Trial record **1 of 1** for: TMC278-C204
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A Study of TMC278 in Human Immunodeficiency Virus Type 1 Infected Patients, Who Are Not Treated With Antiretroviral Medicines

This study has been completed.

Sponsor:
Tibotec Pharmaceuticals, Ireland

Information provided by (Responsible Party):
Tibotec Pharmaceuticals, Ireland

ClinicalTrials.gov Identifier:
NCT00110305

First received: May 5, 2005
Last updated: June 11, 2014
Last verified: June 2014
History of Changes

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Results First Received: April 26, 2013

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor); Primary Purpose: Treatment
Condition:	Human Immunodeficiency Virus Type 1
Interventions:	Drug: TMC278 25 mg Drug: TMC278 75 mg Drug: TMC278 150 mg Drug: Efavirenz Drug: Non-nucleoside reverse transcriptase inhibitor (NRTIs)

Participant Flow

Hide Participant Flow

Recruitment Details

Key information relevant to the recruitment process for the overall study, such as dates of the recruitment period and locations
368 participants were enrolled at multiple centers in different countries.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
368 participants were randomly assigned to 4 treatment groups (TMC278 25 mg: 93; TMC278 75 mg: 95; TMC278 150 mg: 91; and Efavirenz: 89). Participant flow through Week 240 was reported for the combined TMC278 and Efavirenz groups, as all TMC278 participants were switched after Week 96 initially to 75 mg and subsequently to 25 mg dose.

Reporting Groups

	Description
All TMC278	TMC278 25 mg, 75 mg, and 150 mg once daily
Efavirenz	Efavirenz 600 mg once daily

Participant Flow: Overall Study

	All TMC278	Efavirenz
STARTED	**279**	**89**

COMPLETED	**165**	**57**
NOT COMPLETED	**114**	**32**
Adverse Event	**46**	**13**
Sponsors Decision	**1**	**0**
Subject Non-Compliant	**9**	**2**
Subject Ineligible To Continue The Trial	**2**	**1**
Subject Reached A Virologic Endpoint	**21**	**3**
Protocol Violation	**0**	**1**
Withdrawal by Subject	**7**	**7**
Lost to Follow-up	**20**	**3**
Unspecified	**8**	**2**

Baseline Characteristics

Hide Baseline Characteristics

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
No text entered.

Reporting Groups

	Description
TMC278 25 mg	TMC278 25 mg once daily
TMC278 75 mg	TMC278 75 mg once daily
TMC 150 mg	TMC278 150 mg once daily
Efavirenz	Efavirenz 600 mg once daily
Total	Total of all reporting groups

Baseline Measures

	TMC278 25 mg	**TMC278 75 mg**	**TMC 150 mg**	**Efavirenz**	**Total**
Number of Participants [units: participants]	**93**	**95**	**91**	**89**	**368**
Age [units: participants]					
<=18 years	**0**	**0**	**0**	**0**	**0**
Between 18 and 65 years	**92**	**95**	**89**	**89**	**365**
>=65 years	**1**	**0**	**2**	**0**	**3**
Age [units: years] Mean (Standard Deviation)	**36.7 (8.9)**	**36.3 (8.3)**	**35.9 (9.7)**	**35.4 (8.1)**	**36.1 (8.75)**
Gender [units: participants]					
Female	**28**	**31**	**33**	**29**	**121**
Male	**65**	**64**	**58**	**60**	**247**
Region Enroll [units: participants]					
Asia, South Africa and Uganda	**32**	**32**	**31**	**29**	**124**
Europe, USA and Russia	**33**	**33**	**32**	**32**	**130**
Latin America	**28**	**30**	**28**	**28**	**114**

Outcome Measures

Hide All Outcome Measures

1. Primary: Number of Participants With Virologic Response at Week 48 (Viral Load Less Than 50 Copies Per mL) - as Defined by the Time to Loss of Virologic Response (TLOVR) Algorithm [Time Frame: Week 48]

Measure Type	Primary
Measure Title	Number of Participants With Virologic Response at Week 48 (Viral Load Less Than 50 Copies Per mL) - as Defined by the Time to Loss of Virologic Response (TLOVR) Algorithm
Measure Description	The TLOVR algorithm was used to derive response, ie, response and loss of response needed to be confirmed at 2 consecutive visits and participants who permanently discontinued were considered nonresponders. Participants with intermittent missing viral load values were considered responders if the preceeding and succeeding visits indicated response. In all other cases, intermittent values were imputed with nonresponse. Resuppression after confirmed virologic failure was considered as failure in this algorithm.
Time Frame	Week 48
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Intent to treat population: Participants who received at least 1 dose of study medication.

Reporting Groups

	Description
TMC278 25 mg	TMC278 25 mg once daily
TMC278 75 mg	TMC278 75 mg once daily
TMC278 150 mg	TMC278 150 mg once daily
All TMC278	TMC278 25 mg, 75 mg, and 150 mg once daily
Efavirenz	Efaviren 600 mg once daily

Measured Values

	TMC278 25 mg	**TMC278 75 mg**	**TMC278 150 mg**	**All TMC278**	**Efavirenz**
Number of Participants Analyzed [units: participants]	**93**	**95**	**91**	**279**	**89**
Number of Participants With Virologic Response at Week 48 (Viral Load Less Than 50 Copies Per mL) - as Defined by the Time to Loss of Virologic Response (TLOVR) Algorithm [units: Participants]	**74**	**76**	**70**	**220**	**72**

Statistical Analysis 1 for Number of Participants With Virologic Response at Week 48 (Viral Load Less Than 50 Copies Per mL) - as Defined by the Time to Loss of Virologic Response (TLOVR) Algorithm

Groups [1]	TMC278 25 mg vs. TMC278 75 mg
Method [2]	Regression, Logistic
P Value [3]	0.92
Differences in response rate [4]	0.5
95% Confidence Interval	-10.4 to 11.3

[1]	Additional details about the analysis, such as null hypothesis and power calculation:

	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	This model with factors treatment, region, and Nucleoside/tide reverse transcriptase inhibitors (N[t]RTIs) used, and baseline viral load as covariate.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	The significance level for each comparison was 5% (two-sided). No further adjustment of this significance level was applied.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 2 for Number of Participants With Virologic Response at Week 48 (Viral Load Less Than 50 Copies Per mL) - as Defined by the Time to Loss of Virologic Response (TLOVR) Algorithm

Groups [1]	TMC278 25 mg vs. TMC278 150 mg
Method [2]	Regression, Logistic
P Value [3]	0.56
Difference in response rate [4]	-2.3
95% Confidence Interval	-13.6 to 9.0

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	This model with factors treatment, region, and N(t)RTIs used, and baseline viral load as covariate.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	The significance level for each comparison was 5% (two-sided). No further adjustment of this significance level was applied.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 3 for Number of Participants With Virologic Response at Week 48 (Viral Load Less Than 50 Copies Per mL) - as Defined by the Time to Loss of Virologic Response (TLOVR) Algorithm

Groups [1]	TMC278 75 mg vs. TMC278 150 mg
Method [2]	Regression, Logistic
P Value [3]	0.62
Difference in response rate [4]	-2.8
95% Confidence Interval	-14.0 to 8.4

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	This model with factors treatment, region, and N(t)RTIs used, and baseline viral load as covariate.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	The significance level for each comparison was 5% (two-sided). No further adjustment of this significance level was applied.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 4 for Number of Participants With Virologic Response at Week 48 (Viral Load Less Than 50 Copies Per mL) - as Defined by the Time to Loss of Virologic Response (TLOVR) Algorithm

Groups [1]	All TMC278 vs. Efavirenz
Method [2]	Regression, Logistic
P Value [3]	0.80
Difference in response rate [4]	-1.5
95% Confidence Interval	-10.5 to 7.5

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	This model with factors treatment, region, and N(t)RTIs used, and baseline viral load as covariate.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	The significance level for each comparison was 5% (two-sided). No further adjustment of this significance level was applied.
[4]	Other relevant estimation information:
	No text entered.

2. Secondary: Number of Participants With Virologic Response at Week 96 (Viral Load Less Than 50 Copies Per mL) - as Defined by the Time to Loss of Virologic Response (TLOVR) Algorithm [Time Frame: Week 96]

Measure Type	Secondary
Measure Title	Number of Participants With Virologic Response at Week 96 (Viral Load Less Than 50 Copies Per mL) - as Defined by the Time to Loss of Virologic Response (TLOVR) Algorithm
Measure Description	The TLOVR algorithm was used to derive response, ie, response and loss of response needed to be confirmed at 2 consecutive visits and participants who permanently discontinued were considered nonresponders. Participants with intermittent missing viral load values were considered responders if the preceeding and succeeding visits indicated response. In all other cases, intermittent values were imputed with nonresponse. Resuppression after confirmed virologic failure was considered as failure in this algorithm.
Time Frame	Week 96
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Intent to treat population: Participants who received at least 1 dose of study medication.

Reporting Groups

	Description
TMC278 25 mg	TMC278 25 mg once daily
TMC278 75 mg	TMC278 75 mg once daily
TMC278 150 mg	TMC278 150 mg once daily
All TMC278	TMC278 25 mg, 75 mg, and 150 mg once daily
Efavirenz	Efavirenz 600 mg once daily

Measured Values

	TMC278 25 mg	**TMC278 75 mg**	**TMC278 150 mg**	**All TMC278**	**Efavirenz**
Number of Participants Analyzed [units: participants]	**93**	**95**	**91**	**279**	**89**
Number of Participants With Virologic Response at Week 96 (Viral Load Less Than 50					

Copies Per mL) - as Defined by the Time to Loss of Virologic Response (TLOVR) Algorithm [units: Participants]	**71**	**68**	**65**	**204**	**63**

Statistical Analysis 1 for Number of Participants With Virologic Response at Week 96 (Viral Load Less Than 50 Copies Per mL) - as Defined by the Time to Loss of Virologic Response (TLOVR) Algorithm

Groups [1]	TMC278 25 mg vs. TMC278 75 mg
Method [2]	Regression, Logistic
P Value [3]	0.45
Difference in response rate [4]	-4.8
95% Confidence Interval	-17.1 to 7.6

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	This model with factors treatment, region, and Nucleoside/tide reverse transcriptase inhibitors (N[t]RTIs) used, and baseline viral load as covariate.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	The significance level for each comparison was 5% (two-sided). No further adjustment of this significance level was applied.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 2 for Number of Participants With Virologic Response at Week 96 (Viral Load Less Than 50 Copies Per mL) - as Defined by the Time to Loss of Virologic Response (TLOVR) Algorithm

Groups [1]	TMC278 25 mg vs. TMC278 150 mg
Method [2]	Regression, Logistic
P Value [3]	0.45
Difference in response rate [4]	-4.8
95% Confidence Interval	-17.3 to 7.7

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	This model with factors treatment, region, and N(t)RTIs used, and baseline viral load as covariate.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	The significance level for each comparison was 5% (two-sided). No further adjustment of this significance level was applied.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 3 for Number of Participants With Virologic Response at Week 96 (Viral Load Less Than 50 Copies Per mL) - as Defined by the Time to Loss of Virologic Response (TLOVR) Algorithm

Groups [1]	TMC278 75 mg vs. TMC278 150 mg
Method [2]	Regression, Logistic
P Value [3]	0.99
Difference in response rate [4]	0.0
95% Confidence Interval	-12.9 to 12.8

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	This model with factors treatment, region, and N(t)RTIs used, and baseline viral load as covariate.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	The significance level for each comparison was 5% (two-sided). No further adjustment of this significance level was applied.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 4 for Number of Participants With Virologic Response at Week 96 (Viral Load Less Than 50 Copies Per mL) - as Defined by the Time to Loss of Virologic Response (TLOVR) Algorithm

Groups [1]	All TMC278 vs. Efavirenz
Method [2]	Regression, Logistic
P Value [3]	0.63
Differences in response [4]	2.6
95% Confidence Interval	-8.1 to 13.3

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	This model with factors treatment, region, and N(t)RTIs used, and baseline viral load as covariate.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	The significance level for each comparison was 5% (two-sided). No further adjustment of this significance level was applied.
[4]	Other relevant estimation information:
	No text entered.

3. Secondary: Number of Participants With Virologic Response at Week 96 (Viral Load Less Than 50 Copies Per mL) - Snapshot Analysis [Time Frame: Week 96]

Measure Type	Secondary
Measure Title	Number of Participants With Virologic Response at Week 96 (Viral Load Less Than 50 Copies Per mL) - Snapshot Analysis
Measure Description	The analysis is based on the last observed viral load data within the Week 96 window. Virologic response is defined as a viral load less than 50 copies/mL. Missing viral load was considered as non-response.
Time Frame	Week 96
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Intent to treat population: Participants who received at least 1 dose of study medication.

Reporting Groups

	Description
TMC278 25 mg	TMC278 25 mg once daily
TMC278 75 mg	TMC278 75 mg once daily

TMC278 150 mg	TMC278 150 mg once daily
All TMC278	TMC278 25 mg, 75 mg, and 150 mg once daily
Efavirenz	Efavirenz 600 mg once daily

Measured Values

	TMC278 25 mg	TMC278 75 mg	TMC278 150 mg	All TMC278	Efavirenz
Number of Participants Analyzed [units: participants]	**93**	**95**	**91**	**279**	**89**
Number of Participants With Virologic Response at Week 96 (Viral Load Less Than 50 Copies Per mL) - Snapshot Analysis [units: Participants]	**71**	**70**	**66**	**207**	**64**

No statistical analysis provided for Number of Participants With Virologic Response at Week 96 (Viral Load Less Than 50 Copies Per mL) - Snapshot Analysis

4. Secondary: Number of Participants With Virologic Response at Week 240 (Viral Load Less Than 50 Copies Per mL) - as Defined by the Time to Loss of Virologic Response (TLOVR) Algorithm [Time Frame: Week 240]

Measure Type	Secondary
Measure Title	Number of Participants With Virologic Response at Week 240 (Viral Load Less Than 50 Copies Per mL) - as Defined by the Time to Loss of Virologic Response (TLOVR) Algorithm
Measure Description	The TLOVR algorithm was used to derive response, ie, response and loss of response needed to be confirmed at 2 consecutive visits and participants who permanently discontinued were considered nonresponders. Participants with intermittent missing viral load values were considered responders if the preceeding and succeeding visits indicated response. In all other cases, intermittent values were imputed with nonresponse. Resuppression after confirmed virologic failure was considered as failure in this algorithm.
Time Frame	Week 240
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Intent to treat population: Participants who received at least 1 dose of study medication. This was measured at Week 240 for the combined TMC278 and Efavirenz groups, as all TMC278 participants were switched after Week 96 initially to 75 mg and subsequently to 25 mg dose.

Reporting Groups

	Description
All TMC278	TMC278 25 mg, 75 mg, and 150 mg once daily
Efavirenz	Efavirenz 600 mg once daily

Measured Values

	All TMC278	Efavirenz
Number of Participants Analyzed [units: participants]	**279**	**89**
Number of Participants With Virologic Response at Week 240 (Viral Load Less Than 50 Copies Per mL) - as Defined by the Time to Loss of Virologic Response (TLOVR) Algorithm [units: Participants]	**152**	**51**

Statistical Analysis 1 for Number of Participants With Virologic Response at Week 240 (Viral Load Less Than 50 Copies Per mL) - as Defined by the Time to Loss of Virologic Response (TLOVR) Algorithm

	All groups

Groups [1]	
Difference in response rate [2]	-2.8
95% Confidence Interval	-14.7 to 9.1

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant estimation information:
	No text entered.

5. Secondary: Number of Participants With Virologic Response at Week 240 (Viral Load Less Than 50 Copies Per mL) - Snapshot Analysis [Time Frame: Week 240]

Measure Type	Secondary
Measure Title	Number of Participants With Virologic Response at Week 240 (Viral Load Less Than 50 Copies Per mL) - Snapshot Analysis
Measure Description	The analysis is based on the last observed viral load data within the Week 240 window. Virologic response is defined as a viral load less than 50 copies/mL. Missing viral load was considered as non-response.
Time Frame	Week 240
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Intent to treat population: Participants who received at least 1 dose of study medication. This was measured at Week 240 for the combined TMC278 and Efavirenz groups, as all TMC278 participants were switched after Week 96 initially to 75 mg and subsequently to 25 mg dose.

Reporting Groups

	Description
All TMC278	TMC278 25 mg, 75 mg, and 150 mg once daily
Efavirenz	Efavirenz 600 mg once daily

Measured Values

	All TMC278	**Efavirenz**
Number of Participants Analyzed [units: participants]	**279**	**89**
Number of Participants With Virologic Response at Week 240 (Viral Load Less Than 50 Copies Per mL) - Snapshot Analysis [units: Participants]	**150**	**51**

No statistical analysis provided for Number of Participants With Virologic Response at Week 240 (Viral Load Less Than 50 Copies Per mL) - Snapshot Analysis

6. Secondary: Number of Participants With Virologic Response at Week 240 (Viral Load Less Than 400 Copies/mL) - as Defined by the Time to Loss of Virologic Response (TLOVR) Algorithm [Time Frame: Week 240]

Measure Type	Secondary
Measure Title	Number of Participants With Virologic Response at Week 240 (Viral Load Less Than 400 Copies/mL) - as Defined by the Time to Loss of Virologic Response (TLOVR) Algorithm
Measure Description	The TLOVR algorithm was used to derive response, ie, response and loss of response needed to be confirmed at 2 consecutive visits and participants who permanently discontinued were considered nonresponders. Participants with intermittent missing viral load values were considered responders if the preceeding and succeeding visits indicated

	response. In all other cases, intermittent values were imputed with nonresponse. Resuppression after confirmed virologic failure was considered as failure in this algorithm.
Time Frame	Week 240
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Intent to treat population: Participants who received at least 1 dose of study medication. This was measured at Week 240 for the combined TMC278 and Efavirenz groups, as all TMC278 participants were switched after Week 96 initially to 75 mg and subsequently to 25 mg dose.

Reporting Groups

	Description
All TMC278	TMC278 25 mg, 75 mg, and 150 mg once daily
Efavirenz	Efavirenz 600 mg once daily

Measured Values

	All TMC278	**Efavirenz**
Number of Participants Analyzed [units: participants]	**279**	**89**
Number of Participants With Virologic Response at Week 240 (Viral Load Less Than 400 Copies/mL) - as Defined by the Time to Loss of Virologic Response (TLOVR) Algorithm [units: Participants]	**166**	**54**

No statistical analysis provided for Number of Participants With Virologic Response at Week 240 (Viral Load Less Than 400 Copies/mL) - as Defined by the Time to Loss of Virologic Response (TLOVR) Algorithm

7. Secondary: Change From Baseline in CD4+ Cell Count (Absolute) at Week 96 [Time Frame: Baseline (Day 1 of Week 0) to Week 96]

Measure Type	Secondary
Measure Title	Change From Baseline in CD4+ Cell Count (Absolute) at Week 96
Measure Description	Change from baseline in CD4+ cell count was imputed in case of missing values: in case of premature discontinuation, data were imputed with the baseline value after discontinuation (i.e. change=0, Non-Completer [NC] = Failure); otherwise last observation carried forward was applied.
Time Frame	Baseline (Day 1 of Week 0) to Week 96
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Intent to treat population: Participants who received at least 1 dose of study medication.Efavirenz group, 1 participant was excluded due to missing baseline CD4+ cell count.

Reporting Groups

	Description
TMC278 25mg	TMC278 25 mg once daily
TMC278 75 mg	TMC278 75 mg once daily
TMC278 150 mg	TMC278 150 mg once daily
All TMC278	TMC278 25 mg, 75 mg, and 150 mg once daily
Efavirenz	Efavirenz 600 mg once daily

Measured Values

	TMC278 25mg	TMC278 75 mg	TMC278 150 mg	All TMC278	Efavirenz
Number of Participants Analyzed [units: participants]	**93**	**95**	**91**	**279**	**88**
Change From Baseline in CD4+ Cell Count (Absolute) at Week 96 [units: Cells per microliter] Mean (Standard Deviation)	**145.9 (117.0)**	**172.0 (156.5)**	**158.9 (156.5)**	**159.0 (144.4)**	**159.8 (125.7)**

No statistical analysis provided for Change From Baseline in CD4+ Cell Count (Absolute) at Week 96

8. Secondary: Change From Baseline in CD4+ Cell Count (Relative) at Week 96 [Time Frame: Baseline (Day 1 of Week 0) to Week 96]

Measure Type	Secondary
Measure Title	Change From Baseline in CD4+ Cell Count (Relative) at Week 96
Measure Description	Change from baseline in CD4+ cell count was imputed in case of missing values: in case of premature discontinuation, data were imputed with the baseline value after discontinuation (i.e. change=0, Non-Completer [NC] = Failure); otherwise last observation carried forward was applied.
Time Frame	Baseline (Day 1 of Week 0) to Week 96
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Intent to treat (ITT) population: Participants who received at least 1 dose of study medication. Efavirenz group, 1 participant was excluded due to missing baseline CD4+ cell count.

Reporting Groups

	Description
TMC278 25mg	TMC278 25 mg once daily
TMC278 75 mg	TMC278 75 mg once daily
TMC278 150 mg	TMC278 150 mg once daily
All TMC278	TMC278 25 mg, 75 mg, and 150 mg once daily
Efavirenz	Efavirenz 600 mg once daily

Measured Values

	TMC278 25mg	TMC278 75 mg	TMC278 150 mg	All TMC278	Efavirenz
Number of Participants Analyzed [units: participants]	**93**	**95**	**91**	**279**	**88**
Change From Baseline in CD4+ Cell Count (Relative) at Week 96 [units: Percentage of CD4+ Cells] Mean (Standard Deviation)	**8.6 (6.9)**	**9.9 (7.3)**	**9.3 (7.1)**	**9.3 (7.1)**	**9.6 (7.0)**

No statistical analysis provided for Change From Baseline in CD4+ Cell Count (Relative) at Week 96

9. Secondary: Change From Baseline in CD4+ Cell Count (Absolute) at Week 240 [Time Frame: Baseline (Day 1 of Week 0) to Week 240]

Measure Type	Secondary
Measure Title	Change From Baseline in CD4+ Cell Count (Absolute) at Week 240

Measure Description	Change from baseline in CD4+ cell count was imputed in case of missing values: in case of premature discontinuation, data were imputed with the baseline value after discontinuation (i.e. change=0, Non-Completer [NC] = Failure); otherwise last observation carried forward was applied.
Time Frame	Baseline (Day 1 of Week 0) to Week 240
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
ITT population: Participants who received at least 1 dose of study medication. Efavirenz group, 1 participant was excluded due to missing baseline CD4+ cell count. This was measured at Week 240 for the combined TMC278 and Efavirenz groups, as all TMC278 participants were switched after Week 96 initially to 75 mg and subsequently to 25 mg dose.

Reporting Groups

	Description
All TMC278	TMC278 25 mg, 75 mg, and 150 mg once daily
Efavirenz	Efavirenz 600 mg once daily

Measured Values

	All TMC278	**Efavirenz**
Number of Participants Analyzed [units: participants]	**279**	**88**
Change From Baseline in CD4+ Cell Count (Absolute) at Week 240 [units: Cells per microliter] Mean (Standard Deviation)	**221.0 (227.2)**	**217.9 (213.7)**

No statistical analysis provided for Change From Baseline in CD4+ Cell Count (Absolute) at Week 240

10. Secondary: Change From Baseline in CD4+ Cell Count (Relative) at Week 240 [Time Frame: Baseline (Day 1 of week 0) to Week 240]

Measure Type	Secondary
Measure Title	Change From Baseline in CD4+ Cell Count (Relative) at Week 240
Measure Description	Change from baseline in CD4+ cell count was imputed in case of missing values: in case of premature discontinuation, data were imputed with the baseline value after discontinuation (i.e. change=0, Non-Completer [NC] = Failure); otherwise last observation carried forward was applied.
Time Frame	Baseline (Day 1 of week 0) to Week 240
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
ITT population: Participants who received at least 1 dose of study medication. Efavirenz group, 1 participant was excluded due to missing baseline CD4+ cell count. This was measured at Week 240 for the combined TMC278 and Efavirenz groups, as all TMC278 participants were switched after Week 96 initially to 75 mg and subsequently to 25 mg dose.

Reporting Groups

	Description
All TMC278	TMC278 25 mg, 75 mg, and 150 mg once daily
Efavirenz	Efavirenz 600 mg once daily

Measured Values

	All TMC278	**Efavirenz**
Number of Participants Analyzed [units: participants]	**279**	**88**

Change From Baseline in CD4+ Cell Count (Relative) at Week 240 [units: Percentage of CD4+ cells] Mean (Standard Deviation)	**8.7 (8.7)**	**9.7 (9.1)**

No statistical analysis provided for Change From Baseline in CD4+ Cell Count (Relative) at Week 240

11. Secondary: Number of Participants With Virologic Failure for the Resistance Determinations by Developing Mutations: First Available On-Treatment Genotypic Data After Failure [Time Frame: Week 240]

Measure Type	Secondary
Measure Title	Number of Participants With Virologic Failure for the Resistance Determinations by Developing Mutations: First Available On-Treatment Genotypic Data After Failure
Measure Description	Virologic failure for the resistance determinations was defined as a viral load greater than 0.5 log10 copies /mL above the nadir with a minimum of 500 copies/mL. For this study, treatment-emergent mutations (for at least one treatment) are presented as Resistance associated mutation (RAMs): i) Non-nucleotide reverse transcriptase inhibitor (NNRTI) RAMs, ii) Nucleoside/tide reverse transcriptase inhibitor (N[t]RTI RAMs).
Time Frame	Week 240
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Intent to treat population: Participants who received at least 1 dose of study medication. This was measured at Week 240 for the combined TMC278 and Efavirenz groups, as all TMC278 participants were switched after Week 96 initially to 75 mg and subsequently to 25 mg dose.

Reporting Groups

	Description
All TMC278	TMC278 25 mg, 75 mg, and 150 mg once daily
Efavirenz	Efavirenz 600 mg once daily

Measured Values

	All TMC278	**Efavirenz**
Number of Participants Analyzed [units: participants]	**279**	**89**
Number of Participants With Virologic Failure for the Resistance Determinations by Developing Mutations: First Available On-Treatment Genotypic Data After Failure [units: Participants]		
Treatment-emergent NNRTI RAM	**17**	**4**
E138K	**7**	**0**
K101E	**6**	**0**
K103N	**1**	**3**
Treatment-emergent N(t)RTI RAM	**13**	**0**
M184V	**10**	**0**

No statistical analysis provided for Number of Participants With Virologic Failure for the Resistance Determinations by Developing Mutations: First Available On-Treatment Genotypic Data After Failure

12. Secondary: Area Under the Plasma Concentration Time Curve From Time 0 to 24 Hours (AUC24h) for TMC278 [Time Frame: Up to Week 96]

Measure Type	Secondary

Measure Title	Area Under the Plasma Concentration Time Curve From Time 0 to 24 Hours (AUC24h) for TMC278
Measure Description	For each participant, a single value for area under the plasma concentration-time curve from time of administration up to 24 hours post dosing (AUC24h) of TMC278 was estimated from a population pharmacokinetic model, based on all samples collected throughout the trial up to Week 96.
Time Frame	Up to Week 96
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Analysis included participants with sufficient number of pharmacokinetic samples in order to derive population pharmacokinetic parameter.

Reporting Groups

	Description
TMC278 25 mg	TMC278 25 mg once daily
TMC278 75 mg	TMC278 75 mg once daily
TMC278 150 mg	TMC278 150 mg once daily

Measured Values

	TMC278 25 mg	**TMC278 75 mg**	**TMC278 150 mg**
Number of Participants Analyzed [units: participants]	**89**	**93**	**87**
Area Under the Plasma Concentration Time Curve From Time 0 to 24 Hours (AUC24h) for TMC278 [units: ng*h/mL] Mean (Standard Deviation)	**2767 (1166)**	**5906 (2419)**	**10281 (4208)**

No statistical analysis provided for Area Under the Plasma Concentration Time Curve From Time 0 to 24 Hours (AUC24h) for TMC278

13. Secondary: Trough Plasma Concentration (Ctrough) for TMC278 [Time Frame: Up to Week 96]

Measure Type	Secondary
Measure Title	Trough Plasma Concentration (Ctrough) for TMC278
Measure Description	For each participant, a single value for trough (i.e. predose) plasma concentration (Ctrough) of TMC278 was estimated from a population pharmacokinetic model, based on samples collected throughout the trial up to Week 96.
Time Frame	Up to Week 96
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Analysis included participants with sufficient number of pharnacokintetic samples in order to derive population pharmacokinetic parameter.

Reporting Groups

	Description
TMC278 25 mg	TMC278 25 mg once daily
TMC278 75 mg	TMC278 75 mg once daily
TMC278 150 mg	TMC278 150 mg once daily

Measured Values

	TMC278 25 mg	**TMC278 75 mg**	**TMC278 150 mg**

Number of Participants Analyzed [units: participants]	**89**	**93**	**87**
Trough Plasma Concentration (Ctrough) for TMC278 [units: ng/mL] Mean (Standard Deviation)	**92.7 (45.2)**	**196.0 (90.1)**	**342.0 (154.0)**

No statistical analysis provided for Trough Plasma Concentration (Ctrough) for TMC278

14. Secondary: Number of Participants With Virologic Response (Viral Load Less Than 50 Copies Per mL) - as Defined by the Time to Loss of Virologic Response (TLOVR) Algorithm, by Area Under the Plasma Concentration Time Curve From Time 0 to 24 Hours (AUC24h) Quartiles [Time Frame: Up to Week 96]

Measure Type	Secondary
Measure Title	Number of Participants With Virologic Response (Viral Load Less Than 50 Copies Per mL) - as Defined by the Time to Loss of Virologic Response (TLOVR) Algorithm, by Area Under the Plasma Concentration Time Curve From Time 0 to 24 Hours (AUC24h) Quartiles
Measure Description	Quartile 1, 2, 3 and 4 of AUC24h means the quartile with the lowest 25%, 26-50%, 51-75% and the highest 25% of AUC24h values, respectively, irrespective of the different doses of TMC278. For each participant, a single value for area under the plasma concentration-time curve from time of administration up to 24 hours post dosing (AUC24h) of TMC278 was estimated from a population pharmacokinetic model, based on all samples collected throughout the trial up to Week 96. Virologic response was calculated by time to loss of virologic response (TLOVR) algorithm.
Time Frame	Up to Week 96
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Analysis included participants who received TMC278 with sufficient number of pharnacokintetic samples in order to derive population pharmacokinetic parameter. Participants who discontinued treatment for reasons other than virological failure were excluded from this analysis.

Reporting Groups

	Description
AUC24h Quartile 1	TMC278 25 mg, 75 mg, and 150 mg once daily
AUC24h Quartile 2	TMC278 25 mg, 75 mg, and 150 mg once daily
AUC24h Quartile 3	TMC278 25 mg, 75 mg, and 150 mg once daily
AUC24h Quartile 4	TMC278 25 mg, 75 mg, and 150 mg once daily

Measured Values

	AUC24h Quartile 1	**AUC24h Quartile 2**	**AUC24h Quartile 3**	**AUC24h Quartile 4**
Number of Participants Analyzed [units: participants]	**58**	**54**	**59**	**56**
Number of Participants With Virologic Response (Viral Load Less Than 50 Copies Per mL) - as Defined by the Time to Loss of Virologic Response (TLOVR) Algorithm, by Area Under the Plasma Concentration Time Curve From Time 0 to 24 Hours (AUC24h) Quartiles [units: Participants]	**48**	**50**	**55**	**51**

No statistical analysis provided for Number of Participants With Virologic Response (Viral Load Less Than 50 Copies Per mL) - as Defined by the Time to Loss of Virologic Response (TLOVR) Algorithm, by Area Under the Plasma Concentration Time Curve From Time 0 to 24 Hours (AUC24h) Quartiles

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	Up to 336 weeks for participants in the TMC278 treatment group and up to 260 weeks for participants in the efavirenz treatment group.
Additional Description	Adverse events were reported at Week 240 for the combined TMC278 and Efavirenz groups, as all TMC278 participants were switched after Week 96 initially to 75 mg and subsequently to 25 mg dose.

Reporting Groups

	Description
All TMC278	TMC278 25 mg, 75 mg, and 150 mg once daily
Efavirenz	Efavirenz 600 mg once daily

Serious Adverse Events

	All TMC278	Efavirenz
Total, serious adverse events		
# participants affected / at risk	**49/279 (17.56%)**	**17/89 (19.10%)**
Blood and lymphatic system disorders		
Anaemia † 1		
# participants affected / at risk	**5/279 (1.79%)**	**0/89 (0.00%)**
Leukopenia † 1		
# participants affected / at risk	**1/279 (0.36%)**	**0/89 (0.00%)**
Neutropenia † 1		
# participants affected / at risk	**1/279 (0.36%)**	**0/89 (0.00%)**
Cardiac disorders		
Acute myocardial infarction † 1		
# participants affected / at risk	**1/279 (0.36%)**	**0/89 (0.00%)**
Angina unstable † 1		
# participants affected / at risk	**1/279 (0.36%)**	**0/89 (0.00%)**
Supraventricular tachycardia † 1		
# participants affected / at risk	**1/279 (0.36%)**	**0/89 (0.00%)**
Gastrointestinal disorders		
Abdominal pain † 1		
# participants affected / at risk	**1/279 (0.36%)**	**0/89 (0.00%)**
Anal fissure † 1		
# participants affected / at risk	**1/279 (0.36%)**	**0/89 (0.00%)**
Anal fistula † 1		
# participants affected / at risk	**2/279 (0.72%)**	**0/89 (0.00%)**
Appendicitis perforated † 1		
# participants affected / at risk	**1/279 (0.36%)**	**0/89 (0.00%)**
Colitis † 1		
# participants affected / at risk	**0/279 (0.00%)**	**1/89 (1.12%)**
Constipation † 1		
# participants affected / at risk	**1/279 (0.36%)**	**0/89 (0.00%)**
Diarrhoea haemorrhagic † 1		
# participants affected / at risk	**0/279 (0.00%)**	**1/89 (1.12%)**
Intestinal infarction † 1		
# participants affected / at risk	**1/279 (0.36%)**	**0/89 (0.00%)**
Intestinal obstruction † 1		
# participants affected / at risk	**1/279 (0.36%)**	**0/89 (0.00%)**
Pancreatitis † 1		

# participants affected / at risk	1/279 (0.36%)	0/89 (0.00%)
Pancreatitis acute † 1		
# participants affected / at risk	1/279 (0.36%)	0/89 (0.00%)
Peritonitis † 1		
# participants affected / at risk	0/279 (0.00%)	1/89 (1.12%)
Rectal haemorrhage † 1		
# participants affected / at risk	1/279 (0.36%)	0/89 (0.00%)
General disorders		
Chest pain † 1		
# participants affected / at risk	1/279 (0.36%)	0/89 (0.00%)
Death † 1		
# participants affected / at risk	1/279 (0.36%)	0/89 (0.00%)
Pyrexia † 1		
# participants affected / at risk	2/279 (0.72%)	0/89 (0.00%)
Hepatobiliary disorders		
Bile duct stone † 1		
# participants affected / at risk	1/279 (0.36%)	0/89 (0.00%)
Cholecystitis acute † 1		
# participants affected / at risk	1/279 (0.36%)	0/89 (0.00%)
Cholelithiasis † 1		
# participants affected / at risk	1/279 (0.36%)	0/89 (0.00%)
Cytolytic hepatitis † 1		
# participants affected / at risk	1/279 (0.36%)	0/89 (0.00%)
Hepatitis † 1		
# participants affected / at risk	1/279 (0.36%)	0/89 (0.00%)
Hepatitis acute † 1		
# participants affected / at risk	0/279 (0.00%)	1/89 (1.12%)
Hydrocholecystis † 1		
# participants affected / at risk	1/279 (0.36%)	0/89 (0.00%)
Infections and infestations		
Abscess neck † 1		
# participants affected / at risk	1/279 (0.36%)	0/89 (0.00%)
Appendicitis † 1		
# participants affected / at risk	0/279 (0.00%)	1/89 (1.12%)
Arthritis bacterial † 1		
# participants affected / at risk	1/279 (0.36%)	0/89 (0.00%)
Cellulitis † 1		
# participants affected / at risk	0/279 (0.00%)	1/89 (1.12%)
Clostridial infection † 1		
# participants affected / at risk	1/279 (0.36%)	1/89 (1.12%)
Cytomegalovirus colitis † 1		
# participants affected / at risk	1/279 (0.36%)	0/89 (0.00%)
Hepatitis C † 1		
# participants affected / at risk	0/279 (0.00%)	1/89 (1.12%)
Implant site infection † 1		
# participants affected / at risk	1/279 (0.36%)	0/89 (0.00%)
Lobar pneumonia † 1		
# participants affected / at risk	1/279 (0.36%)	1/89 (1.12%)

Lung infection † 1		
# participants affected / at risk	**1/279 (0.36%)**	**0/89 (0.00%)**
Malaria † 1		
# participants affected / at risk	**0/279 (0.00%)**	**1/89 (1.12%)**
Meningitis tuberculous † 1		
# participants affected / at risk	**1/279 (0.36%)**	**0/89 (0.00%)**
Oral candidiasis † 1		
# participants affected / at risk	**1/279 (0.36%)**	**0/89 (0.00%)**
Osteomyelitis † 1		
# participants affected / at risk	**1/279 (0.36%)**	**0/89 (0.00%)**
Perianal abscess † 1		
# participants affected / at risk	**1/279 (0.36%)**	**0/89 (0.00%)**
Pneumonia † 1		
# participants affected / at risk	**3/279 (1.08%)**	**0/89 (0.00%)**
Pneumonia streptococcal † 1		
# participants affected / at risk	**1/279 (0.36%)**	**0/89 (0.00%)**
Respiratory tract infection † 1		
# participants affected / at risk	**1/279 (0.36%)**	**0/89 (0.00%)**
Sepsis syndrome † 1		
# participants affected / at risk	**1/279 (0.36%)**	**0/89 (0.00%)**
Septic shock † 1		
# participants affected / at risk	**1/279 (0.36%)**	**0/89 (0.00%)**
Subcutaneous abscess † 1		
# participants affected / at risk	**0/279 (0.00%)**	**2/89 (2.25%)**
Injury, poisoning and procedural complications		
Ankle fracture † 1		
# participants affected / at risk	**1/279 (0.36%)**	**0/89 (0.00%)**
Brain contusion † 1		
# participants affected / at risk	**1/279 (0.36%)**	**0/89 (0.00%)**
Drug toxicity † 1		
# participants affected / at risk	**1/279 (0.36%)**	**0/89 (0.00%)**
Humerus fracture † 1		
# participants affected / at risk	**0/279 (0.00%)**	**1/89 (1.12%)**
Muscle injury † 1		
# participants affected / at risk	**0/279 (0.00%)**	**1/89 (1.12%)**
Road traffic accident † 1		
# participants affected / at risk	**1/279 (0.36%)**	**1/89 (1.12%)**
Investigations		
Alanine aminotransferase increased † 1		
# participants affected / at risk	**1/279 (0.36%)**	**0/89 (0.00%)**
Aspartate aminotransferase increased † 1		
# participants affected / at risk	**1/279 (0.36%)**	**0/89 (0.00%)**
Blood amylase increased † 1		
# participants affected / at risk	**1/279 (0.36%)**	**1/89 (1.12%)**
Metabolism and nutrition disorders		
Anorexia † 1		
# participants affected / at risk	**1/279 (0.36%)**	**0/89 (0.00%)**
Dehydration † 1		
# participants affected / at risk	**1/279 (0.36%)**	**0/89 (0.00%)**

Diabetes mellitus † 1		
# participants affected / at risk	1/279 (0.36%)	0/89 (0.00%)
Metabolic acidosis † 1		
# participants affected / at risk	1/279 (0.36%)	0/89 (0.00%)
Musculoskeletal and connective tissue disorders		
Arthralgia † 1		
# participants affected / at risk	0/279 (0.00%)	1/89 (1.12%)
Back pain † 1		
# participants affected / at risk	1/279 (0.36%)	0/89 (0.00%)
Costochondritis † 1		
# participants affected / at risk	1/279 (0.36%)	0/89 (0.00%)
Lumbar spinal stenosis † 1		
# participants affected / at risk	1/279 (0.36%)	0/89 (0.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
Burkitt's lymphoma † 1		
# participants affected / at risk	2/279 (0.72%)	0/89 (0.00%)
Cervix cancer metastatic † 1		
# participants affected / at risk	1/279 (0.36%)	1/89 (1.12%)
Chondrosarcoma metastatic † 1		
# participants affected / at risk	0/279 (0.00%)	1/89 (1.12%)
Kaposi's sarcoma † 1		
# participants affected / at risk	1/279 (0.36%)	0/89 (0.00%)
Lymphoma † 1		
# participants affected / at risk	2/279 (0.72%)	0/89 (0.00%)
Squamous cell carcinoma † 1		
# participants affected / at risk	1/279 (0.36%)	0/89 (0.00%)
Uterine leiomyoma † 1		
# participants affected / at risk	1/279 (0.36%)	0/89 (0.00%)
Nervous system disorders		
Epilepsy † 1		
# participants affected / at risk	1/279 (0.36%)	0/89 (0.00%)
Headache † 1		
# participants affected / at risk	0/279 (0.00%)	1/89 (1.12%)
Pregnancy, puerperium and perinatal conditions		
Pregnancy † 1		
# participants affected / at risk	0/279 (0.00%)	1/89 (1.12%)
Psychiatric disorders		
Depression † 1		
# participants affected / at risk	1/279 (0.36%)	0/89 (0.00%)
Intentional self-injury † 1		
# participants affected / at risk	1/279 (0.36%)	0/89 (0.00%)
Major depression † 1		
# participants affected / at risk	1/279 (0.36%)	0/89 (0.00%)
Suicide attempt † 1		
# participants affected / at risk	1/279 (0.36%)	0/89 (0.00%)
Renal and urinary disorders		
Renal failure † 1		
# participants affected / at risk	1/279 (0.36%)	0/89 (0.00%)

Renal impairment † 1		
# participants affected / at risk	1/279 (0.36%)	0/89 (0.00%)
Reproductive system and breast disorders		
Ovarian cyst † 1		
# participants affected / at risk	1/279 (0.36%)	0/89 (0.00%)
Prostatitis † 1		
# participants affected / at risk	0/279 (0.00%)	1/89 (1.12%)
Respiratory, thoracic and mediastinal disorders		
Alveolitis allergic † 1		
# participants affected / at risk	1/279 (0.36%)	0/89 (0.00%)
Skin and subcutaneous tissue disorders		
Rash maculo-papular † 1		
# participants affected / at risk	1/279 (0.36%)	0/89 (0.00%)
Surgical and medical procedures		
Ovarian cystectomy † 1		
# participants affected / at risk	1/279 (0.36%)	0/89 (0.00%)
Penile prosthesis insertion † 1		
# participants affected / at risk	1/279 (0.36%)	0/89 (0.00%)
Vascular disorders		
Arterial occlusive disease † 1		
# participants affected / at risk	1/279 (0.36%)	0/89 (0.00%)
Deep vein thrombosis † 1		
# participants affected / at risk	0/279 (0.00%)	1/89 (1.12%)

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA 11.0

Other Adverse Events

Hide Other Adverse Events

Time Frame	Up to 336 weeks for participants in the TMC278 treatment group and up to 260 weeks for participants in the efavirenz treatment group.
Additional Description	Adverse events were reported at Week 240 for the combined TMC278 and Efavirenz groups, as all TMC278 participants were switched after Week 96 initially to 75 mg and subsequently to 25 mg dose.

Frequency Threshold

Threshold above which other adverse events are reported	5

Reporting Groups

	Description
All TMC278	TMC278 25 mg, 75 mg, and 150 mg once daily
Efavirenz	Efavirenz 600 mg once daily

Other Adverse Events

	All TMC278	Efavirenz
Total, other (not including serious) adverse events		
# participants affected / at risk	241/279 (86.38%)	82/89 (92.13%)
Blood and lymphatic system disorders		
Anaemia † 1		
# participants affected / at risk	24/279 (8.60%)	2/89 (2.25%)

Ear and labyrinth disorders		
Vertigo † 1		
# participants affected / at risk	**4/279 (1.43%)**	**10/89 (11.24%)**
Eye disorders		
Conjunctivitis † 1		
# participants affected / at risk	**9/279 (3.23%)**	**5/89 (5.62%)**
Gastrointestinal disorders		
Abdominal pain † 1		
# participants affected / at risk	**20/279 (7.17%)**	**4/89 (4.49%)**
Abdominal pain upper † 1		
# participants affected / at risk	**13/279 (4.66%)**	**5/89 (5.62%)**
Diarrhoea † 1		
# participants affected / at risk	**33/279 (11.83%)**	**16/89 (17.98%)**
Dyspepsia † 1		
# participants affected / at risk	**36/279 (12.90%)**	**7/89 (7.87%)**
Haemorrhoids † 1		
# participants affected / at risk	**10/279 (3.58%)**	**7/89 (7.87%)**
Nausea † 1		
# participants affected / at risk	**100/279 (35.84%)**	**26/89 (29.21%)**
Vomiting † 1		
# participants affected / at risk	**33/279 (11.83%)**	**11/89 (12.36%)**
General disorders		
Fatigue † 1		
# participants affected / at risk	**23/279 (8.24%)**	**4/89 (4.49%)**
Pyrexia † 1		
# participants affected / at risk	**19/279 (6.81%)**	**3/89 (3.37%)**
Infections and infestations		
Body tinea † 1		
# participants affected / at risk	**4/279 (1.43%)**	**7/89 (7.87%)**
Bronchitis † 1		
# participants affected / at risk	**20/279 (7.17%)**	**3/89 (3.37%)**
Condyloma acuminatum † 1		
# participants affected / at risk	**17/279 (6.09%)**	**3/89 (3.37%)**
Gastroenteritis † 1		
# participants affected / at risk	**11/279 (3.94%)**	**5/89 (5.62%)**
Herpes simplex † 1		
# participants affected / at risk	**25/279 (8.96%)**	**7/89 (7.87%)**
Herpes zoster † 1		
# participants affected / at risk	**15/279 (5.38%)**	**4/89 (4.49%)**
Influenza † 1		
# participants affected / at risk	**27/279 (9.68%)**	**8/89 (8.99%)**
Nasopharyngitis † 1		
# participants affected / at risk	**45/279 (16.13%)**	**19/89 (21.35%)**
Pharyngitis † 1		
# participants affected / at risk	**18/279 (6.45%)**	**4/89 (4.49%)**
Respiratory tract infection † 1		
# participants affected / at risk	**9/279 (3.23%)**	**5/89 (5.62%)**
Respiratory tract infection viral † 1		

# participants affected / at risk	1/279 (0.36%)	7/89 (7.87%)
Rhinitis † 1		
# participants affected / at risk	12/279 (4.30%)	5/89 (5.62%)
Sinusitis † 1		
# participants affected / at risk	20/279 (7.17%)	3/89 (3.37%)
Tinea pedis † 1		
# participants affected / at risk	8/279 (2.87%)	5/89 (5.62%)
Upper respiratory tract infection † 1		
# participants affected / at risk	49/279 (17.56%)	9/89 (10.11%)
Urinary tract infection † 1		
# participants affected / at risk	21/279 (7.53%)	6/89 (6.74%)
Investigations		
Alanine aminotransferase increased † 1		
# participants affected / at risk	21/279 (7.53%)	6/89 (6.74%)
Aspartate aminotransferase increased † 1		
# participants affected / at risk	17/279 (6.09%)	5/89 (5.62%)
Blood cholesterol increased † 1		
# participants affected / at risk	13/279 (4.66%)	11/89 (12.36%)
Low density lipoprotein increased † 1		
# participants affected / at risk	16/279 (5.73%)	9/89 (10.11%)
Metabolism and nutrition disorders		
Anorexia † 1		
# participants affected / at risk	19/279 (6.81%)	7/89 (7.87%)
Musculoskeletal and connective tissue disorders		
Arthralgia † 1		
# participants affected / at risk	39/279 (13.98%)	11/89 (12.36%)
Back pain † 1		
# participants affected / at risk	31/279 (11.11%)	5/89 (5.62%)
Myalgia † 1		
# participants affected / at risk	18/279 (6.45%)	3/89 (3.37%)
Nervous system disorders		
Dizziness † 1		
# participants affected / at risk	31/279 (11.11%)	27/89 (30.34%)
Headache † 1		
# participants affected / at risk	62/279 (22.22%)	15/89 (16.85%)
Somnolence † 1		
# participants affected / at risk	10/279 (3.58%)	10/89 (11.24%)
Psychiatric disorders		
Abnormal dreams † 1		
# participants affected / at risk	6/279 (2.15%)	5/89 (5.62%)
Depression † 1		
# participants affected / at risk	19/279 (6.81%)	9/89 (10.11%)
Insomnia † 1		
# participants affected / at risk	23/279 (8.24%)	6/89 (6.74%)
Nightmare † 1		
# participants affected / at risk	1/279 (0.36%)	5/89 (5.62%)
Respiratory, thoracic and mediastinal disorders		
Cough † 1		

# participants affected / at risk	29/279 (10.39%)	12/89 (13.48%)
Skin and subcutaneous tissue disorders		
Dry skin † 1		
# participants affected / at risk	14/279 (5.02%)	1/89 (1.12%)
Pruritus † 1		
# participants affected / at risk	18/279 (6.45%)	4/89 (4.49%)
Rash † 1		
# participants affected / at risk	5/279 (1.79%)	7/89 (7.87%)
Seborrhoeic dermatitis † 1		
# participants affected / at risk	7/279 (2.51%)	5/89 (5.62%)
Vascular disorders		
Hypertension † 1		
# participants affected / at risk	22/279 (7.89%)	3/89 (3.37%)

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA 11.0

Limitations and Caveats

Hide Limitations and Caveats

Limitations of the study, such as early termination leading to small numbers of participants analyzed and technical problems with measurement leading to unreliable or uninterpretable data

No text entered.

More Information

Hide More Information

Certain Agreements:

Principal Investigators are **NOT** employed by the organization sponsoring the study.

There **IS** an agreement between Principal Investigators and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

The agreement is:

☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **less than or equal to 60 days**. The sponsor cannot require changes to the communication and cannot extend the embargo.

☑ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **more than 60 days but less than or equal to 180 days**. The sponsor cannot require changes to the communication and cannot extend the embargo.

☐ Other disclosure agreement that restricts the right of the PI to discuss or publish trial results after the trial is completed.

Results Point of Contact:

Name/Title: Director
Organization: Janssen-Virco BE
phone: 32 14 641418

Publications automatically indexed to this study by ClinicalTrials.gov Identifier (NCT Number):

Pozniak AL, Morales-Ramirez J, Katabira E, Steyn D, Lupo SH, Santoscoy M, Grinsztejn B, Ruxrungtham K, Rimsky LT, Vanveggel S, Boven K; TMC278-C204 Study Group. Efficacy and safety of TMC278 in antiretroviral-naive HIV-1 patients: week 96 results of a phase IIb randomized trial. AIDS. 2010 Jan 2;24(1):55-65. doi: 10.1097/QAD.0b013e32833032ed.

Responsible Party: Tibotec Pharmaceuticals, Ireland
ClinicalTrials.gov Identifier: NCT00110305 History of Changes
Obsolete Identifiers: NCT00980837

Other Study ID Numbers:	CR006760 **TMC278-C204** (Other Identifier: Tibotec Pharmaceuticals, Ireland) R278474-C204 (Other Identifier: Tibotec Pharmaceuticals, Ireland)
Study First Received:	May 5, 2005
Results First Received:	April 26, 2013
Last Updated:	June 11, 2014
Health Authority:	United States: Food and Drug Administration Great Britain: Medicines and Healthcare Products Regulatory Agency

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