Clinical trial results:
TMC125-TiDP35-C239 - Continued Access to Etravirine (ETR) in Treatment Experienced HIV-1 Infected Participants

Summary

EudraCT number	2009-013126-16
Trial protocol	GB FR ES IT
Global end of trial date	08 April 2026

Results information

Result version number	v1 (current)
This version publication date	18 October 2026
First version publication date	18 October 2026

Trial information

Trial identification

Sponsor protocol code	TMC125-TIDP35-C239

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00980538
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Janssen-Cilag International NV
Sponsor organisation address	Turnhoutseweg 30, Beerse, Belgium, B-2340
Public contact	Clinical Registry Group, Janssen-Cilag International N.V., ClinicalTrialsEU@its.jnj.com
Scientific contact	Clinical Registry Group, Janssen-Cilag International N.V., ClinicalTrialsEU@its.jnj.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	08 April 2026
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	08 April 2026
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The main objective of the trial was to continue the provision of Etravirine (ETR) for adult and pediatric subjects who previously received ETR in a clinical study sponsored by Janssen Research & Development (JRD), and who continued to benefit from the use of ETR, in countries where at the time parent trial closed, ETR was not commercially available for the subject's indication, was not reimbursed, could not be accessed through another source (for example, access program or government program), or where the subject was not eligible for ongoing studies/programs with ETR. Trial was closed when last subject was switched to commercial available ETR or to other locally available Human Immunodeficiency Virus (HIV) treatment.

Protection of trial subjects:

This study was conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki and that are consistent with Good Clinical Practice and applicable regulatory requirements.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	09 December 2009
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Argentina: 11
Country: Number of subjects enrolled	Brazil: 8
Country: Number of subjects enrolled	Canada: 1
Country: Number of subjects enrolled	Spain: 7
Country: Number of subjects enrolled	France: 3
Country: Number of subjects enrolled	Italy: 6
Country: Number of subjects enrolled	Panama: 4
Country: Number of subjects enrolled	Romania: 1
Country: Number of subjects enrolled	Thailand: 12
Country: Number of subjects enrolled	United States: 5
Country: Number of subjects enrolled	South Africa: 122
Worldwide total number of subjects	180
EEA total number of subjects	17

Notes:

Subjects enrolled per age group	
In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	27
Adolescents (12-17 years)	44
Adults (18-64 years)	106
From 65 to 84 years	3
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Total of 180 subjects who previously received etravirine (ETR) in a clinical trial with ETR (EudraCT numbers: 2005-003145-13,2006-001287-23,2006-001287-23,2007-007086-21,2012-002630-36) continued its use, in countries where at time parent clinical trial closed, ETR was not available, could not be accessed through any source were enrolled in study.

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

Blinding implementation details:

Not blinded

Arms

Arm title	Etravirine

Arm description:

Subjects who previously received etravirine(ETR) in clinical trial with ETR(2005-003145-13, 2006-001287-23, 2006-001287-23, 2007-007086-21, 2012-002630-36) sponsored by/in collaboration with Janssen Research & Development, continued to benefit from its use, in countries where ETR was not available, could not be accessed through another source, or where subject was not eligible for ongoing trials with ETR received ETR 200milligrams (mg) twice daily (bid) in adults. Pediatric subjects received ETR doses as received in previous ETR (parent) trial, with weight based dose adjustment if necessary(ETR 100mg twice daily for weight 10 to less than [<] 20 kilograms [kg]; ETR 125mg bid for weight 20 to <25kg; ETR 150mg bid for weight 25 to <30kg; and 200mg bid for weight greater than or equal to [>=] 30kg). Treatment continued until one of following criteria was met: subject no longer benefited from ETR treatment, toxicity, loss to follow up, ETR became commercially available for

Arm type	Experimental
Investigational medicinal product name	Etravirine
Investigational medicinal product code	
Other name	TMC125
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Adult subjects received a dose of ETR 200 mg twice daily. Pediatric subjects received ETR, dosed as they had received in the previous ETR (parent) trial, with weight based dose adjustment if necessary (ETR 100 mg twice daily for weight 10 to less than [<] 20 kilograms [kg]; ETR 125 mg bid for weight 20 to <25 kg; ETR 150 mg bid for weight 25 to <30 kg; and 200 mg bid for weight greater than or equal to [>=] 30 kg).

Number of subjects in period 1	Etravirine
Started	180
Completed	180

Baseline characteristics

Reporting groups	
Reporting group title	Etravirine

Reporting group description:

Subjects who previously received etravirine(ETR) in clinical trial with ETR(2005-003145-13, 2006-001287-23, 2006-001287-23, 2007-007086-21, 2012-002630-36) sponsored by/in collaboration with Janssen Research & Development, continued to benefit from its use, in countries where ETR was not available, could not be accessed through another source, or where subject was not eligible for ongoing trials with ETR received ETR 200milligrams (mg) twice daily (bid) in adults. Pediatric subjects received ETR doses as received in previous ETR (parent) trial, with weight based dose adjustment if necessary(ETR 100mg twice daily for weight 10 to less than [<] 20 kilograms [kg]; ETR 125mg bid for weight 20 to <25kg; ETR 150mg bid for weight 25 to <30kg; and 200mg bid for weight greater than or equal to [>=] 30kg). Treatment continued until one of following criteria was met: subject no longer benefited from ETR treatment, toxicity, loss to follow up, ETR became commercially available for

Reporting group values	Etravirine	Total	
Number of subjects	180	180	
Age categorical Units: Subjects			
In Utero	0	0	
Preterm newborn infants (gestional age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days - 23 months)	0	0	
Children (2 - 11 years)	27	27	
12 - 17 years	44	44	
Adults (18 - 64 years)	106	106	
From 65 - 84 years	3	3	
85 years and over	0	0	
Age continuous Units: years			
arithmetic mean	30.9		
standard deviation	± 16.92	-	
Gender categorical Units: Subjects			
Male	68	68	
Female	112	112	

End points

End points reporting groups

Reporting group title	Etravirine

Reporting group description:

Subjects who previously received etravirine(ETR) in clinical trial with ETR(2005-003145-13, 2006-001287-23, 2006-001287-23, 2007-007086-21, 2012-002630-36) sponsored by/in collaboration with Janssen Research & Development, continued to benefit from its use, in countries where ETR was not available, could not be accessed through another source, or where subject was not eligible for ongoing trials with ETR received ETR 200milligrams (mg) twice daily (bid) in adults. Pediatric subjects received ETR doses as received in previous ETR (parent) trial, with weight based dose adjustment if necessary(ETR 100mg twice daily for weight 10 to less than [<] 20 kilograms [kg]; ETR 125mg bid for weight 20 to <25kg; ETR 150mg bid for weight 25 to <30kg; and 200mg bid for weight greater than or equal to [>=] 30kg). Treatment continued until one of following criteria was met: subject no longer benefited from ETR treatment, toxicity, loss to follow up, ETR became commercially available for

Primary: Number of Subjects With at Least One Adverse Event as a Measure of Safety Through the Time Etravirine (ETR)-Based Treatment Regimen Became Commercially Available

End point title	Number of Subjects With at Least One Adverse Event as a Measure of Safety Through the Time Etravirine (ETR)-Based Treatment Regimen Became Commercially Available[1]

End point description:

An adverse event is any untoward medical event that occurs in a subject administered an investigational product, and it does not necessarily indicate only events with clear causal relationship with the relevant investigational product. Safety analysis set included all subjects who received at least one dose of etravirine.

End point type	Primary

End point timeframe:

Up to 10 years 11 months

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive data was planned to be reported for this endpoint.

End point values	Etravirine			
Subject group type	Reporting group			
Number of subjects analysed	180			
Units: Subjects	42			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
Up to 10 years 11 months	
Adverse event reporting additional description:	
Safety analysis set included all subjects who received at least one dose of etravirine.	
Assessment type	Non-systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	23.0

Reporting groups	
Reporting group title	Etravirine

Reporting group description:

Subjects who previously received etravirine(ETR) in a clinical trial with ETR (2005-003145-13, 2006-001287-23, 2006-001287-23, 2007-007086-21, 2012-002630-36) sponsored by/in collaboration with Janssen Research & Development, continued to benefit from its use, in countries where ETR was not available, could not be accessed through another source, or where subject was not eligible for ongoing trials with ETR received ETR 200milligrams (mg) twice daily (bid) in adults. Pediatric subjects received ETR doses as received in previous ETR (parent) trial, with weight based dose adjustment if necessary(ETR 100mg twice daily for weight 10 to less than [<] 20kilograms [kg]; ETR 125mg bid for weight 20 to <25kg; ETR 150mg bid for weight 25 to<30kg; and 200mg bid for weight greater than or equal to [>=] 30kg). Treatment continued until one of following criteria was met: subject no longer benefited from ETR treatment, toxicity, loss to follow up, ETR became commercially available for

Serious adverse events	Etravirine		
Total subjects affected by serious adverse events			
subjects affected / exposed	18 / 180 (10.00%)		
number of deaths (all causes)	6		
number of deaths resulting from adverse events	0		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Metastases to Lymph Nodes			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Metastases to Central Nervous System			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Melanoma Recurrent			

subjects affected / exposed	1 / 180 (0.56%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Malignant Melanoma			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Injury, poisoning and procedural complications			
Brain Herniation			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Radius Fracture			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Limb Injury			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Head Injury			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Vascular disorders			
Hypovolaemic Shock			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Cardiac disorders			
Myocardial Infarction			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		

Pregnancy, puerperium and perinatal conditions			
Abortion Spontaneous			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
Encephalopathy			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
Death			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Accidental Death			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Skin and subcutaneous tissue disorders			
Angioedema			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Renal and urinary disorders			
Acute Kidney Injury			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Psychiatric disorders			
Depression			
subjects affected / exposed	2 / 180 (1.11%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 1		
Infections and infestations			

Chronic Tonsillitis				
subjects affected / exposed	1 / 180 (0.56%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Gastroenteritis				
subjects affected / exposed	2 / 180 (1.11%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Pneumonia				
subjects affected / exposed	1 / 180 (0.56%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Sepsis				
subjects affected / exposed	1 / 180 (0.56%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Disseminated Tuberculosis				
subjects affected / exposed	1 / 180 (0.56%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Metabolism and nutrition disorders				
Hyperglycaemia				
subjects affected / exposed	1 / 180 (0.56%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Hypovolaemia				
subjects affected / exposed	1 / 180 (0.56%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Hyponatraemia				
subjects affected / exposed	1 / 180 (0.56%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	Etravirine		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	32 / 180 (17.78%)		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Skin Papilloma			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences (all)	1		
Pregnancy, puerperium and perinatal conditions			
Pregnancy			
subjects affected / exposed	4 / 180 (2.22%)		
occurrences (all)	4		
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	2 / 180 (1.11%)		
occurrences (all)	3		
Reproductive system and breast disorders			
Amenorrhoea			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences (all)	2		
Respiratory, thoracic and mediastinal disorders			
Nasal Congestion			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences (all)	1		
Cough			
subjects affected / exposed	5 / 180 (2.78%)		
occurrences (all)	7		
Psychiatric disorders			
Anxiety			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences (all)	1		
Investigations			
Lipase Increased			

subjects affected / exposed	1 / 180 (0.56%)		
occurrences (all)	1		
Hepatic Enzyme Increased			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences (all)	1		
Injury, poisoning and procedural complications			
Ligament Sprain			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences (all)	1		
Cardiac disorders			
Mitral Valve Incompetence			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences (all)	1		
Sinus Tachycardia			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences (all)	1		
Nervous system disorders			
Syncope			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences (all)	1		
Neuropathy Peripheral			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences (all)	1		
Headache			
subjects affected / exposed	2 / 180 (1.11%)		
occurrences (all)	2		
Blood and lymphatic system disorders			
Lymphadenopathy			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences (all)	1		
Thrombocytopenia			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences (all)	2		
Eye disorders			
Conjunctival Haemorrhage			

subjects affected / exposed	1 / 180 (0.56%)		
occurrences (all)	1		
Gastrointestinal disorders			
Vomiting			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences (all)	1		
Odynophagia			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences (all)	1		
Abdominal Pain			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences (all)	1		
Abdominal Pain Upper			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences (all)	1		
Diarrhoea			
subjects affected / exposed	3 / 180 (1.67%)		
occurrences (all)	4		
Aphthous Ulcer			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences (all)	1		
Skin and subcutaneous tissue disorders			
Rash			
subjects affected / exposed	4 / 180 (2.22%)		
occurrences (all)	4		
Prurigo			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences (all)	1		
Neurodermatitis			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences (all)	1		
Lipohypertrophy			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences (all)	1		
Lipoatrophy			

subjects affected / exposed occurrences (all) Acne subjects affected / exposed occurrences (all) Skin Hypopigmentation subjects affected / exposed occurrences (all)	1 / 180 (0.56%) 1 1 / 180 (0.56%) 1 1 / 180 (0.56%) 1		
Renal and urinary disorders Nephropathy subjects affected / exposed occurrences (all)	 1 / 180 (0.56%) 1		
Musculoskeletal and connective tissue disorders Myalgia subjects affected / exposed occurrences (all) Back Pain subjects affected / exposed occurrences (all) Pain in Extremity subjects affected / exposed occurrences (all)	 1 / 180 (0.56%) 1 1 / 180 (0.56%) 1 1 / 180 (0.56%) 2		
Infections and infestations Conjunctivitis subjects affected / exposed occurrences (all) Gastroenteritis subjects affected / exposed occurrences (all) Gastroenteritis Viral subjects affected / exposed occurrences (all) Tonsillitis subjects affected / exposed occurrences (all) Respiratory Tract Infection	 1 / 180 (0.56%) 1 2 / 180 (1.11%) 2 1 / 180 (0.56%) 1 4 / 180 (2.22%) 5		

subjects affected / exposed	1 / 180 (0.56%)		
occurrences (all)	1		
Otitis Media			
subjects affected / exposed	2 / 180 (1.11%)		
occurrences (all)	2		
Oral Herpes			
subjects affected / exposed	2 / 180 (1.11%)		
occurrences (all)	2		
Nasopharyngitis			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences (all)	1		
Lower Respiratory Tract Infection			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences (all)	1		
Lice Infestation			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences (all)	1		
Influenza			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences (all)	1		
Herpes Simplex			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences (all)	1		
Tracheobronchitis			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences (all)	1		
Upper Respiratory Tract Infection			
subjects affected / exposed	5 / 180 (2.78%)		
occurrences (all)	6		
Vulvovaginal Candidiasis			
subjects affected / exposed	2 / 180 (1.11%)		
occurrences (all)	2		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported