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

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

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

Dictionary used	
Dictionary name	MedDRA
Dictionary version	22.0

Reporting groups	
Reporting group title	Overall study

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

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

Amnesia subjects affected / exposed occurrences (all)	1 / 30 (3.33%) 1		
Dizziness subjects affected / exposed occurrences (all)	2 / 30 (6.67%) 2		
Headache subjects affected / exposed occurrences (all)	7 / 30 (23.33%) 7		
Memory impairment subjects affected / exposed occurrences (all)	1 / 30 (3.33%) 1		
Paraesthesia subjects affected / exposed occurrences (all)	1 / 30 (3.33%) 1		
Presyncope subjects affected / exposed occurrences (all)	1 / 30 (3.33%) 1		
Somnolence subjects affected / exposed occurrences (all)	1 / 30 (3.33%) 1		
Ear and labyrinth disorders Ear pain subjects affected / exposed occurrences (all)	1 / 30 (3.33%) 1		
Vertigo subjects affected / exposed occurrences (all)	1 / 30 (3.33%) 3		
Eye disorders Blepharitis subjects affected / exposed occurrences (all)	1 / 30 (3.33%) 1		
Gastrointestinal disorders Abdominal distension subjects affected / exposed occurrences (all)	1 / 30 (3.33%) 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 occurrences (all)	3 / 30 (10.00%) 3			
Back pain subjects affected / exposed occurrences (all)	2 / 30 (6.67%) 4			
Myalgia subjects affected / exposed occurrences (all)	3 / 30 (10.00%) 3			
Neck pain subjects affected / exposed occurrences (all)	2 / 30 (6.67%) 2			
Tendonitis subjects affected / exposed occurrences (all)	2 / 30 (6.67%) 2			
Infections and infestations				
Body tinea subjects affected / exposed occurrences (all)	1 / 30 (3.33%) 1			
Cystitis subjects affected / exposed occurrences (all)	1 / 30 (3.33%) 1			
Folliculitis subjects affected / exposed occurrences (all)	1 / 30 (3.33%) 1			
Herpes zoster subjects affected / exposed occurrences (all)	1 / 30 (3.33%) 1			
Nasopharyngitis subjects affected / exposed occurrences (all)	1 / 30 (3.33%) 1			
Periodontitis subjects affected / exposed occurrences (all)	1 / 30 (3.33%) 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		

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