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Trial record **1 of 1** for: TMC125-C217
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An Open-label Trial With TMC125 in Patients Who Have Virologically Failed in a DUET Trial (TMC125-C206 or TMC125-C216).

This study has been completed.

Sponsor:
Tibotec Pharmaceuticals, Ireland

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

ClinicalTrials.gov Identifier:
NCT00359021

First received: July 28, 2006
Last updated: May 6, 2014
Last verified: May 2014
History of Changes

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Results First Received: January 29, 2013

Study Type:	Interventional
Study Design:	Allocation: Non-Randomized; Endpoint Classification: Safety Study; Intervention Model: Single Group Assignment; Masking: Open Label; Primary Purpose: Treatment
Condition:	HIV-1
Intervention:	Drug: TMC125

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
No text entered.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
Participants with human immunodeficiency virus – type 1 (HIV-1) infection were enrolled in this study from DUET Study TMC125-C206 or TMC125-C216 and met the definition of virologic failure at Week 24 or later in these studies, or who completed one of the DUET studies after 96 weeks of treatment.

Reporting Groups

	Description
DUET PLACEBO	Participants who received Placebo in a previous DUET study and received open-label treatment with 200 mg twice daily etravirine, also known as TMC125 (ETR) and 600/100 mg twice daily darunavir (DRV)/low-dose ritonavir (rtv) were referred to as ETR-naïve participants.
DUET TMC125	Participants who received etravirine, also known as TMC125 (ETR) in a previous DUET study and received open-label treatment with 200 mg twice daily ETR and 600/100 mg twice daily darunavir (DRV)/low-dose ritonavir (rtv) were referred to as ETR-experienced participants.

Participant Flow: Overall Study

	DUET PLACEBO	DUET TMC125
STARTED	256	247
COMPLETED	175	195
NOT COMPLETED	81	52
Adverse Event	26	8
Subject Non-Compliant	1	2
Subject Ineligible To Continue The Trial	1	0
Subject Reached A Virologic Endpoint	45	32
Withdrawal by Subject	2	9
Lost to Follow-up	1	0
Not specified	4	1
Pregnancy	1	0

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
DUET PLACEBO	Participants who received Placebo in a previous DUET study and received open-label treatment with 200 mg twice daily etravirine, also known as TMC125 (ETR) and 600/100 mg twice daily darunavir (DRV)/low-dose ritonavir (rtv) were referred to as ETR-naïve participants.
DUET TMC125	Participants who received etravirine, also known as TMC125 (ETR) in a previous DUET study and received open-label treatment with 200 mg twice daily ETR and 600/100 mg twice daily darunavir (DRV)/low-dose ritonavir (rtv) were referred to as ETR-experienced participants.
Total	Total of all reporting groups

Baseline Measures

	DUET PLACEBO	DUET TMC125	Total
Number of Participants [units: participants]	256	247	503
Age [units: participants]			
<=18 years	0	0	0
Between 18 and 65 years	252	245	497
>=65 years	4	2	6
Age [units: years] Mean (Standard Deviation)	46.9 (8.28)	46.6 (7.01)	46.7 (7.68)
Gender [units: participants]			
Female	27	37	64

Male	**229**	**210**	**439**

Outcome Measures

Hide All Outcome Measures

1. Primary: The Number of Participants Experiencing Adverse Events [Time Frame: 1 week to 180 weeks, with a median of 62 weeks]

Measure Type	Primary
Measure Title	The Number of Participants Experiencing Adverse Events
Measure Description	The table below provides the number of participants who experienced Serious Adverse Events (SAEs) and Other Adverse Events (except SAEs) that started or worsened in severity during the overall TMC125-C217 treatment period. The duration of treatment ranged per patient from 1 week to 180 weeks, with a median of 62 weeks.
Time Frame	1 week to 180 weeks, with a median of 62 weeks
Safety Issue	Yes

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 safety analysis was carried out on the ITT population, which included all participants who received at least one dose of investigational medication.

Reporting Groups

	Description
DUET PLACEBO	Participants who received Placebo in a previous DUET study received open-label treatment with 200 mg twice daily etravirine, also known as TMC125 (ETR) and 600/100 mg twice daily darunavir (DRV)/low-dose ritonavir (rtv) were referred to as ETR-naïve participants.
DUET TMC125	Participants who received etravirine, also known as TMC125 (ETR) in a previous DUET study and received open-label treatment with 200 mg twice daily ETR and 600/100 mg twice daily darunavir (DRV)/low-dose ritonavir (rtv) were referred to as ETR-experienced participants.
All Participants	DUET Placebo + DUET TMC125

Measured Values

	DUET PLACEBO	**DUET TMC125**	**All Participants**
Number of Participants Analyzed [units: participants]	**256**	**247**	**503**
The Number of Participants Experiencing Adverse Events [units: Participants]			
Serious Adverse Events (SAEs)	**46**	**42**	**88**
Other Adverse Events (AEs)	**160**	**137**	**297**

No statistical analysis provided for The Number of Participants Experiencing Adverse Events

2. Secondary: The Percentage of Participants With Virologic Outcomes Over Time [Time Frame: Weeks 24, 48, and 96]

Measure Type	Secondary
Measure Title	The Percentage of Participants With Virologic Outcomes Over Time
Measure Description	The table below shows the percentage of participants with virologic suppression (< 50 copies/mL), the percentage of

	participants who were virologic failures (VF) (>50 copies/mL, discontinued prior to time X for reasons of VF or for other reasons, except for VF or adverse event, with a last viral load >50 copies/mL), and the percentage of participants with no viral load (VL) data available over time (ie, at Weeks 24, 48, and 96).
Time Frame	Weeks 24, 48, and 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 (ITT) population was used as the primary analysis population for the efficacy analysis and included all participants who took at least one dose of etravirine (ETR) (also known as TMC125) in the TMC125-C217 study.

Reporting Groups

	Description
DUET PLACEBO	Participants who received Placebo in a previous DUET study received open-label treatment with 200 mg twice daily etravirine, also known as TMC125 (ETR) and 600/100 mg twice daily darunavir (DRV)/low-dose ritonavir (rtv) were referred to as ETR-naïve participants.
DUET TMC125	Participants who received etravirine, also known as TMC125 (ETR) in a previous DUET study and received open-label treatment with 200 mg twice daily ETR and 600/100 mg twice daily darunavir (DRV)/low-dose ritonavir (rtv) were referred to as ETR-experienced participants.

Measured Values

	DUET PLACEBO	**DUET TMC125**
Number of Participants Analyzed [units: participants]	**256**	**247**
The Percentage of Participants With Virologic Outcomes Over Time [units: Percentage of Participants]		
Week 24 - Virologic Response (<50 cop/mL)	**43.0**	**62.3**
Week 24 - Virologic Failure	**46.9**	**31.6**
Week 24 - No VL Data available	**10.2**	**6.1**
Week 48 - Virologic Response (<50 cop/mL)	**35.2**	**44.5**
Week 48 - Virologic Failure	**50.4**	**31.2**
Week 48 - No VL Data available	**14.5**	**24.3**
Week 96 -Virologic Response (<50 cop/mL)	**7.4**	**4.5**
Week 96 - Virologic Failure	**48.0**	**27.5**
Week 96 - No VL Data available	**44.5**	**68.0**

No statistical analysis provided for The Percentage of Participants With Virologic Outcomes Over Time

3. Secondary: Change in Plasma Viral Load Versus Baseline (ie, Mean Change in log10 Plasma Viral Load From Baseline Over Time) [Time Frame: Baseline, Week 24, Week 48, and Week 96]

Measure Type	Secondary
Measure Title	Change in Plasma Viral Load Versus Baseline (ie, Mean Change in log10 Plasma Viral Load From Baseline Over Time)
Measure Description	In the table below, the total number of participants analyzed in the Duet Placebo and Duet TMC125 groups, respectively at each time point were: Baseline (256;247 participants), Week 24 (251;240 participants), Week 48 (235;192 participants), and Week 96 (123;69 participants).

Time Frame	Baseline, Week 24, 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 intent-to-treat (ITT) population was used as the primary analysis population for the efficacy analysis and included all participants who took at least one dose of etravirine (ETR) (also known as TMC125) in the TMC125-C217 study.

Reporting Groups

	Description
DUET PLACEBO	Participants who received Placebo in a previous DUET study received open-label treatment with 200 mg twice daily etravirine, also known as TMC125 (ETR) and 600/100 mg twice daily darunavir (DRV)/low-dose ritonavir (rtv) were referred to as ETR-naïve participants.
DUET TMC125	Participants who received etravirine, also known as TMC125 (ETR) in a previous DUET study and received open-label treatment with 200 mg twice daily ETR and 600/100 mg twice daily darunavir (DRV)/low-dose ritonavir (rtv) were referred to as ETR-experienced participants.

Measured Values

	DUET PLACEBO	DUET TMC125
Number of Participants Analyzed [units: participants]	**256**	**247**
Change in Plasma Viral Load Versus Baseline (ie, Mean Change in log10 Plasma Viral Load From Baseline Over Time) [units: log10 copies/mL] Mean (95% Confidence Interval)		
Week 24	**-0.8 (-0.93 to -0.63)**	**0 (-0.11 to 0.03)**
Week 48	**-0.7 (-0.86 to -0.54)**	**-0.1 (-0.16 to -0.02)**
Week 96	**-0.5 (-0.66 to -0.30)**	**-0.2 (-0.38 to -0.04)**

No statistical analysis provided for Change in Plasma Viral Load Versus Baseline (ie, Mean Change in log10 Plasma Viral Load From Baseline Over Time)

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	07-Jun-2006 to 24-Jan-2012.
Additional Description	All "Serious Adverse Events (SAEs)" emerging during the TMC125-C217 treatment period are reported below; "Other Adverse Events (not including SAEs)" provided below occurred in at least 0.5% of participants. The duration of the TMC125 treatment period ranged per patient from 1 week to 180 weeks, with a median of 62 weeks.

Reporting Groups

	Description

DUET PLACEBO	Participants who received Placebo in a previous DUET study and received open-label treatment with 200 mg twice daily etravirine, also known as TMC125 (ETR) and 600/100 mg twice daily darunavir (DRV)/low-dose ritonavir (rtv) were referred to as ETR-naïve participants.
DUET TMC125	Participants who received etravirine, also known as TMC125 (ETR) in a previous DUET study and received open-label treatment with 200 mg twice daily ETR and 600/100 mg twice daily darunavir (DRV)/low-dose ritonavir (rtv) were referred to as ETR-experienced participants.
All Participants	Participants who received placebo or TMC125 in a previous DUET study (DUET Placebo + DUET TMC125).

Serious Adverse Events

	DUET PLACEBO	DUET TMC125	All Participants
Total, serious adverse events			
# participants affected / at risk	**46/256 (17.97%)**	**42/247 (17.00%)**	**88/503 (17.50%)**
Blood and lymphatic system disorders			
Anaemia [*1]			
# participants affected / at risk	**2/256 (0.78%)**	**2/247 (0.81%)**	**4/503 (0.80%)**
Febrile bone marrow aplasia [*1]			
# participants affected / at risk	**1/256 (0.39%)**	**0/247 (0.00%)**	**1/503 (0.20%)**
Febrile neutropenia [*1]			
# participants affected / at risk	**2/256 (0.78%)**	**0/247 (0.00%)**	**2/503 (0.40%)**
Haemorrhagic diathesis [*1]			
# participants affected / at risk	**0/256 (0.00%)**	**1/247 (0.40%)**	**1/503 (0.20%)**
Pancytopenia [*1]			
# participants affected / at risk	**0/256 (0.00%)**	**1/247 (0.40%)**	**1/503 (0.20%)**
Thrombocytopenia [*1]			
# participants affected / at risk	**0/256 (0.00%)**	**1/247 (0.40%)**	**1/503 (0.20%)**
Thrombotic thrombocytopenic purpura [*1]			
# participants affected / at risk	**0/256 (0.00%)**	**1/247 (0.40%)**	**1/503 (0.20%)**
Cardiac disorders			
Angina unstable [*1]			
# participants affected / at risk	**0/256 (0.00%)**	**1/247 (0.40%)**	**1/503 (0.20%)**
Atrial fibrillation [*1]			
# participants affected / at risk	**0/256 (0.00%)**	**1/247 (0.40%)**	**1/503 (0.20%)**
Atrial flutter [*1]			
# participants affected / at risk	**1/256 (0.39%)**	**0/247 (0.00%)**	**1/503 (0.20%)**
Bradycardia [*1]			
# participants affected / at risk	**1/256 (0.39%)**	**0/247 (0.00%)**	**1/503 (0.20%)**
Cardiac failure [*1]			
# participants affected / at risk	**0/256 (0.00%)**	**1/247 (0.40%)**	**1/503 (0.20%)**
Cardio-respiratory arrest [*1]			
# participants affected / at risk	**1/256 (0.39%)**	**0/247 (0.00%)**	**1/503 (0.20%)**
Cardiopulmonary failure [*1]			
# participants affected / at risk	**1/256 (0.39%)**	**0/247 (0.00%)**	**1/503 (0.20%)**
Coronary artery disease [*1]			
# participants affected / at risk	**0/256 (0.00%)**	**1/247 (0.40%)**	**1/503 (0.20%)**
Coronary artery occlusion [*1]			

# participants affected / at risk	0/256 (0.00%)	1/247 (0.40%)	1/503 (0.20%)
Myocardial infarction * 1			
# participants affected / at risk	2/256 (0.78%)	2/247 (0.81%)	4/503 (0.80%)
Pericarditis * 1			
# participants affected / at risk	1/256 (0.39%)	0/247 (0.00%)	1/503 (0.20%)
Gastrointestinal disorders			
Abdominal pain * 1			
# participants affected / at risk	1/256 (0.39%)	0/247 (0.00%)	1/503 (0.20%)
Ascites * 1			
# participants affected / at risk	1/256 (0.39%)	0/247 (0.00%)	1/503 (0.20%)
Colitis * 1			
# participants affected / at risk	1/256 (0.39%)	0/247 (0.00%)	1/503 (0.20%)
Diarrhoea * 1			
# participants affected / at risk	1/256 (0.39%)	0/247 (0.00%)	1/503 (0.20%)
Dysphagia * 1			
# participants affected / at risk	0/256 (0.00%)	1/247 (0.40%)	1/503 (0.20%)
Eructation * 1			
# participants affected / at risk	0/256 (0.00%)	1/247 (0.40%)	1/503 (0.20%)
Gastric ulcer * 1			
# participants affected / at risk	0/256 (0.00%)	1/247 (0.40%)	1/503 (0.20%)
Haematemesis * 1			
# participants affected / at risk	1/256 (0.39%)	0/247 (0.00%)	1/503 (0.20%)
Haemorrhoids * 1			
# participants affected / at risk	1/256 (0.39%)	0/247 (0.00%)	1/503 (0.20%)
Hernial eventration * 1			
# participants affected / at risk	0/256 (0.00%)	1/247 (0.40%)	1/503 (0.20%)
Intestinal polyp * 1			
# participants affected / at risk	1/256 (0.39%)	0/247 (0.00%)	1/503 (0.20%)
Mesenteric vein thrombosis * 1			
# participants affected / at risk	1/256 (0.39%)	0/247 (0.00%)	1/503 (0.20%)
Pancreatitis * 1			
# participants affected / at risk	1/256 (0.39%)	0/247 (0.00%)	1/503 (0.20%)
Proctitis * 1			
# participants affected / at risk	1/256 (0.39%)	0/247 (0.00%)	1/503 (0.20%)
Rectal ulcer * 1			
# participants affected / at risk	1/256 (0.39%)	0/247 (0.00%)	1/503 (0.20%)
Subileus * 1			
# participants affected / at risk	1/256 (0.39%)	0/247 (0.00%)	1/503 (0.20%)
General disorders			
Asthenia * 1			
# participants affected / at risk	2/256 (0.78%)	0/247 (0.00%)	2/503 (0.40%)
Non-cardiac chest pain * 1			
# participants affected / at risk	1/256 (0.39%)	1/247 (0.40%)	2/503 (0.40%)
Oedema peripheral * 1			

# participants affected / at risk	1/256 (0.39%)	0/247 (0.00%)	1/503 (0.20%)
Pyrexia [*1]			
# participants affected / at risk	0/256 (0.00%)	1/247 (0.40%)	1/503 (0.20%)
Hepatobiliary disorders			
Chronic hepatic failure [*1]			
# participants affected / at risk	1/256 (0.39%)	0/247 (0.00%)	1/503 (0.20%)
Immune system disorders			
Drug hypersensitivity [*1]			
# participants affected / at risk	1/256 (0.39%)	0/247 (0.00%)	1/503 (0.20%)
Infections and infestations			
Anal abscess [*1]			
# participants affected / at risk	1/256 (0.39%)	0/247 (0.00%)	1/503 (0.20%)
Appendicitis [*1]			
# participants affected / at risk	1/256 (0.39%)	1/247 (0.40%)	2/503 (0.40%)
Bronchopneumonia [*1]			
# participants affected / at risk	1/256 (0.39%)	0/247 (0.00%)	1/503 (0.20%)
Cellulitis [*1]			
# participants affected / at risk	3/256 (1.17%)	0/247 (0.00%)	3/503 (0.60%)
Cerebral toxoplasmosis [*1]			
# participants affected / at risk	1/256 (0.39%)	1/247 (0.40%)	2/503 (0.40%)
Clostridium difficile colitis [*1]			
# participants affected / at risk	1/256 (0.39%)	0/247 (0.00%)	1/503 (0.20%)
Cryptococcosis [*1]			
# participants affected / at risk	1/256 (0.39%)	0/247 (0.00%)	1/503 (0.20%)
Cytomegalovirus chorioretinitis [*1]			
# participants affected / at risk	1/256 (0.39%)	1/247 (0.40%)	2/503 (0.40%)
Cytomegalovirus colitis [*1]			
# participants affected / at risk	1/256 (0.39%)	0/247 (0.00%)	1/503 (0.20%)
Cytomegalovirus infection [*1]			
# participants affected / at risk	1/256 (0.39%)	0/247 (0.00%)	1/503 (0.20%)
Cytomegalovirus myelomeningoradiculitis [*1]			
# participants affected / at risk	1/256 (0.39%)	0/247 (0.00%)	1/503 (0.20%)
Gastroenteritis [*1]			
# participants affected / at risk	2/256 (0.78%)	2/247 (0.81%)	4/503 (0.80%)
HIV infection [*1]			
# participants affected / at risk	0/256 (0.00%)	1/247 (0.40%)	1/503 (0.20%)
Hepatitis c [*1]			
# participants affected / at risk	0/256 (0.00%)	1/247 (0.40%)	1/503 (0.20%)
Herpes simplex [*1]			
# participants affected / at risk	0/256 (0.00%)	1/247 (0.40%)	1/503 (0.20%)
Herpes zoster [*1]			
# participants affected / at risk	1/256 (0.39%)	0/247 (0.00%)	1/503 (0.20%)
Histoplasmosis [*1]			
# participants affected / at risk	1/256 (0.39%)	0/247 (0.00%)	1/503 (0.20%)

Histoplasmosis disseminated [*1]			
# participants affected / at risk	**1/256 (0.39%)**	**0/247 (0.00%)**	**1/503 (0.20%)**
Keratitis fungal [*1]			
# participants affected / at risk	**1/256 (0.39%)**	**0/247 (0.00%)**	**1/503 (0.20%)**
Localised infection [*1]			
# participants affected / at risk	**1/256 (0.39%)**	**0/247 (0.00%)**	**1/503 (0.20%)**
Meningitis [*1]			
# participants affected / at risk	**1/256 (0.39%)**	**0/247 (0.00%)**	**1/503 (0.20%)**
Mycobacterium avium complex infection [*1]			
# participants affected / at risk	**0/256 (0.00%)**	**1/247 (0.40%)**	**1/503 (0.20%)**
Oesophageal candidiasis [*1]			
# participants affected / at risk	**1/256 (0.39%)**	**0/247 (0.00%)**	**1/503 (0.20%)**
Oral candidiasis [*1]			
# participants affected / at risk	**1/256 (0.39%)**	**0/247 (0.00%)**	**1/503 (0.20%)**
Papilloma viral infection [*1]			
# participants affected / at risk	**1/256 (0.39%)**	**0/247 (0.00%)**	**1/503 (0.20%)**
Pneumocystis jiroveci pneumonia [*1]			
# participants affected / at risk	**3/256 (1.17%)**	**0/247 (0.00%)**	**3/503 (0.60%)**
Pneumonia [*1]			
# participants affected / at risk	**5/256 (1.95%)**	**4/247 (1.62%)**	**9/503 (1.79%)**
Pneumonia influenzal [*1]			
# participants affected / at risk	**0/256 (0.00%)**	**1/247 (0.40%)**	**1/503 (0.20%)**
Postoperative wound infection [*1]			
# participants affected / at risk	**0/256 (0.00%)**	**1/247 (0.40%)**	**1/503 (0.20%)**
Pyomyositis [*1]			
# participants affected / at risk	**1/256 (0.39%)**	**0/247 (0.00%)**	**1/503 (0.20%)**
Pyothorax [*1]			
# participants affected / at risk	**1/256 (0.39%)**	**0/247 (0.00%)**	**1/503 (0.20%)**
Scrotal abscess [*1]			
# participants affected / at risk	**0/256 (0.00%)**	**1/247 (0.40%)**	**1/503 (0.20%)**
Sepsis [*1]			
# participants affected / at risk	**2/256 (0.78%)**	**2/247 (0.81%)**	**4/503 (0.80%)**
Staphylococcal bacteraemia [*1]			
# participants affected / at risk	**1/256 (0.39%)**	**0/247 (0.00%)**	**1/503 (0.20%)**
Staphylococcal sepsis [*1]			
# participants affected / at risk	**1/256 (0.39%)**	**0/247 (0.00%)**	**1/503 (0.20%)**
Strongyloidiasis [*1]			
# participants affected / at risk	**1/256 (0.39%)**	**0/247 (0.00%)**	**1/503 (0.20%)**
Tuberculosis of central nervous system [*1]			
# participants affected / at risk	**1/256 (0.39%)**	**0/247 (0.00%)**	**1/503 (0.20%)**
Urinary tract infection [*1]			
# participants affected / at risk	**1/256 (0.39%)**	**0/247 (0.00%)**	**1/503 (0.20%)**
Urinary tract infection fungal [*1]			
# participants affected / at risk	**1/256 (0.39%)**	**0/247 (0.00%)**	**1/503 (0.20%)**

Injury, poisoning and procedural complications			
Subdural haematoma [*1]			
# participants affected / at risk	**1/256 (0.39%)**	**0/247 (0.00%)**	**1/503 (0.20%)**
Wrist fracture [*1]			
# participants affected / at risk	**1/256 (0.39%)**	**0/247 (0.00%)**	**1/503 (0.20%)**
Investigations			
Arteriogram coronary [*1]			
# participants affected / at risk	**1/256 (0.39%)**	**0/247 (0.00%)**	**1/503 (0.20%)**
Blood amylase increased [*1]			
# participants affected / at risk	**0/256 (0.00%)**	**1/247 (0.40%)**	**1/503 (0.20%)**
Blood creatinine increased [*1]			
# participants affected / at risk	**0/256 (0.00%)**	**1/247 (0.40%)**	**1/503 (0.20%)**
Haemoglobin decreased [*1]			
# participants affected / at risk	**0/256 (0.00%)**	**1/247 (0.40%)**	**1/503 (0.20%)**
Lipase increased [*1]			
# participants affected / at risk	**0/256 (0.00%)**	**1/247 (0.40%)**	**1/503 (0.20%)**
Weight decreased [*1]			
# participants affected / at risk	**0/256 (0.00%)**	**1/247 (0.40%)**	**1/503 (0.20%)**
Metabolism and nutrition disorders			
Dehydration [*1]			
# participants affected / at risk	**2/256 (0.78%)**	**1/247 (0.40%)**	**3/503 (0.60%)**
Gout [*1]			
# participants affected / at risk	**1/256 (0.39%)**	**0/247 (0.00%)**	**1/503 (0.20%)**
Hypertriglyceridaemia [*1]			
# participants affected / at risk	**1/256 (0.39%)**	**0/247 (0.00%)**	**1/503 (0.20%)**
Hypokalaemia [*1]			
# participants affected / at risk	**1/256 (0.39%)**	**0/247 (0.00%)**	**1/503 (0.20%)**
Hyponatraemia [*1]			
# participants affected / at risk	**1/256 (0.39%)**	**0/247 (0.00%)**	**1/503 (0.20%)**
Musculoskeletal and connective tissue disorders			
Arthralgia [*1]			
# participants affected / at risk	**1/256 (0.39%)**	**0/247 (0.00%)**	**1/503 (0.20%)**
Back pain [*1]			
# participants affected / at risk	**0/256 (0.00%)**	**1/247 (0.40%)**	**1/503 (0.20%)**
Muscular weakness [*1]			
# participants affected / at risk	**0/256 (0.00%)**	**1/247 (0.40%)**	**1/503 (0.20%)**
Osteoarthritis [*1]			
# participants affected / at risk	**0/256 (0.00%)**	**1/247 (0.40%)**	**1/503 (0.20%)**
Osteonecrosis [*1]			
# participants affected / at risk	**1/256 (0.39%)**	**2/247 (0.81%)**	**3/503 (0.60%)**
Osteoporosis [*1]			
# participants affected / at risk	**0/256 (0.00%)**	**1/247 (0.40%)**	**1/503 (0.20%)**
Pain in extremity [*1]			
# participants affected / at risk	**0/256 (0.00%)**	**1/247 (0.40%)**	**1/503 (0.20%)**

Pathological fracture [*1]			
# participants affected / at risk	**0/256 (0.00%)**	**1/247 (0.40%)**	**1/503 (0.20%)**
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Anal cancer [*1]			
# participants affected / at risk	**0/256 (0.00%)**	**1/247 (0.40%)**	**1/503 (0.20%)**
Female reproductive tract carcinoma in situ [*1]			
# participants affected / at risk	**0/256 (0.00%)**	**1/247 (0.40%)**	**1/503 (0.20%)**
Haemangioma of liver [*1]			
# participants affected / at risk	**1/256 (0.39%)**	**0/247 (0.00%)**	**1/503 (0.20%)**
Hodgkin's disease [*1]			
# participants affected / at risk	**0/256 (0.00%)**	**2/247 (0.81%)**	**2/503 (0.40%)**
Lymphoma [*1]			
# participants affected / at risk	**1/256 (0.39%)**	**0/247 (0.00%)**	**1/503 (0.20%)**
Squamous cell carcinoma [*1]			
# participants affected / at risk	**1/256 (0.39%)**	**0/247 (0.00%)**	**1/503 (0.20%)**
Uterine leiomyoma [*1]			
# participants affected / at risk	**0/256 (0.00%)**	**1/247 (0.40%)**	**1/503 (0.20%)**
Nervous system disorders			
Cerebrovascular accident [*1]			
# participants affected / at risk	**0/256 (0.00%)**	**1/247 (0.40%)**	**1/503 (0.20%)**
Coma [*1]			
# participants affected / at risk	**0/256 (0.00%)**	**1/247 (0.40%)**	**1/503 (0.20%)**
Dementia [*1]			
# participants affected / at risk	**0/256 (0.00%)**	**1/247 (0.40%)**	**1/503 (0.20%)**
Hypoaesthesia [*1]			
# participants affected / at risk	**0/256 (0.00%)**	**1/247 (0.40%)**	**1/503 (0.20%)**
Lacunar infarction [*1]			
# participants affected / at risk	**0/256 (0.00%)**	**1/247 (0.40%)**	**1/503 (0.20%)**
Post herpetic neuralgia [*1]			
# participants affected / at risk	**1/256 (0.39%)**	**0/247 (0.00%)**	**1/503 (0.20%)**
Transient ischaemic attack [*1]			
# participants affected / at risk	**1/256 (0.39%)**	**0/247 (0.00%)**	**1/503 (0.20%)**
Psychiatric disorders			
Confusional state [*1]			
# participants affected / at risk	**1/256 (0.39%)**	**0/247 (0.00%)**	**1/503 (0.20%)**
Depression [*1]			
# participants affected / at risk	**0/256 (0.00%)**	**1/247 (0.40%)**	**1/503 (0.20%)**
Generalised anxiety disorder [*1]			
# participants affected / at risk	**0/256 (0.00%)**	**1/247 (0.40%)**	**1/503 (0.20%)**
Major depression [*1]			
# participants affected / at risk	**0/256 (0.00%)**	**1/247 (0.40%)**	**1/503 (0.20%)**
Mood disorder due to a general medical condition [*1]			
# participants affected / at risk	**0/256 (0.00%)**	**1/247 (0.40%)**	**1/503 (0.20%)**

Psychotic disorder * 1			
# participants affected / at risk	**0/256 (0.00%)**	**1/247 (0.40%)**	**1/503 (0.20%)**
Renal and urinary disorders			
Renal failure * 1			
# participants affected / at risk	**2/256 (0.78%)**	**0/247 (0.00%)**	**2/503 (0.40%)**
Renal failure acute * 1			
# participants affected / at risk	**1/256 (0.39%)**	**2/247 (0.81%)**	**3/503 (0.60%)**
Renal impairment * 1			
# participants affected / at risk	**1/256 (0.39%)**	**0/247 (0.00%)**	**1/503 (0.20%)**
Reproductive system and breast disorders			
Cervical dysplasia * 1			
# participants affected / at risk	**0/256 (0.00%)**	**1/247 (0.40%)**	**1/503 (0.20%)**
Respiratory, thoracic and mediastinal disorders			
Cough * 1			
# participants affected / at risk	**1/256 (0.39%)**	**0/247 (0.00%)**	**1/503 (0.20%)**
Skin and subcutaneous tissue disorders			
Night sweats * 1			
# participants affected / at risk	**1/256 (0.39%)**	**0/247 (0.00%)**	**1/503 (0.20%)**
Rash macular * 1			
# participants affected / at risk	**1/256 (0.39%)**	**0/247 (0.00%)**	**1/503 (0.20%)**
Surgical and medical procedures			
Abdominal hernia repair * 1			
# participants affected / at risk	**0/256 (0.00%)**	**1/247 (0.40%)**	**1/503 (0.20%)**
Abdominoplasty * 1			
# participants affected / at risk	**0/256 (0.00%)**	**1/247 (0.40%)**	**1/503 (0.20%)**
Breast cosmetic surgery * 1			
# participants affected / at risk	**1/256 (0.39%)**	**0/247 (0.00%)**	**1/503 (0.20%)**
Liposuction * 1			
# participants affected / at risk	**1/256 (0.39%)**	**0/247 (0.00%)**	**1/503 (0.20%)**
Vascular disorders			
Hypertension * 1			
# participants affected / at risk	**1/256 (0.39%)**	**0/247 (0.00%)**	**1/503 (0.20%)**
Phlebitis * 1			
# participants affected / at risk	**1/256 (0.39%)**	**0/247 (0.00%)**	**1/503 (0.20%)**

* Events were collected by non-systematic assessment
1 Term from vocabulary, MedDRA 9.1

Other Adverse Events

Hide Other Adverse Events

Time Frame	07-Jun-2006 to 24-Jan-2012.
Additional Description	All "Serious Adverse Events (SAEs)" emerging during the TMC125-C217 treatment period are reported below; "Other Adverse Events (not including SAEs)" provided below occurred in at least 0.5% of participants. The duration of the TMC125 treatment period ranged per patient from 1 week to 180 weeks, with a median of 62 weeks.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
DUET PLACEBO	Participants who received Placebo in a previous DUET study and received open-label treatment with 200 mg twice daily etravirine, also known as TMC125 (ETR) and 600/100 mg twice daily darunavir (DRV)/low-dose ritonavir (rtv) were referred to as ETR-naïve participants.
DUET TMC125	Participants who received etravirine, also known as TMC125 (ETR) in a previous DUET study and received open-label treatment with 200 mg twice daily ETR and 600/100 mg twice daily darunavir (DRV)/low-dose ritonavir (rtv) were referred to as ETR-experienced participants.
All Participants	Participants who received placebo or TMC125 in a previous DUET study (DUET Placebo + DUET TMC125).

Other Adverse Events

	DUET PLACEBO	DUET TMC125	All Participants
Total, other (not including serious) adverse events			
# participants affected / at risk	**160/256 (62.50%)**	**137/247 (55.47%)**	**297/503 (59.05%)**
Gastrointestinal disorders			
Diarrhoea [*1]			
# participants affected / at risk	**32/256 (12.50%)**	**24/247 (9.72%)**	**56/503 (11.13%)**
Nausea [*1]			
# participants affected / at risk	**20/256 (7.81%)**	**15/247 (6.07%)**	**35/503 (6.96%)**
General disorders			
Injection site nodule [*1]			
# participants affected / at risk	**14/256 (5.47%)**	**8/247 (3.24%)**	**22/503 (4.37%)**
Pyrexia [*1]			
# participants affected / at risk	**13/256 (5.08%)**	**6/247 (2.43%)**	**19/503 (3.78%)**
Infections and infestations			
Bronchitis [*1]			
# participants affected / at risk	**18/256 (7.03%)**	**12/247 (4.86%)**	**30/503 (5.96%)**
Herpes simplex [*1]			
# participants affected / at risk	**32/256 (12.50%)**	**17/247 (6.88%)**	**49/503 (9.74%)**
Influenza [*1]			
# participants affected / at risk	**18/256 (7.03%)**	**18/247 (7.29%)**	**36/503 (7.16%)**
Nasopharyngitis [*1]			
# participants affected / at risk	**21/256 (8.20%)**	**15/247 (6.07%)**	**36/503 (7.16%)**
Oral candidiasis [*1]			
# participants affected / at risk	**23/256 (8.98%)**	**14/247 (5.67%)**	**37/503 (7.36%)**
Sinusitis [*1]			
# participants affected / at risk	**19/256 (7.42%)**	**23/247 (9.31%)**	**42/503 (8.35%)**
Upper respiratory tract infection [*1]			
# participants affected / at risk	**14/256 (5.47%)**	**11/247 (4.45%)**	**25/503 (4.97%)**
Urinary tract infection [*1]			
# participants affected / at risk	**14/256 (5.47%)**	**8/247 (3.24%)**	**22/503 (4.37%)**
Metabolism and nutrition disorders			

Hypertriglyceridaemia [*1]			
# participants affected / at risk	**12/256 (4.69%)**	**15/247 (6.07%)**	**27/503 (5.37%)**
Musculoskeletal and connective tissue disorders			
Arthralgia [*1]			
# participants affected / at risk	**7/256 (2.73%)**	**14/247 (5.67%)**	**21/503 (4.17%)**
Nervous system disorders			
Headache [*1]			
# participants affected / at risk	**18/256 (7.03%)**	**10/247 (4.05%)**	**28/503 (5.57%)**
Psychiatric disorders			
Insomnia [*1]			
# participants affected / at risk	**13/256 (5.08%)**	**7/247 (2.83%)**	**20/503 (3.98%)**
Respiratory, thoracic and mediastinal disorders			
Cough [*1]			
# participants affected / at risk	**12/256 (4.69%)**	**14/247 (5.67%)**	**26/503 (5.17%)**
Skin and subcutaneous tissue disorders			
Rash [*1]			
# participants affected / at risk	**24/256 (9.38%)**	**4/247 (1.62%)**	**28/503 (5.57%)**

* Events were collected by non-systematic assessment
1 Term from vocabulary, MedDRA 9.1

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:** The investigator agrees that before he/she publishes any results of this trial, he/she shall provide the sponsor with at least 45 days for full review of the pre-publication manuscript prior to submission of the manuscript to the publisher.

Results Point of Contact:

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Responsible Party:	Tibotec Pharmaceuticals, Ireland
ClinicalTrials.gov Identifier:	NCT00359021 History of Changes
Other Study ID Numbers:	CR002740 **TMC125-C217** (Other Identifier: Tibotec Pharmaceuticals) TMC125-C206 (Other Identifier: Tibotec Pharmaceuticals) TMC125-C216 (Other Identifier: Tibotec Pharmaceuticals)
Study First Received:	July 28, 2006
Results First Received:	January 29, 2013
Last Updated:	May 6, 2014
Health Authority:	United States: Food and Drug Administration Ireland: Irish Agriculture and Food Development Authority

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.