



Clinical trial results:

A Phase II, Multicenter, Single-Arm, Open-Label Clinical Trial to Evaluate the Safety and Efficacy of Triple Therapy with Dolutegravir plus 2 NRTIs, in Treatment-Naïve HIV-2 Infected Subjects

Summary

EudraCT number	2016-000346-61
Trial protocol	PT
Global end of trial date	02 July 2019

Results information

Result version number	v1 (current)
This version publication date	23 July 2021
First version publication date	23 July 2021
Summary attachment (see zip file)	Synopsis (dtg-01-01-synopsis.pdf)

Trial information

Trial identification

Sponsor protocol code	DTG-01-01
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Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	BlueClinical, Ltd.
Sponsor organisation address	Av. Villagarcia de Arosa, 1919 - 1º, Matosinhos, Portugal, 4460-439
Public contact	Clinical Trials Information, Blueclinical, Ltd., 00351 220 995 159, regulatory@blueclinical.pt
Scientific contact	Clinical Trials Information, Blueclinical, Ltd., 00351 220 995 159, regulatory@blueclinical.pt

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	23 June 2020
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	02 July 2019
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective of this study is to evaluate the efficacy of DTG in combination with two NRTIs [ABC/3TC or TDF/FTC] in the treatment of HIV-2 treatment-naïve subjects, as measured by the proportion of subjects achieving a plasma viral load of <40 copies/mL and/or by the change from baseline in CD4 cell count and in CD4/CD8 ratio at Week 48.

Protection of trial subjects:

Inclusion and exclusion criteria

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	05 April 2017
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	Portugal: 30
Worldwide total number of subjects	30
EEA total number of subjects	30

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)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	28
From 65 to 84 years	2
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

The subjects were selected from the Institution where the Site belongs.

Pre-assignment

Screening details:

At the Screening visit, ICF was discussed and obtained from the subject, prior to the performance of any study-related procedure. The screening period was of 45 days (from Day -45 to Day 0).

Period 1

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

Arms

Arm title	Dolutegravir
Arm description: -	
Arm type	Experimental
Investigational medicinal product name	Dolutegravir
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Dosing schedule: One tablet, once daily

Route/mode of administration: Orally, without regard of food

Number of subjects in period 1	Dolutegravir
Started	30
Completed	27
Not completed	3
Consent withdrawn by subject	1
Adverse event, non-fatal	1
Lost to follow-up	1

Baseline characteristics

Reporting groups

Reporting group title	Dolutegravir
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Reporting group description: -

Reporting group values	Dolutegravir	Total	
Number of subjects	30	30	
Age categorical			
Units: Subjects			
Adults (18-64 years)	28	28	
From 65-84 years	2	2	
Gender categorical			
Units: Subjects			
Female	22	22	
Male	8	8	

End points

End points reporting groups

Reporting group title	Dolutegravir
Reporting group description: -	

Primary: Overall treatment succes

End point title	Overall treatment succes ^[1]
End point description:	

End point type	Primary
End point timeframe:	
Global Success at Week 48	

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: The overall treatment success defined as the proportion of patients with "global success": n/N, in wich n= number of Subjects that Achieved Success; and N=Total Number of Subjects with Evaluable Data

End point values	Dolutegravir			
Subject group type	Reporting group			
Number of subjects analysed	27			
Units: number of subjects				
number (confidence interval 95%)	55.56 (36.81 to 72.88)			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

17MAY2017 to 02JUL2019

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	22.0
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Reporting groups

Reporting group title	Overall study
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Reporting group description: -

Serious adverse events	Overall study		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 30 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

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

Non-serious adverse events	Overall study		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	24 / 30 (80.00%)		
Vascular disorders			
Hypertension			
subjects affected / exposed	3 / 30 (10.00%)		
occurrences (all)	4		
Hypertensive crisis			
subjects affected / exposed	1 / 30 (3.33%)		
occurrences (all)	1		
Surgical and medical procedures			
Knee operation			
subjects affected / exposed	1 / 30 (3.33%)		
occurrences (all)	1		
General disorders and administration site conditions			

Asthenia subjects affected / exposed occurrences (all) Influenza like illness subjects affected / exposed occurrences (all) Oedema peripheral subjects affected / exposed occurrences (all) Inflammation subjects affected / exposed occurrences (all)	1 / 30 (3.33%)		
	1		
	2 / 30 (6.67%)		
	3		
Oedema peripheral subjects affected / exposed occurrences (all) Inflammation subjects affected / exposed occurrences (all)	1 / 30 (3.33%)		
	1		
	1 / 30 (3.33%)		
	1		
Reproductive system and breast disorders			
Dysmenorrhoea			
subjects affected / exposed	1 / 30 (3.33%)		
occurrences (all)	1		
Vulvovaginal pruritus			
subjects affected / exposed	1 / 30 (3.33%)		
occurrences (all)	1		
Vulvovaginal erythema			
subjects affected / exposed	1 / 30 (3.33%)		
occurrences (all)	1		
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	1 / 30 (3.33%)		
occurrences (all)	2		
Nasal obstruction			
subjects affected / exposed	1 / 30 (3.33%)		
occurrences (all)	1		
Productive cough			
subjects affected / exposed	2 / 30 (6.67%)		
occurrences (all)	2		
Rhinorrhoea			
subjects affected / exposed	1 / 30 (3.33%)		
occurrences (all)	1		
Psychiatric disorders			

Anxiety subjects affected / exposed occurrences (all)	1 / 30 (3.33%) 2		
Insomnia subjects affected / exposed occurrences (all)	3 / 30 (10.00%) 5		
Investigations Blood creatine phosphokinase increased subjects affected / exposed occurrences (all)	1 / 30 (3.33%) 1		
Mean cell volume increased subjects affected / exposed occurrences (all)	1 / 30 (3.33%) 1		
Weight increased subjects affected / exposed occurrences (all)	1 / 30 (3.33%) 1		
Transaminases increased subjects affected / exposed occurrences (all)	2 / 30 (6.67%) 3		
Blood alkaline phosphatase increased subjects affected / exposed occurrences (all)	1 / 30 (3.33%) 1		
Injury, poisoning and procedural complications Fall subjects affected / exposed occurrences (all)	1 / 30 (3.33%) 1		
Fracture subjects affected / exposed occurrences (all)	1 / 30 (3.33%) 1		
Anaemia postoperative subjects affected / exposed occurrences (all)	1 / 30 (3.33%) 1		
Joint injury subjects affected / exposed occurrences (all)	2 / 30 (6.67%) 2		
Nervous system disorders			

Amnesia			
subjects affected / exposed	1 / 30 (3.33%)		
occurrences (all)	1		
Dizziness			
subjects affected / exposed	2 / 30 (6.67%)		
occurrences (all)	2		
Headache			
subjects affected / exposed	7 / 30 (23.33%)		
occurrences (all)	7		
Memory impairment			
subjects affected / exposed	1 / 30 (3.33%)		
occurrences (all)	1		
Paraesthesia			
subjects affected / exposed	1 / 30 (3.33%)		
occurrences (all)	1		
Presyncope			
subjects affected / exposed	1 / 30 (3.33%)		
occurrences (all)	1		
Somnolence			
subjects affected / exposed	1 / 30 (3.33%)		
occurrences (all)	1		
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	1 / 30 (3.33%)		
occurrences (all)	1		
Vertigo			
subjects affected / exposed	1 / 30 (3.33%)		
occurrences (all)	3		
Eye disorders			
Blepharitis			
subjects affected / exposed	1 / 30 (3.33%)		
occurrences (all)	1		
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	1 / 30 (3.33%)		
occurrences (all)	1		
Abdominal pain			

subjects affected / exposed	3 / 30 (10.00%)		
occurrences (all)	6		
Chronic gastritis			
subjects affected / exposed	1 / 30 (3.33%)		
occurrences (all)	1		
Constipation			
subjects affected / exposed	1 / 30 (3.33%)		
occurrences (all)	1		
Diarrhoea			
subjects affected / exposed	3 / 30 (10.00%)		
occurrences (all)	4		
Flatulence			
subjects affected / exposed	1 / 30 (3.33%)		
occurrences (all)	1		
Nausea			
subjects affected / exposed	5 / 30 (16.67%)		
occurrences (all)	5		
Rectal haemorrhage			
subjects affected / exposed	1 / 30 (3.33%)		
occurrences (all)	1		
Toothache			
subjects affected / exposed	1 / 30 (3.33%)		
occurrences (all)	1		
Renal and urinary disorders			
Nocturia			
subjects affected / exposed	1 / 30 (3.33%)		
occurrences (all)	1		
Urinary incontinence			
subjects affected / exposed	1 / 30 (3.33%)		
occurrences (all)	1		
Urinary retention			
subjects affected / exposed	1 / 30 (3.33%)		
occurrences (all)	1		
Musculoskeletal and connective tissue disorders			

Arthralgia			
subjects affected / exposed	3 / 30 (10.00%)		
occurrences (all)	3		
Back pain			
subjects affected / exposed	2 / 30 (6.67%)		
occurrences (all)	4		
Myalgia			
subjects affected / exposed	3 / 30 (10.00%)		
occurrences (all)	3		
Neck pain			
subjects affected / exposed	2 / 30 (6.67%)		
occurrences (all)	2		
Tendonitis			
subjects affected / exposed	2 / 30 (6.67%)		
occurrences (all)	2		
Infections and infestations			
Body tinea			
subjects affected / exposed	1 / 30 (3.33%)		
occurrences (all)	1		
Cystitis			
subjects affected / exposed	1 / 30 (3.33%)		
occurrences (all)	1		
Folliculitis			
subjects affected / exposed	1 / 30 (3.33%)		
occurrences (all)	1		
Herpes zoster			
subjects affected / exposed	1 / 30 (3.33%)		
occurrences (all)	1		
Nasopharyngitis			
subjects affected / exposed	1 / 30 (3.33%)		
occurrences (all)	1		
Periodontitis			
subjects affected / exposed	1 / 30 (3.33%)		
occurrences (all)	1		
Strongyloidiasis			

subjects affected / exposed	1 / 30 (3.33%)		
occurrences (all)	1		
Tonsillitis			
subjects affected / exposed	1 / 30 (3.33%)		
occurrences (all)	1		
Tracheobronchitis			
subjects affected / exposed	2 / 30 (6.67%)		
occurrences (all)	2		
Upper respiratory tract infection			
subjects affected / exposed	1 / 30 (3.33%)		
occurrences (all)	1		
Urinary tract infection			
subjects affected / exposed	1 / 30 (3.33%)		
occurrences (all)	1		
Vaginal infection			
subjects affected / exposed	1 / 30 (3.33%)		
occurrences (all)	1		
Tooth infection			
subjects affected / exposed	1 / 30 (3.33%)		
occurrences (all)	1		
Respiratory tract infection			
subjects affected / exposed	2 / 30 (6.67%)		
occurrences (all)	2		
Latent tuberculosis			
subjects affected / exposed	1 / 30 (3.33%)		
occurrences (all)	1		
Metabolism and nutrition disorders			
Folate deficiency			
subjects affected / exposed	1 / 30 (3.33%)		
occurrences (all)	1		
Glucose tolerance impaired			
subjects affected / exposed	1 / 30 (3.33%)		
occurrences (all)	1		
Dyslipidaemia			
subjects affected / exposed	1 / 30 (3.33%)		
occurrences (all)	1		

Hyperlipidaemia subjects affected / exposed occurrences (all)	1 / 30 (3.33%) 1		
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More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
14 June 2018	Protocol version 4.0 created after a "Dear Investigator Letter"

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported