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Trial record **1 of 1** for: TMC278-TIDP6-C209
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TMC278-TiDP6-C209: A Clinical Trial in Treatment Naive HIV-1 Patients Comparing TMC278 to Efavirenz in Combination With Tenofovir + Emtricitabine.

This study has been completed.

Sponsor:
Tibotec Pharmaceuticals, Ireland

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

ClinicalTrials.gov Identifier:
NCT00540449

First received: October 4, 2007
Last updated: March 1, 2016
Last verified: February 2016
History of Changes

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Results First Received: June 14, 2011

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
Conditions:	HIV Infections HIV-1 Human Immunodeficiency Virus Type 1
Interventions:	Drug: TMC278 Drug: Efavirenz

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
One hundred and twelve sites in 21 countries randomized participants. In total, 694 participants were randomized: four participants did not start treatment and 690 participants started treatment (346 in the TMC278 group and 344 in the efavirenz [control] group).

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
No text entered.

Reporting Groups

	Description
TMC278	25 milligram (mg) tablet once daily for 96 weeks.
Efavirenz	600 mg once daily for 96 weeks.

Participant Flow: Overall Study

	TMC278	Efavirenz
STARTED	**346**	**344**
COMPLETED	**262**	**266**
NOT COMPLETED	**84**	**78**
Adverse Event	**12**	**32**
Sponsor's Decision	**1**	**1**
Subject Ineligible To Continue The Trial	**2**	**1**
Lost to Follow-up	**19**	**17**
Subject Non-Compliant	**7**	**5**
Subject Reached A Virologic Endpoint	**32**	**8**
Withdrawal by Subject	**10**	**10**
Not specified	**1**	**4**

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.
The analysis population included intent to treat (ITT) population defined as all randomized participants who received at least one dose of the study medication.

Reporting Groups

	Description
TMC278	25 milligram (mg) tablet once daily for 96 weeks.
Efavirenz	600 mg once daily for 96 weeks.
Total	Total of all reporting groups

Baseline Measures

	TMC278	Efavirenz	Total
Number of Participants [units: participants]	**346**	**344**	**690**
Age [units: participants]			
<=18 years	**1**	**0**	**1**
Between 18 and 65 years	**343**	**343**	**686**
>=65 years	**2**	**1**	**3**
Age [units: years] Mean (Standard Deviation)	**37 (9.68)**	**36.7 (9.51)**	**36.8 (9.59)**
Gender [units: participants]			
Female	**78**	**69**	**147**
Male	**268**	**275**	**543**
Region Enroll			

[units: participants]			
Africa	32	31	63
Asia	47	51	98
Latin America	60	69	129
USA, Canada, Europe, Australia	207	193	400

Outcome Measures

Hide All Outcome Measures

1. Primary: Number of Participants With Virological Response (Intent-to-Treat - Time to Loss of Virologic Response [TLOVR], <50 Copies/ml) at Week 48 [Time Frame: Week 48]

Measure Type	Primary
Measure Title	Number of Participants With Virological Response (Intent-to-Treat - Time to Loss of Virologic Response [TLOVR], <50 Copies/ml) at Week 48
Measure Description	Virological response is defined as confirmed plasma viral load less than (<) 50 human immunodeficiency virus-1 (HIV-1) (ribonucleic acid [RNA]) copies/milliliter (ml) at Week 48. The TLOVR algorithm was used to derive response. Response needed to be confirmed at 2 consecutive visits and participants who permanently discontinued were considered nonresponders after discontinuation. Resuppression after confirmed virologic failure was considered as failure. Virologic Failure includes participants who were rebounder (confirmed viral load >= 50 copies/ml after being responder) or who were never suppressed (no confirmed viral load <50 copies/ml).
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.
The ITT analysis set was considered the primary efficacy analysis set.

Reporting Groups

	Description
TMC278	25 milligram (mg) tablet once daily for 96 weeks.
Efavirenz	600 mg once daily for 96 weeks.

Measured Values

	TMC278	Efavirenz
Number of Participants Analyzed [units: participants]	**346**	**344**
Number of Participants With Virological Response (Intent-to-Treat - Time to Loss of Virologic Response [TLOVR], <50 Copies/ml) at Week 48 [units: Participants]		
Responder	**287**	**285**
Virologic failure	**38**	**15**
Discontinued due to Adverse Event (AE)	**6**	**25**
Discontinued due to other reason than AE	**15**	**19**

Statistical Analysis 1 for Number of Participants With Virological Response (Intent-to-Treat - Time to Loss of Virologic Response [TLOVR], <50 Copies/ml) at Week 48

Groups [1]	All groups
Non-Inferiority/Equivalence Test [2]	Yes
Method [3]	Regression, Logistic
P Value [4]	<0.0001
Difference in proportion of response [5]	-0.4
95% Confidence Interval	-5.9 to 5.2

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	Assuming a response rate of 75% at 48 weeks for both treatment groups, 340 subjects were needed per treatment (TMC278 or EFV) to establish non-inferiority of TMC278 versus EFV with a maximum allowable difference of 12% and a 1-sided significance level of 2.5%, to yield 95% power.
[2]	Details of power calculation, definition of non-inferiority margin, and other key parameters:
	If the lower limit of the 95% 2-sided confidence interval of the difference in proportions (TMC278 – EFV) exceeds -12%, non-inferiority of TMC278 versus EFV can be concluded.
[3]	Other relevant method information, such as adjustments or degrees of freedom:
	Logistic regression model included treatment arm as factor and baseline (log10) viral load as covariate.
[4]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	Significance level was set at 2.5% (one-sided). No adjustment of p-value for multiple comparisons, since there was only single comparison for the primary endpoint.
[5]	Other relevant estimation information:
	Difference in proportion responders was estimated through the logistic regression model.

2. Secondary: The Number of Participants With Virological Response (Intent-to-Treat - Snapshot, <50 Copies/ml) at Week 48 [Time Frame: Week 48]

Measure Type	Secondary
Measure Title	The Number of Participants With Virological Response (Intent-to-Treat - Snapshot, <50 Copies/ml) at Week 48
Measure Description	The analysis is based on the last observed viral load (VL) data within the Week 48 window. Virologic response is defined as a VL<50 copies/ml (observed case). Missing VL was considered as non-response. Virologic Failure includes subjects who had VL>=50 copies/ml in the Wk48 window, subjects who discontinued early due to lack or loss of efficacy, subjects who discontinued for reasons other than an adverse event, death or lack or loss of efficacy and at the time of discontinuation had a VL>=50 copies/ml and subjects who had a switch in background regimen that was not permitted by the protocol.
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.
The ITT analysis set was considered the primary efficacy analysis set.

Reporting Groups

	Description
TMC278	25 milligram (mg) tablet once daily for 96 weeks.
Efavirenz	600 mg once daily for 96 weeks.

Measured Values

	TMC278	Efavirenz
Number of Participants Analyzed [units: participants]	**346**	**344**
The Number of Participants With Virological Response (Intent-to-Treat - Snapshot, <50 Copies/ml) at Week 48 [units: Participants]		
Virologic Response HIV RNA <50 copies/mL at Wk 48	**285**	**281**
Virologic Failure	**47**	**24**
No Viral Load Data in 48 week window	**14**	**39**

Statistical Analysis 1 for The Number of Participants With Virological Response (Intent-to-Treat - Snapshot, <50 Copies/ml) at Week 48

Groups [1]	All groups
Non-Inferiority/Equivalence Test [2]	Yes
Method [3]	Regression, Logistic
P Value [4]	<0.0001
Difference in proportion of response [5]	0.3
95% Confidence Interval	-5.4 to 5.9

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Details of power calculation, definition of non-inferiority margin, and other key parameters:
	If the lower limit of the 95% 2-sided confidence interval of the difference in proportions (TMC278 – EFV) exceeds -12%, non-inferiority of TMC278 versus EFV can be concluded.
[3]	Other relevant method information, such as adjustments or degrees of freedom:
	Logistic regression model included treatment arm as factor and baseline (log10) viral load as covariate.
[4]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[5]	Other relevant estimation information:
	Difference in proportion responders was estimated through the logistic regression model.

3. Secondary: Number of Participants With Virological Response (Intent-to-Treat - Time to Loss of Virologic Response [TLOVR], <50 Copies/ml) at Week 96 [Time Frame: Week 96]

Measure Type	Secondary
Measure Title	Number of Participants With Virological Response (Intent-to-Treat - Time to Loss of Virologic Response [TLOVR], <50 Copies/ml) at Week 96
Measure Description	No text entered.
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.
The ITT analysis set was considered the primary efficacy analysis set.

Reporting Groups

	Description
TMC278	25 milligram (mg) tablet once daily for 96 weeks.
Efavirenz	600 mg once daily for 96 weeks.

Measured Values

	TMC278	**Efavirenz**
Number of Participants Analyzed [units: participants]	**346**	**344**
Number of Participants With Virological Response (Intent-to-Treat - Time to Loss of Virologic Response [TLOVR], <50 Copies/ml) at Week 96 [units: Participants]		
Responder	**263**	**271**
Virologic failure	**45**	**16**
Death	**0**	**3**
Discontinued due to AE	**10**	**29**
Discontinued due to other reason than AE	**28**	**25**

Statistical Analysis 1 for Number of Participants With Virological Response (Intent-to-Treat - Time to Loss of Virologic Response [TLOVR], <50 Copies/ml) at Week 96

Groups [1]	All groups
Non-Inferiority/Equivalence Test [2]	Yes
Method [3]	Regression, Logistic
P Value [4]	0.0055
Difference in proportion of response [5]	-3.2
95% Confidence Interval	-9.4 to 3.1

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Details of power calculation, definition of non-inferiority margin, and other key parameters:
	If the lower limit of the 95% 2-sided confidence interval of the difference in proportions (TMC278 – EFV) exceeds -12%, non-inferiority of TMC278 versus EFV can be concluded.
[3]	Other relevant method information, such as adjustments or degrees of freedom:
	Logistic regression model included treatment arm as factor and baseline (log10) viral load as covariate.
[4]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:

	No text entered.
[5]	Other relevant estimation information:
	Difference in proportion responders was estimated through the logistic regression model.

4. Secondary: The Number of Participants With Virological Response (Intent-to-Treat - Snapshot, <50 Copies/ml) at Week 96 [Time Frame: Week 96]

Measure Type	Secondary
Measure Title	The Number of Participants With Virological Response (Intent-to-Treat - Snapshot, <50 Copies/ml) at Week 96
Measure Description	No text entered.
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.
The Intent-to-Treat analysis set was considered the primary efficacy analysis set.

Reporting Groups

	Description
TMC278	25 milligram (mg) tablet once daily for 96 weeks.
Efavirenz	600 mg once daily for 96 weeks.

Measured Values

	TMC278	Efavirenz
Number of Participants Analyzed [units: participants]	**346**	**344**
The Number of Participants With Virological Response (Intent-to-Treat - Snapshot, <50 Copies/ml) at Week 96 [units: Participants]		
Virologic Response, <50 copies/ml	**265**	**268**
Virologic failure	**54**	**27**
No viral load data in the 96 week window	**27**	**49**

Statistical Analysis 1 for The Number of Participants With Virological Response (Intent-to-Treat - Snapshot, <50 Copies/ml) at Week 96

Groups [1]	All groups
Non-Inferiority/Equivalence Test [2]	Yes
Method [3]	Regression, Logistic
P Value [4]	0.0013
Difference in proportion of response [5]	-1.7
95% Confidence Interval	-8.0 to 4.5

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

[2]	Details of power calculation, definition of non-inferiority margin, and other key parameters:
	If the lower limit of the 95% 2-sided confidence interval of the difference in proportions (TMC278 – EFV) exceeds -12%, non-inferiority of TMC278 versus EFV can be concluded.
[3]	Other relevant method information, such as adjustments or degrees of freedom:
	Logistic regression model included treatment arm as factor and baseline (log10) viral load as covariate.
[4]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[5]	Other relevant estimation information:
	No text entered.

5. Secondary: Number of Participants With Virological Response (Observed, <50 Copies/ml) at Last On-Treatment Visit (Post-Week 96). [Time Frame: Variable, ranging from 3 months up to maximum 15 months for TMC278 and 12 months for Efavirenz after the 96-week visit]

Measure Type	Secondary
Measure Title	Number of Participants With Virological Response (Observed, <50 Copies/ml) at Last On-Treatment Visit (Post-Week 96).
Measure Description	Virological response is defined as (observed) plasma viral load less than 50 human immunodeficiency virus-type 1 (HIV-1) ribonucleic acid (RNA) copies per ml at the last on-treatment visit (post-Week 96).
Time Frame	Variable, ranging from 3 months up to maximum 15 months for TMC278 and 12 months for Efavirenz after the 96-week visit
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.
Participants with at least 1 Post-Week 96 visit were included in the analysis.

Reporting Groups

	Description
TMC278	25 milligram (mg) tablet once daily for 96 weeks.
Efavirenz	600 mg once daily for 96 weeks.

Measured Values

	TMC278	Efavirenz
Number of Participants Analyzed [units: participants]	**258**	**271**
Number of Participants With Virological Response (Observed, <50 Copies/ml) at Last On-Treatment Visit (Post-Week 96). [units: Participants]	**245**	**261**

No statistical analysis provided for Number of Participants With Virological Response (Observed, <50 Copies/ml) at Last On-Treatment Visit (Post-Week 96).

6. Secondary: Number of Participants With Virological Response (Intent-to-Treat - Time to Loss of Virologic Response [TLOVR], <400

Copies/ml) at Week 48 [Time Frame: Week 48]

Measure Type	Secondary
Measure Title	Number of Participants With Virological Response (Intent-to-Treat - Time to Loss of Virologic Response [TLOVR], <400 Copies/ml) at Week 48
Measure Description	No text entered.
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.
The ITT analysis set was considered the primary efficacy analysis set.

Reporting Groups

	Description
TMC278	25 milligram (mg) tablet once daily for 96 weeks.
Efavirenz	600 mg once daily for 96 weeks.

Measured Values

	TMC278	**Efavirenz**
Number of Participants Analyzed [units: participants]	**346**	**344**
Number of Participants With Virological Response (Intent-to-Treat - Time to Loss of Virologic Response [TLOVR], <400 Copies/ml) at Week 48 [units: Participants]	**297**	**293**

No statistical analysis provided for Number of Participants With Virological Response (Intent-to-Treat - Time to Loss of Virologic Response [TLOVR], <400 Copies/ml) at Week 48

7. Secondary: Number of Participants With Virological Response (Intent-to-Treat - Time to Loss of Virologic Response [TLOVR], <400 Copies/ml) at Week 96 [Time Frame: Week 96]

Measure Type	Secondary
Measure Title	Number of Participants With Virological Response (Intent-to-Treat - Time to Loss of Virologic Response [TLOVR], <400 Copies/ml) at Week 96
Measure Description	No text entered.
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.
The ITT analysis set was considered the primary efficacy analysis set.

Reporting Groups

	Description

TMC278	25 milligram (mg) tablet once daily for 96 weeks.
Efavirenz	600 mg once daily for 96 weeks.

Measured Values

	TMC278	Efavirenz
Number of Participants Analyzed [units: participants]	**346**	**344**
Number of Participants With Virological Response (Intent-to-Treat - Time to Loss of Virologic Response [TLOVR], <400 Copies/ml) at Week 96 [units: Participants]	**273**	**278**

No statistical analysis provided for Number of Participants With Virological Response (Intent-to-Treat - Time to Loss of Virologic Response [TLOVR], <400 Copies/ml) at Week 96

8. Secondary: Mean Change From Baseline to Week 48 and Week 96 in Absolute and Relative CD4+ Cell Counts (Using Imputed Data) [Time Frame: Baseline, Week 48, and Week 96]

Measure Type	Secondary
Measure Title	Mean Change From Baseline to Week 48 and Week 96 in Absolute and Relative CD4+ Cell Counts (Using Imputed Data)
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, Week 48, and 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.
The ITT analysis set was considered the primary efficacy analysis set.

Reporting Groups

	Description
TMC278	25 milligram (mg) tablet once daily for 96 weeks.
Efavirenz	600 mg once daily for 96 weeks.

Measured Values

	TMC278	Efavirenz
Number of Participants Analyzed [units: participants]	**346**	**344**
Mean Change From Baseline to Week 48 and Week 96 in Absolute and Relative CD4+ Cell Counts (Using Imputed Data) [units: cells per microliter] Mean (Standard Deviation)		
Absolute cell count, Week 48	**195.5 (151.7)**	**181.6 (156.9)**
Absolute cell count, Week 96	**220.7 (167.1)**	**226.7 (188.9)**

Relative cell count, Week 48	**8.6 (5.8)**	**8.7 (6.0)**
Relative cell count, Week 96	**10.1 (7.5)**	**10.2 (7.2)**

No statistical analysis provided for Mean Change From Baseline to Week 48 and Week 96 in Absolute and Relative CD4+ Cell Counts (Using Imputed Data)

9. Secondary: Number of Participants With Virologic Failure for the Resistance Determination by Emerging Resistance Associated Mutations: First Available On-Treatment Genotypic Data After Failure [Time Frame: Week 96]

Measure Type	Secondary
Measure Title	Number of Participants With Virologic Failure for the Resistance Determination by Emerging Resistance Associated Mutations: First Available On-Treatment Genotypic Data After Failure
Measure Description	Virologic failure for the resistance determinations was defined as lack of virologic response (never having had 2 consecutive plasma viral load <50 copies/mL) and plasma viral load increase of >=0.5 log 10 copies/mL above nadir (i.e., never suppressed), or confirmed loss of virologic response (2 consecutive plasma viral load >=50 copies/mL after having had 2 consecutive plasma viral load <50 copies/mL; i.e., rebounder), or discontinued with a last observed on-treatment plasma viral load >=50 copies/mL after having had 2 consecutive plasma viral load <50 copies/mL. For this study, treatment-emergent reverse transcriptase (RT) resistance associated mutations (RAMs) occurring in at least 2 virologic failures (for at least one treatment group) for the following lists are presented: i) Extended list of Non-nucleoside reverse transcriptase inhibitor (NNRTI RAMs) ii) IAS-USA list of Nucleoside/tide reverse transcriptase inhibitor (N[t]RTI RAMs).
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.
The ITT analysis set was considered the primary efficacy analysis set. Here "N" (Number of Participants Analyzed) signifies number of Participants who were evaluable (had data) for this outcome measure.

Reporting Groups

	Description
TMC278	25 milligram (mg) tablet once daily for 96 weeks.
Efavirenz	600 mg once daily for 96 weeks.

Measured Values

	TMC278	**Efavirenz**
Number of Participants Analyzed [units: participants]	**52**	**18**
Number of Participants With Virologic Failure for the Resistance Determination by Emerging Resistance Associated Mutations: First Available On-Treatment Genotypic Data After Failure [units: Participants]		
Any RAM from Extended NNRTI RAMs list	**29**	**9**
NNRTI RAM: E138K	**18**	**0**
NNRTI RAM: K101E	**5**	**0**
NNRTI RAM: Y181C	**5**	**0**
NNRTI RAM: V90I	**4**	**0**

NNRTI RAM: V189I	**4**	**0**
NNRTI RAM: H221Y	**4**	**0**
NNRTI RAM: E138Q	**3**	**0**
NNRTI RAM: K103N	**1**	**8**
Any RAM from IAS-USA N(t)RTI RAMs list	**31**	**5**
N(t)RTI RAM: M184I	**24**	**3**
N(t)RTI RAM: M184V	**7**	**3**
N(t)RTI RAM: K065R	**3**	**0**
N(t)RTI RAM: K219E	**3**	**0**
N(t)RTI RAM: Y115F	**2**	**0**

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

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	Up to a maximum of 160 weeks for participants in the TMC278 treatment group and up to 147 weeks for participants in the efavirenz treatment group.
Additional Description	Only subjects who had at least one of the TEAEs listed in the Other (non Serious) AE table are included in the Total no. subjects with Non-Serious Adverse Events.

Reporting Groups

	Description
TMC278	25 milligram (mg) tablet once daily for 96 weeks.
Efavirenz	600 mg once daily for 96 weeks.

Serious Adverse Events

	TMC278	**Efavirenz**
Total, serious adverse events		
# participants affected / at risk	**40/346 (11.56%)**	**43/344 (12.50%)**
Blood and lymphatic system disorders		
Febrile neutropenia * 1		
# participants affected / at risk	**0/346 (0.00%)**	**1/344 (0.29%)**
Agranulocytosis * 1		
# participants affected / at risk	**1/346 (0.29%)**	**0/344 (0.00%)**
Splenic lesion * 1		
# participants affected / at risk	**1/346 (0.29%)**	**0/344 (0.00%)**
Cardiac disorders		
Atrial flutter * 1		
# participants affected / at risk	**0/346 (0.00%)**	**1/344 (0.29%)**
Tachycardia * 1		
# participants affected / at risk	**0/346 (0.00%)**	**1/344 (0.29%)**
Coronary artery disease * 1		

# participants affected / at risk	1/346 (0.29%)	0/344 (0.00%)
Congenital, familial and genetic disorders		
Thyroglossal cyst [*1]		
# participants affected / at risk	0/346 (0.00%)	1/344 (0.29%)
Pyloric stenosis [*1]		
# participants affected / at risk	1/346 (0.29%)	0/344 (0.00%)
Gastrointestinal disorders		
Haematemesis [*1]		
# participants affected / at risk	1/346 (0.29%)	0/344 (0.00%)
Peritoneal haemorrhage [*1]		
# participants affected / at risk	1/346 (0.29%)	0/344 (0.00%)
Anal inflammation [*1]		
# participants affected / at risk	0/346 (0.00%)	1/344 (0.29%)
Diarrhoea [*1]		
# participants affected / at risk	0/346 (0.00%)	1/344 (0.29%)
Gastrointestinal haemorrhage [*1]		
# participants affected / at risk	0/346 (0.00%)	1/344 (0.29%)
Nausea [*1]		
# participants affected / at risk	0/346 (0.00%)	1/344 (0.29%)
Vomiting [*1]		
# participants affected / at risk	0/346 (0.00%)	1/344 (0.29%)
Abdominal pain [*1]		
# participants affected / at risk	1/346 (0.29%)	0/344 (0.00%)
Anal fissure [*1]		
# participants affected / at risk	1/346 (0.29%)	0/344 (0.00%)
General disorders		
Chest pain [*1]		
# participants affected / at risk	1/346 (0.29%)	0/344 (0.00%)
Adverse drug reaction [*1]		
# participants affected / at risk	0/346 (0.00%)	1/344 (0.29%)
Pelvic mass [*1]		
# participants affected / at risk	0/346 (0.00%)	1/344 (0.29%)
Pyrexia [*1]		
# participants affected / at risk	0/346 (0.00%)	1/344 (0.29%)
Hepatobiliary disorders		
Cholecystitis acute [*1]		
# participants affected / at risk	1/346 (0.29%)	0/344 (0.00%)
Cholelithiasis [*1]		
# participants affected / at risk	1/346 (0.29%)	1/344 (0.29%)
Cholecystitis [*1]		
# participants affected / at risk	0/346 (0.00%)	1/344 (0.29%)
Liver disorder [*1]		
# participants affected / at risk	1/346 (0.29%)	0/344 (0.00%)
Immune system disorders		

Anaphylactic reaction [*1]		
# participants affected / at risk	**0/346 (0.00%)**	**1/344 (0.29%)**
Infections and infestations		
Abscess limb [*1]		
# participants affected / at risk	**1/346 (0.29%)**	**1/344 (0.29%)**
Anogenital warts [*1]		
# participants affected / at risk	**1/346 (0.29%)**	**0/344 (0.00%)**
Appendicitis [*1]		
# participants affected / at risk	**1/346 (0.29%)**	**0/344 (0.00%)**
Bacterial infection [*1]		
# participants affected / at risk	**1/346 (0.29%)**	**0/344 (0.00%)**
Bronchiectasis [*1]		
# participants affected / at risk	**1/346 (0.29%)**	**0/344 (0.00%)**
Cellulitis [*1]		
# participants affected / at risk	**2/346 (0.58%)**	**0/344 (0.00%)**
Diverticulitis [*1]		
# participants affected / at risk	**1/346 (0.29%)**	**0/344 (0.00%)**
Helicobacter gastritis [*1]		
# participants affected / at risk	**1/346 (0.29%)**	**0/344 (0.00%)**
Herpes zoster [*1]		
# participants affected / at risk	**1/346 (0.29%)**	**0/344 (0.00%)**
Lobar pneumonia [*1]		
# participants affected / at risk	**1/346 (0.29%)**	**0/344 (0.00%)**
Neurosyphilis [*1]		
# participants affected / at risk	**1/346 (0.29%)**	**0/344 (0.00%)**
Pneumonia [*1]		
# participants affected / at risk	**3/346 (0.87%)**	**2/344 (0.58%)**
Sepsis [*1]		
# participants affected / at risk	**1/346 (0.29%)**	**0/344 (0.00%)**
Syphilis [*1]		
# participants affected / at risk	**1/346 (0.29%)**	**0/344 (0.00%)**
Arthritis bacterial [*1]		
# participants affected / at risk	**0/346 (0.00%)**	**1/344 (0.29%)**
Bronchitis [*1]		
# participants affected / at risk	**0/346 (0.00%)**	**1/344 (0.29%)**
Cerebral toxoplasmosis [*1]		
# participants affected / at risk	**0/346 (0.00%)**	**1/344 (0.29%)**
Gastroenteritis [*1]		
# participants affected / at risk	**0/346 (0.00%)**	**1/344 (0.29%)**
Streptococcal bacteraemia [*1]		
# participants affected / at risk	**0/346 (0.00%)**	**1/344 (0.29%)**
Tuberculous pleurisy [*1]		
# participants affected / at risk	**0/346 (0.00%)**	**1/344 (0.29%)**
Upper respiratory tract infection [*1]		

# participants affected / at risk	0/346 (0.00%)	1/344 (0.29%)
Bone tuberculosis * 1		
# participants affected / at risk	1/346 (0.29%)	0/344 (0.00%)
Folliculitis * 1		
# participants affected / at risk	0/346 (0.00%)	1/344 (0.29%)
Meningococcal sepsis * 1		
# participants affected / at risk	0/346 (0.00%)	1/344 (0.29%)
Mycobacterium avium complex infection * 1		
# participants affected / at risk	1/346 (0.29%)	0/344 (0.00%)
Osteomyelitis * 1		
# participants affected / at risk	1/346 (0.29%)	0/344 (0.00%)
Papilloma viral infection * 1		
# participants affected / at risk	0/346 (0.00%)	1/344 (0.29%)
Respiratory tract infection * 1		
# participants affected / at risk	0/346 (0.00%)	1/344 (0.29%)
Tuberculosis * 1		
# participants affected / at risk	1/346 (0.29%)	0/344 (0.00%)
Injury, poisoning and procedural complications		
Alcohol poisoning * 1		
# participants affected / at risk	1/346 (0.29%)	0/344 (0.00%)
Overdose * 1		
# participants affected / at risk	1/346 (0.29%)	0/344 (0.00%)
Drug toxicity * 1		
# participants affected / at risk	0/346 (0.00%)	1/344 (0.29%)
Ankle fracture * 1		
# participants affected / at risk	1/346 (0.29%)	0/344 (0.00%)
Concussion * 1		
# participants affected / at risk	0/346 (0.00%)	1/344 (0.29%)
Facial bones fracture * 1		
# participants affected / at risk	0/346 (0.00%)	1/344 (0.29%)
Injury * 1		
# participants affected / at risk	1/346 (0.29%)	0/344 (0.00%)
Jaw fracture * 1		
# participants affected / at risk	0/346 (0.00%)	1/344 (0.29%)
Poisoning * 1		
# participants affected / at risk	1/346 (0.29%)	0/344 (0.00%)
Sternal fracture * 1		
# participants affected / at risk	1/346 (0.29%)	0/344 (0.00%)
Investigations		
Alanine aminotransferase increased * 1		
# participants affected / at risk	0/346 (0.00%)	2/344 (0.58%)
Aspartate aminotransferase increased * 1		
# participants affected / at risk	0/346 (0.00%)	1/344 (0.29%)
Blood alkaline phosphatase increased * 1		

# participants affected / at risk	0/346 (0.00%)	1/344 (0.29%)
Transaminases increased * 1		
# participants affected / at risk	0/346 (0.00%)	1/344 (0.29%)
Metabolism and nutrition disorders		
Anorexia * 1		
# participants affected / at risk	0/346 (0.00%)	1/344 (0.29%)
Musculoskeletal and connective tissue disorders		
Arthralgia * 1		
# participants affected / at risk	1/346 (0.29%)	0/344 (0.00%)
Joint swelling * 1		
# participants affected / at risk	1/346 (0.29%)	0/344 (0.00%)
Spondylitis * 1		
# participants affected / at risk	1/346 (0.29%)	0/344 (0.00%)
Back pain * 1		
# participants affected / at risk	0/346 (0.00%)	1/344 (0.29%)
Intervertebral disc protrusion * 1		
# participants affected / at risk	0/346 (0.00%)	1/344 (0.29%)
Spinal osteoarthritis * 1		
# participants affected / at risk	1/346 (0.29%)	0/344 (0.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
Bladder cancer * 1		
# participants affected / at risk	1/346 (0.29%)	0/344 (0.00%)
Haemangioma * 1		
# participants affected / at risk	1/346 (0.29%)	0/344 (0.00%)
Kaposi's sarcoma * 1		
# participants affected / at risk	1/346 (0.29%)	0/344 (0.00%)
Uterine leiomyoma * 1		
# participants affected / at risk	1/346 (0.29%)	1/344 (0.29%)
Anal cancer stage 0 * 1		
# participants affected / at risk	0/346 (0.00%)	1/344 (0.29%)
Burkitt's lymphoma * 1		
# participants affected / at risk	2/346 (0.58%)	2/344 (0.58%)
Anal cancer * 1		
# participants affected / at risk	0/346 (0.00%)	1/344 (0.29%)
Hepatic neoplasm * 1		
# participants affected / at risk	0/346 (0.00%)	1/344 (0.29%)
Hepatic neoplasm malignant * 1		
# participants affected / at risk	0/346 (0.00%)	1/344 (0.29%)
Nervous system disorders		
Miller fisher syndrome * 1		
# participants affected / at risk	1/346 (0.29%)	0/344 (0.00%)
Cerebral ischaemia * 1		
# participants affected / at risk	0/346 (0.00%)	1/344 (0.29%)
Cerebrovascular accident * 1		

# participants affected / at risk	0/346 (0.00%)	1/344 (0.29%)
Coma [*1]		
# participants affected / at risk	0/346 (0.00%)	1/344 (0.29%)
Headache [*1]		
# participants affected / at risk	1/346 (0.29%)	1/344 (0.29%)
Sciatica [*1]		
# participants affected / at risk	0/346 (0.00%)	1/344 (0.29%)
Psychiatric disorders		
Alcoholism [*1]		
# participants affected / at risk	1/346 (0.29%)	0/344 (0.00%)
Depression [*1]		
# participants affected / at risk	2/346 (0.58%)	2/344 (0.58%)
Drug dependence [*1]		
# participants affected / at risk	1/346 (0.29%)	0/344 (0.00%)
Major depression [*1]		
# participants affected / at risk	1/346 (0.29%)	0/344 (0.00%)
Suicide attempt [*1]		
# participants affected / at risk	1/346 (0.29%)	0/344 (0.00%)
Bipolar disorder [*1]		
# participants affected / at risk	0/346 (0.00%)	1/344 (0.29%)
Homicidal ideation [*1]		
# participants affected / at risk	1/346 (0.29%)	1/344 (0.29%)
Acute psychosis [*1]		
# participants affected / at risk	1/346 (0.29%)	0/344 (0.00%)
Panic attack [*1]		
# participants affected / at risk	0/346 (0.00%)	1/344 (0.29%)
Psychotic disorder [*1]		
# participants affected / at risk	0/346 (0.00%)	2/344 (0.58%)
Suicidal ideation [*1]		
# participants affected / at risk	3/346 (0.87%)	1/344 (0.29%)
Renal and urinary disorders		
Calculus ureteric [*1]		
# participants affected / at risk	1/346 (0.29%)	0/344 (0.00%)
Glomerulonephritis membranous [*1]		
# participants affected / at risk	1/346 (0.29%)	0/344 (0.00%)
Reproductive system and breast disorders		
Cystocele [*1]		
# participants affected / at risk	1/346 (0.29%)	0/344 (0.00%)
Uterovaginal prolapse [*1]		
# participants affected / at risk	1/346 (0.29%)	0/344 (0.00%)
Respiratory, thoracic and mediastinal disorders		
Asthma [*1]		
# participants affected / at risk	1/346 (0.29%)	0/344 (0.00%)

Dyspnoea * 1		
# participants affected / at risk	**0/346 (0.00%)**	**1/344 (0.29%)**
Pneumothorax * 1		
# participants affected / at risk	**1/346 (0.29%)**	**1/344 (0.29%)**
Pulmonary embolism * 1		
# participants affected / at risk	**0/346 (0.00%)**	**1/344 (0.29%)**
Asphyxia * 1		
# participants affected / at risk	**0/346 (0.00%)**	**1/344 (0.29%)**
Skin and subcutaneous tissue disorders		
Erythema * 1		
# participants affected / at risk	**1/346 (0.29%)**	**0/344 (0.00%)**
Rash generalised * 1		
# participants affected / at risk	**0/346 (0.00%)**	**1/344 (0.29%)**
Surgical and medical procedures		
Bowel preparation * 1		
# participants affected / at risk	**0/346 (0.00%)**	**1/344 (0.29%)**
Drug rehabilitation * 1		
# participants affected / at risk	**0/346 (0.00%)**	**1/344 (0.29%)**
Vascular disorders		
Circulatory collapse * 1		
# participants affected / at risk	**1/346 (0.29%)**	**0/344 (0.00%)**

* Events were collected by non-systematic assessment
1 Term from vocabulary, MedDRA 11.0

Other Adverse Events

Hide Other Adverse Events

Time Frame	Up to a maximum of 160 weeks for participants in the TMC278 treatment group and up to 147 weeks for participants in the efavirenz treatment group.
Additional Description	Only subjects who had at least one of the TEAEs listed in the Other (non Serious) AE table are included in the Total no. subjects with Non-Serious Adverse Events.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
TMC278	25 milligram (mg) tablet once daily for 96 weeks.
Efavirenz	600 mg once daily for 96 weeks.

Other Adverse Events

	TMC278	**Efavirenz**
Total, other (not including serious) adverse events		
# participants affected / at risk	**231/346 (66.76%)**	**268/344 (77.91%)**
Gastrointestinal disorders		

Nausea [*1]		
# participants affected / at risk	**44/346 (12.72%)**	**38/344 (11.05%)**
Diarrhoea [*1]		
# participants affected / at risk	**51/346 (14.74%)**	**61/344 (17.73%)**
Vomiting [*1]		
# participants affected / at risk	**15/346 (4.34%)**	**21/344 (6.10%)**
General disorders		
Fatigue [*1]		
# participants affected / at risk	**20/346 (5.78%)**	**31/344 (9.01%)**
Infections and infestations		
Upper respiratory tract infection [*1]		
# participants affected / at risk	**53/346 (15.32%)**	**51/344 (14.83%)**
Nasopharyngitis [*1]		
# participants affected / at risk	**45/346 (13.01%)**	**44/344 (12.79%)**
Influenza [*1]		
# participants affected / at risk	**37/346 (10.69%)**	**34/344 (9.88%)**
Syphilis [*1]		
# participants affected / at risk	**22/346 (6.36%)**	**15/344 (4.36%)**
Musculoskeletal and connective tissue disorders		
Arthralgia [*1]		
# participants affected / at risk	**15/346 (4.34%)**	**20/344 (5.81%)**
Back pain [*1]		
# participants affected / at risk	**23/346 (6.65%)**	**24/344 (6.98%)**
Nervous system disorders		
Headache [*1]		
# participants affected / at risk	**50/346 (14.45%)**	**44/344 (12.79%)**
Dizziness [*1]		
# participants affected / at risk	**28/346 (8.09%)**	**91/344 (26.45%)**
Somnolence [*1]		
# participants affected / at risk	**14/346 (4.05%)**	**24/344 (6.98%)**
Psychiatric disorders		
Abnormal dreams [*1]		
# participants affected / at risk	**29/346 (8.38%)**	**41/344 (11.92%)**
Insomnia [*1]		
# participants affected / at risk	**36/346 (10.40%)**	**39/344 (11.34%)**
Depression [*1]		
# participants affected / at risk	**25/346 (7.23%)**	**21/344 (6.10%)**
Anxiety [*1]		
# participants affected / at risk	**9/346 (2.60%)**	**27/344 (7.85%)**
Respiratory, thoracic and mediastinal disorders		
Cough [*1]		
# participants affected / at risk	**23/346 (6.65%)**	**20/344 (5.81%)**
Skin and subcutaneous tissue disorders		

Rash * 1		
# participants affected / at risk	**26/346 (7.51%)**	**42/344 (12.21%)**
Pruritus * 1		
# participants affected / at risk	**8/346 (2.31%)**	**18/344 (5.23%)**
Vascular disorders		
Hypertension * 1		
# participants affected / at risk	**21/346 (6.07%)**	**18/344 (5.23%)**

* Events were collected by non-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.

Restriction Description: No text entered.

Results Point of Contact:

Name/Title: Medical Leader
Organization: Janssen Infectious Diseases BVBA
e-mail: ClinicalTrialDisclosure@its.jnj.com

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

Rimsky L, Van Eygen V, Hoogstoel A, Stevens M, Boven K, Picchio G, Vingerhoets J. 96-Week resistance analyses of rilpivirine in treatment-naive, HIV-1-infected adults from the ECHO and THRIVE Phase III trials. Antivir Ther. 2013;18(8):967-77. doi: 10.3851/IMP2636. Epub 2013 May 28.

Nelson M, Amaya G, Clumeck N, Arns da Cunha C, Jayaweera D, Junod P, Li T, Tebas P, Stevens M, Buelens A, Vanveggel S, Boven K; ECHO and THRIVE Study Groups. Efficacy and safety of rilpivirine in treatment-naive, HIV-1-infected patients with hepatitis B virus/hepatitis C virus coinfection enrolled in the Phase III randomized, double-blind ECHO and THRIVE trials. J Antimicrob Chemother. 2012 Aug;67(8):2020-8. doi: 10.1093/jac/dks130. Epub 2012 Apr 24.

Molina JM, Cahn P, Grinsztejn B, Lazzarin A, Mills A, Saag M, Supparatpinyo K, Walmsley S, Crauwels H, Rimsky LT, Vanveggel S, Boven K;

ECHO study group. Rilpivirine versus efavirenz with tenofovir and emtricitabine in treatment-naive adults infected with HIV-1 (ECHO): a phase 3 randomised double-blind active-controlled trial. Lancet. 2011 Jul 16;378(9787):238-46. doi: 10.1016/S0140-6736(11)60936-7.

Responsible Party:	Tibotec Pharmaceuticals, Ireland
ClinicalTrials.gov Identifier:	NCT00540449 History of Changes
Obsolete Identifiers:	NCT00613639
Other Study ID Numbers:	CR002689 **TMC278-TIDP6-C209** (Other Identifier: Tibotec Pharmaceuticals, Ireland)
Study First Received:	October 4, 2007
Results First Received:	June 14, 2011
Last Updated:	March 1, 2016
Health Authority:	United States: Food and Drug Administration Ireland: Irish Agriculture and Food Development Authority Canada: Health Canada Great Britain: Medicines and Healthcare Products Regulatory Agency Taiwan: Department of Health Great Britain: Research Ethics Committee

Disclaimer

Information in this posting shall not be considered to be a claim for any marketed Product. Some information in this posting may differ from the approved labeling for the Product. Please refer to the full prescribing information for indications and proper use of the product.