severity Grade*						Severity Grade*						Severity Grade*			
	N	(%)	1	2	3	4	N	(%)	1	2	3	4	N	(%)	1	2	3	4
System Organ Class and MedDRA (v9.0) preferred term																		
Cachexia	2	(0.5)	1	1	0	0	1	(0.2)	0	0	1	0	0		0	0	0	0
Decreased appetite	10	(2.4)	6	4	0	0	14	(3.3)	9	5	0	0	5	(2.4)	4	1	0	0
Dehydration	2	(0.5)	0	2	0	0	5	(1.2)	0	2	3	0	3	(1.4)	2	1	0	0
Diabetes mellitus	1	(0.2)	0	1	0	0	1	(0.2)	0	1	0	0	0		0	0	0	0
Diabetes mellitus inadequate control	0		0	0	0	0	0		0	0	0	0	1	(0.5)	0	0	1	0
Diabetes mellitus non-insulin-dependent	0		0	0	0	0	0		0	0	0	0	1	(0.5)	0	0	1	0
Fluid retention	1	(0.2)	1	0	0	0	0		0	0	0	0	0		0	0	0	0
Gout	2	(0.5)	1	1	0	0	3	(0.7)	2	0	0	1	2	(1.0)	1	1	0	0
Hyperamylasaemia	1	(0.2)	1	0	0	0	0		0	0	0	0	0		0	0	0	0
Hypercholesterolaemia	0		0	0	0	0	0		0	0	0	0	1	(0.5)	1	0	0	0
Hyperglycaemia	1	(0.2)	0	0	1	0	3	(0.7)	0	3	0	0	2	(1.0)	1	0	1	0
Hyperkalaemia	0		0	0	0	0	1	(0.2)	0	1	0	0	0		0	0	0	0
Hyperlipidaemia	1	(0.2)	1	0	0	0	1	(0.2)	0	1	0	0	2	(1.0)	0	0	0	2
Hypertriglyceridaemia	0		0	0	0	0	5	(1.2)	1	4	0	0	0		0	0	0	0
Hypervitaminosis	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Hypocalcaemia	0		0	0	0	0	1	(0.2)	0	0	1	0	1	(0.5)	0	1	0	0
Hypoglycaemia	2	(0.5)	1	1	0	0	0		0	0	0	0	0		0	0	0	0
Hypokalaemia	3	(0.7)	0	2	1	0	1	(0.2)	0	1	0	0	1	(0.5)	1	0	0	0
Hyponatraemia	0		0	0	0	0	1	(0.2)	0	0	1	0	0		0	0	0	0
Hypovolaemia	1	(0.2)	0	1	0	0	0		0	0	0	0	0		0	0	0	0
Increased appetite	2	(0.5)	2	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Insulin resistant diabetes	0		0	0	0	0	1	(0.2)	0	1	0	0	0		0	0	0	0
Iron deficiency	1	(0.2)	1	0	0	0	1	(0.2)	1	0	0	0	1	(0.5)	1	0	0	0
Lactic acidosis	0		0	0	0	0	0		0	0	0	0	1	(0.5)	0	0	1	0
Polydipsia	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Tetany	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0

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In this case, the reported severity is summarized. Missing baseline severities are imputed as grade 1.
Includes data up to 7 days after last dose of study drug.
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Number of Subjects evaluable for adverse events	maraviroc QD (n=414)						maraviroc BID (n=426)						Placebo (n=209)					
			Severity Grade*						Severity Grade*						Severity Grade*			
	N	(%)	1	2	3	4	N	(%)	1	2	3	4	N	(%)	1	2	3	4
System Organ Class and MedDRA (v9.0) preferred term																		
Vitamin B12 deficiency	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Vitamin D deficiency	0		0	0	0	0	0		0	0	0	0	1	(0.5)	0	1	0	0
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	93	(22.5)	63	24	6	0	82	(19.2)	50	26	3	3	38	(18.2)	22	15	1	0
Arthralgia	18	(4.3)	12	6	0	0	22	(5.2)	14	7	0	1	6	(2.9)	5	1	0	0
Arthritis	4	(1.0)	2	2	0	0	0		0	0	0	0	0		0	0	0	0
Arthropathy	1	(0.2)	1	0	0	0	0		0	0	0	0	0		0	0	0	0
Back pain	22	(5.3)	16	5	1	0	21	(4.9)	15	5	1	0	6	(2.9)	3	3	0	0
Bone pain	0		0	0	0	0	2	(0.5)	2	0	0	0	1	(0.5)	1	0	0	0
Bursitis	0		0	0	0	0	3	(0.7)	2	1	0	0	2	(1.0)	0	2	0	0
Costochondritis	0		0	0	0	0	0		0	0	0	0	1	(0.5)	0	1	0	0
Flank pain	4	(1.0)	2	2	0	0	2	(0.5)	1	0	0	1	0		0	0	0	0
Ganglion	1	(0.2)	1	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Gouty arthritis	0		0	0	0	0	1	(0.2)	0	1	0	0	0		0	0	0	0
Groin pain	0		0	0	0	0	1	(0.2)	0	1	0	0	0		0	0	0	0
Intervertebral disc degeneration	1	(0.2)	0	0	1	0	0		0	0	0	0	0		0	0	0	0
Joint swelling	3	(0.7)	3	0	0	0	4	(0.9)	1	3	0	0	0		0	0	0	0
Monarthritis	2	(0.5)	2	0	0	0	0		0	0	0	0	1	(0.5)	0	1	0	0
Muscle fatigue	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Muscle spasms	13	(3.1)	13	0	0	0	9	(2.1)	7	2	0	0	9	(4.3)	7	2	0	0
Muscle tightness	0		0	0	0	0	2	(0.5)	2	0	0	0	0		0	0	0	0
Muscle twitching	1	(0.2)	1	0	0	0	0		0	0	0	0	0		0	0	0	0
Muscular weakness	2	(0.5)	1	0	1	0	1	(0.2)	1	0	0	0	3	(1.4)	3	0	0	0
Musculoskeletal chest pain	3	(0.7)	2	0	1	0	0		0	0	0	0	1	(0.5)	0	1	0	0
Musculoskeletal discomfort	1	(0.2)	0	1	0	0	0		0	0	0	0	0		0	0	0	0

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In this case, the reported severity is summarized. Missing baseline severities are imputed as grade 1.
Includes data up to 7 days after last dose of study drug.
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Number of Subjects evaluable for adverse events	maraviroc QD (n=414)						maraviroc BID (n=426)						Placebo (n=209)					
			Severity Grade*						Severity Grade*						Severity Grade*			
	N	(%)	1	2	3	4	N	(%)	1	2	3	4	N	(%)	1	2	3	4
System Organ Class and MedDRA (v9.0) preferred term																		
Musculoskeletal pain	0		0	0	0	0	2	(0.5)	1	1	0	0	0		0	0	0	0
Musculoskeletal stiffness	3	(0.7)	2	1	0	0	3	(0.7)	2	1	0	0	3	(1.4)	1	2	0	0
Myalgia	19	(4.6)	14	4	1	0	12	(2.8)	8	4	0	0	1	(0.5)	1	0	0	0
Myopathy	0		0	0	0	0	1	(0.2)	1	0	0	0	1	(0.5)	1	0	0	0
Myositis	1	(0.2)	0	0	1	0	0		0	0	0	0	0		0	0	0	0
Neck pain	3	(0.7)	3	0	0	0	2	(0.5)	1	1	0	0	2	(1.0)	1	1	0	0
Osteoarthritis	3	(0.7)	2	1	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Osteonecrosis	0		0	0	0	0	2	(0.5)	1	0	1	0	0		0	0	0	0
Osteoporosis	1	(0.2)	0	1	0	0	2	(0.5)	1	1	0	0	0		0	0	0	0
Pain in extremity	12	(2.9)	9	2	1	0	11	(2.6)	6	5	0	0	5	(2.4)	3	1	1	0
Plantar fasciitis	0		0	0	0	0	0		0	0	0	0	1	(0.5)	0	1	0	0
Rhabdomyolysis	1	(0.2)	0	0	1	0	3	(0.7)	1	0	1	1	0		0	0	0	0
Rotator cuff syndrome	1	(0.2)	1	0	0	0	1	(0.2)	0	1	0	0	0		0	0	0	0
Shoulder pain	4	(1.0)	0	4	0	0	1	(0.2)	1	0	0	0	4	(1.9)	1	3	0	0
Spinal disorder	1	(0.2)	0	0	1	0	0		0	0	0	0	0		0	0	0	0
Synovial cyst	1	(0.2)	1	0	0	0	0		0	0	0	0	0		0	0	0	0
Tendon disorder	1	(0.2)	1	0	0	0	0		0	0	0	0	1	(0.5)	1	0	0	0
Tendonitis	2	(0.5)	2	0	0	0	0		0	0	0	0	0		0	0	0	0
Tenosynovitis	1	(0.2)	1	0	0	0	0		0	0	0	0	0		0	0	0	0
Vertebral column mass	1	(0.2)	0	1	0	0	0		0	0	0	0	0		0	0	0	0
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	26	(6.3)	16	5	1	4	20	(4.7)	9	5	2	4	14	(6.7)	4	6	3	1
Abdominal neoplasm	0		0	0	0	0	1	(0.2)	0	1	0	0	1	(0.5)	1	0	0	0
Anal cancer	2	(0.5)	0	1	0	1	3	(0.7)	0	1	0	2	3	(1.4)	0	3	0	0

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In this case, the reported severity is summarized. Missing baseline severities are imputed as grade 1.
Includes data up to 7 days after last dose of study drug.
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Number of Subjects evaluable for adverse events	maraviroc QD (n=414)						maraviroc BID (n=426)						Placebo (n=209)					
			Severity Grade*						Severity Grade*						Severity Grade*			
	N	(%)	1	2	3	4	N	(%)	1	2	3	4	N	(%)	1	2	3	4
System Organ Class and MedDRA (v9.0) preferred term																		
Anal cancer stage 0	1	(0.2)	0	0	1	0	0		0	0	0	0	0		0	0	0	0
Basal cell carcinoma	1	(0.2)	1	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Benign neoplasm of orbit	1	(0.2)	1	0	0	0	0		0	0	0	0	0		0	0	0	0
Benign oesophageal neoplasm	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Bowen's disease	0		0	0	0	0	1	(0.2)	0	0	1	0	0		0	0	0	0
Diffuse large B-cell lymphoma	0		0	0	0	0	0		0	0	0	0	1	(0.5)	0	0	0	1
Haemangioma	1	(0.2)	1	0	0	0	0		0	0	0	0	0		0	0	0	0
Haemangioma of liver	1	(0.2)	1	0	0	0	0		0	0	0	0	0		0	0	0	0
Kaposi's sarcoma	1	(0.2)	0	0	0	1	2	(0.5)	2	0	0	0	3	(1.4)	1	1	1	0
Lipoma	1	(0.2)	1	0	0	0	0		0	0	0	0	1	(0.5)	1	0	0	0
Lymphoma	2	(0.5)	0	1	0	1	1	(0.2)	0	0	0	1	1	(0.5)	0	0	1	0
Metastases to liver	1	(0.2)	0	1	0	0	0		0	0	0	0	0		0	0	0	0
Neoplasm	0		0	0	0	0	1	(0.2)	0	1	0	0	1	(0.5)	0	1	0	0
Oesophageal carcinoma	1	(0.2)	0	0	0	1	0		0	0	0	0	0		0	0	0	0
Seborrhoeic keratosis	1	(0.2)	1	0	0	0	2	(0.5)	1	1	0	0	0		0	0	0	0
Skin papilloma	11	(2.7)	10	1	0	0	8	(1.9)	6	2	0	0	3	(1.4)	1	2	0	0
Squamous cell carcinoma	1	(0.2)	0	1	0	0	0		0	0	0	0	1	(0.5)	0	0	1	0
Squamous cell carcinoma of skin	1	(0.2)	1	0	0	0	0		0	0	0	0	0		0	0	0	0
Sweat gland tumour	1	(0.2)	1	0	0	0	1	(0.2)	0	0	0	1	0		0	0	0	0
Testicular neoplasm	1	(0.2)	1	0	0	0	0		0	0	0	0	0		0	0	0	0
Tongue neoplasm malignant stage unspecified	0		0	0	0	0	1	(0.2)	0	0	1	0	0		0	0	0	0
NERVOUS SYSTEM DISORDERS	136	(32.9)	78	49	6	3	135	(31.7)	93	30	8	4	63	(30.1)	35	24	4	0
Ageusia	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Amnesia	2	(0.5)	2	0	0	0	3	(0.7)	3	0	0	0	0		0	0	0	0

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In this case, the reported severity is summarized. Missing baseline severities are imputed as grade 1.
Includes data up to 7 days after last dose of study drug.
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Number of Subjects evaluable for adverse events	maraviroc QD (n=414)						maraviroc BID (n=426)						Placebo (n=209)					
			Severity Grade*						Severity Grade*						Severity Grade*			
	N	(%)	1	2	3	4	N	(%)	1	2	3	4	N	(%)	1	2	3	4
System Organ Class and MedDRA (v9.0) preferred term																		
Areflexia	3	(0.7)	3	0	0	0	2	(0.5)	2	0	0	0	0		0	0	0	0
Balance disorder	2	(0.5)	1	1	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Burning sensation	3	(0.7)	2	1	0	0	0		0	0	0	0	0		0	0	0	0
Carpal tunnel syndrome	1	(0.2)	0	1	0	0	0		0	0	0	0	0		0	0	0	0
Cerebral haemorrhage	1	(0.2)	0	1	0	0	0		0	0	0	0	0		0	0	0	0
Cerebrovascular accident	1	(0.2)	0	0	0	1	1	(0.2)	0	0	0	1	0		0	0	0	0
Convulsion	3	(0.7)	0	1	1	1	1	(0.2)	0	0	0	1	0		0	0	0	0
Depressed level of consciousness	1	(0.2)	1	0	0	0	0		0	0	0	0	0		0	0	0	0
Disturbance in attention	3	(0.7)	2	1	0	0	3	(0.7)	2	1	0	0	3	(1.4)	3	0	0	0
Dizziness	39	(9.4)	35	4	0	0	34	(8.0)	27	6	1	0	14	(6.7)	9	5	0	0
Dizziness postural	5	(1.2)	5	0	0	0	1	(0.2)	0	1	0	0	2	(1.0)	2	0	0	0
Dysaesthesia	1	(0.2)	0	1	0	0	0		0	0	0	0	0		0	0	0	0
Dysarthria	0		0	0	0	0	0		0	0	0	0	1	(0.5)	1	0	0	0
Dysgeusia	3	(0.7)	1	2	0	0	12	(2.8)	11	1	0	0	2	(1.0)	2	0	0	0
Dyskinesia	0		0	0	0	0	0		0	0	0	0	1	(0.5)	1	0	0	0
Epilepsy	1	(0.2)	0	1	0	0	2	(0.5)	0	0	2	0	0		0	0	0	0
Facial palsy	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Headache	61	(14.7)	42	15	3	1	54	(12.7)	47	7	0	0	32	(15.3)	20	11	1	0
Hyperaesthesia	5	(1.2)	3	2	0	0	0		0	0	0	0	0		0	0	0	0
Hypoaesthesia	10	(2.4)	7	3	0	0	11	(2.6)	10	1	0	0	2	(1.0)	1	0	1	0
IIIrd nerve disorder	0		0	0	0	0	0		0	0	0	0	1	(0.5)	0	1	0	0
Lethargy	5	(1.2)	2	3	0	0	4	(0.9)	3	0	1	0	3	(1.4)	1	2	0	0
Loss of consciousness	0		0	0	0	0	1	(0.2)	0	1	0	0	0		0	0	0	0
Memory impairment	2	(0.5)	1	0	1	0	0		0	0	0	0	2	(1.0)	1	1	0	0
Mental impairment	1	(0.2)	1	0	0	0	0		0	0	0	0	0		0	0	0	0
Migraine	4	(1.0)	0	4	0	0	1	(0.2)	0	1	0	0	1	(0.5)	0	1	0	0

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In this case, the reported severity is summarized. Missing baseline severities are imputed as grade 1.
Includes data up to 7 days after last dose of study drug.
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Number of Subjects evaluable for adverse events	maraviroc QD (n=414)						maraviroc BID (n=426)						Placebo (n=209)					
			Severity Grade*						Severity Grade*						Severity Grade*			
	N	(%)	1	2	3	4	N	(%)	1	2	3	4	N	(%)	1	2	3	4
System Organ Class and MedDRA (v9.0) preferred term																		
Nervous system disorder	1	(0.2)	0	1	0	0	0		0	0	0	0	0		0	0	0	0
Neuralgia	1	(0.2)	0	1	0	0	2	(0.5)	0	2	0	0	0		0	0	0	0
Neuritis	1	(0.2)	1	0	0	0	0		0	0	0	0	0		0	0	0	0
Neuropathy	4	(1.0)	2	2	0	0	4	(0.9)	1	2	1	0	2	(1.0)	1	1	0	0
Neuropathy peripheral	9	(2.2)	4	4	1	0	9	(2.1)	6	2	1	0	4	(1.9)	2	2	0	0
Paraesthesia	11	(2.7)	10	1	0	0	11	(2.6)	10	1	0	0	5	(2.4)	4	0	1	0
Parkinsonism	0		0	0	0	0	1	(0.2)	0	1	0	0	0		0	0	0	0
Petit mal epilepsy	1	(0.2)	0	1	0	0	0		0	0	0	0	0		0	0	0	0
Polyneuropathy	2	(0.5)	2	0	0	0	1	(0.2)	1	0	0	0	1	(0.5)	0	1	0	0
Poor quality sleep	3	(0.7)	2	1	0	0	0		0	0	0	0	0		0	0	0	0
Psychomotor hyperactivity	0		0	0	0	0	3	(0.7)	2	1	0	0	0		0	0	0	0
Radicular pain	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Radiculopathy	0		0	0	0	0	1	(0.2)	0	1	0	0	0		0	0	0	0
Restless legs syndrome	2	(0.5)	2	0	0	0	2	(0.5)	2	0	0	0	0		0	0	0	0
Sciatica	1	(0.2)	0	1	0	0	2	(0.5)	0	2	0	0	1	(0.5)	1	0	0	0
Sedation	0		0	0	0	0	2	(0.5)	1	0	0	1	1	(0.5)	0	1	0	0
Sensory disturbance	0		0	0	0	0	1	(0.2)	0	0	1	0	1	(0.5)	1	0	0	0
Sinus headache	2	(0.5)	0	2	0	0	3	(0.7)	3	0	0	0	0		0	0	0	0
Somnolence	7	(1.7)	6	0	1	0	6	(1.4)	6	0	0	0	0		0	0	0	0
Speech disorder	0		0	0	0	0	1	(0.2)	1	0	0	0	1	(0.5)	0	0	1	0
Syncope	2	(0.5)	1	1	0	0	3	(0.7)	0	2	0	1	2	(1.0)	1	0	1	0
Transient ischaemic attack	0		0	0	0	0	0		0	0	0	0	3	(1.4)	0	1	2	0
Tremor	5	(1.2)	5	0	0	0	6	(1.4)	4	0	2	0	0		0	0	0	0
Trigeminal neuralgia	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Visual field defect	0		0	0	0	0	0		0	0	0	0	1	(0.5)	0	1	0	0
PREGNANCY, PUERPERIUM AND PERINATAL CONDITIONS	2	(0.5)	2	0	0	0	0		0	0	0	0	0		0	0	0	0

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In this case, the reported severity is summarized. Missing baseline severities are imputed as grade 1.
Includes data up to 7 days after last dose of study drug.
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Table 3.4.3.3
Maraviroc Summary of Clinical Safety
Incidence and Severity of Treatment-Emergent Adverse Events (All Causalities)
Phase 3 Treatment Experienced CCR5 Tropic Studies

Number of Subjects evaluable for adverse events	maraviroc QD (n=414)						maraviroc BID (n=426)						Placebo (n=209)					
			Severity Grade*						Severity Grade*						Severity Grade*			
	N	(%)	1	2	3	4	N	(%)	1	2	3	4	N	(%)	1	2	3	4
System Organ Class and MedDRA (v9.0) preferred term																		
Pregnancy	2	(0.5)	2	0	0	0	0		0	0	0	0	0		0	0	0	0
PSYCHIATRIC DISORDERS	68	(16.4)	35	29	4	0	68	(16.0)	44	21	3	0	27	(12.9)	17	8	2	0
Abnormal dreams	8	(1.9)	4	3	1	0	3	(0.7)	1	2	0	0	2	(1.0)	0	2	0	0
Affective disorder	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Aggression	0		0	0	0	0	0		0	0	0	0	1	(0.5)	1	0	0	0
Agitation	0		0	0	0	0	1	(0.2)	0	0	1	0	1	(0.5)	1	0	0	0
Alcoholism	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Anxiety	8	(1.9)	5	2	1	0	12	(2.8)	6	5	1	0	5	(2.4)	5	0	0	0
Apathy	1	(0.2)	1	0	0	0	0		0	0	0	0	0		0	0	0	0
Attention deficit/hyperactivity disorder	1	(0.2)	1	0	0	0	0		0	0	0	0	0		0	0	0	0
Confusional state	1	(0.2)	0	1	0	0	0		0	0	0	0	1	(0.5)	0	0	1	0
Cyclothymic disorder	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Depressed mood	1	(0.2)	1	0	0	0	1	(0.2)	0	1	0	0	0		0	0	0	0
Depression	13	(3.1)	4	8	1	0	14	(3.3)	5	8	1	0	6	(2.9)	0	5	1	0
Disorientation	2	(0.5)	1	1	0	0	2	(0.5)	2	0	0	0	0		0	0	0	0
Dissociation	0		0	0	0	0	1	(0.2)	0	1	0	0	0		0	0	0	0
Dysthymic disorder	0		0	0	0	0	1	(0.2)	0	1	0	0	0		0	0	0	0
Euphoric mood	1	(0.2)	1	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Excitability	0		0	0	0	0	2	(0.5)	1	1	0	0	0		0	0	0	0
Hallucination	2	(0.5)	1	1	0	0	0		0	0	0	0	0		0	0	0	0
Hallucination, auditory	1	(0.2)	1	0	0	0	0		0	0	0	0	0		0	0	0	0
Initial insomnia	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0

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In this case, the reported severity is summarized. Missing baseline severities are imputed as grade 1.
Includes data up to 7 days after last dose of study drug.
ACTG grades estimate severity as : Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening.
MedDRA (v9.0) coding dictionary applied.

Number of Subjects evaluable for adverse events	maraviroc QD (n=414)						maraviroc BID (n=426)						Placebo (n=209)					
			Severity Grade*						Severity Grade*						Severity Grade*			
	N	(%)	1	2	3	4	N	(%)	1	2	3	4	N	(%)	1	2	3	4
System Organ Class and MedDRA (v9.0) preferred term																		
Insomnia	23	(5.6)	13	9	1	0	29	(6.8)	23	6	0	0	9	(4.3)	8	1	0	0
Libido decreased	4	(1.0)	1	3	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Loss of libido	1	(0.2)	0	1	0	0	0		0	0	0	0	0		0	0	0	0
Mental status changes	0		0	0	0	0	1	(0.2)	0	1	0	0	0		0	0	0	0
Mood altered	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Mood swings	1	(0.2)	1	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Nervousness	2	(0.5)	2	0	0	0	0		0	0	0	0	0		0	0	0	0
Nightmare	3	(0.7)	2	1	0	0	1	(0.2)	0	1	0	0	1	(0.5)	1	0	0	0
Panic attack	1	(0.2)	0	1	0	0	0		0	0	0	0	0		0	0	0	0
Restlessness	1	(0.2)	1	0	0	0	0		0	0	0	0	0		0	0	0	0
Sleep disorder	9	(2.2)	7	2	0	0	6	(1.4)	5	1	0	0	3	(1.4)	3	0	0	0
Stress	0		0	0	0	0	0		0	0	0	0	1	(0.5)	1	0	0	0
Suicidal ideation	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
RENAL AND URINARY DISORDERS	36	(8.7)	22	11	1	2	45	(10.6)	26	16	2	1	12	(5.7)	7	4	0	1
Bladder pain	1	(0.2)	1	0	0	0	0		0	0	0	0	0		0	0	0	0
Chromaturia	2	(0.5)	2	0	0	0	3	(0.7)	2	1	0	0	0		0	0	0	0
Dysuria	6	(1.4)	6	0	0	0	11	(2.6)	9	2	0	0	1	(0.5)	1	0	0	0
Haematuria	4	(1.0)	3	1	0	0	2	(0.5)	2	0	0	0	2	(1.0)	1	1	0	0
Micturition urgency	0		0	0	0	0	1	(0.2)	0	0	1	0	1	(0.5)	1	0	0	0
Nephrolithiasis	6	(1.4)	1	3	0	2	3	(0.7)	0	1	1	1	2	(1.0)	0	2	0	0
Nocturia	6	(1.4)	4	2	0	0	7	(1.6)	4	3	0	0	1	(0.5)	1	0	0	0
Oliguria	0		0	0	0	0	1	(0.2)	1	0	0	0	0		0	0	0	0
Pollakiuria	4	(1.0)	4	0	0	0	6	(1.4)	3	3	0	0	2	(1.0)	2	0	0	0
Polyuria	0		0	0	0	0	3	(0.7)	2	1	0	0	2	(1.0)	2	0	0	0

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