



Clinical trial results:

A Phase IV, multi-center, open-label study to determine the safety, tolerability and clinical outcomes following oral administration of EGATEN™ (Triclabendazole) in patients (6 years of age or older) with fascioliasis.

Summary

EudraCT number	2020-004200-33
Trial protocol	Outside EU/EEA
Global end of trial date	27 March 2026

Results information

Result version number	v1 (current)
This version publication date	27 September 2026
First version publication date	27 September 2026

Trial information

Trial identification

Sponsor protocol code	CEGA230B2404
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04230148
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Novartis Pharma AG
Sponsor organisation address	Lichtstrasse 35, Basel, Switzerland, 4056
Public contact	Clinical Disclosure Office, Novartis Pharma AG, 41 613241111, novartis.email@novartis.com
Scientific contact	Clinical Disclosure Office, Novartis Pharma AG, 41 613241111, novartis.email@novartis.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?	Yes

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	27 March 2026
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	27 March 2026
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate safety and tolerability of EGATEN administered as two 10 mg/kg doses given approximately 12 hours apart in patients with fascioliasis.

Protection of trial subjects:

The study was in compliance with the ethical principles derived from the Declaration of Helsinki and the International Conference on Harmonization (ICH) Good Clinical Practice (GCP) guidelines. All the local regulatory requirements pertinent to safety of trial subjects were also followed during the conduct of the trial.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	11 February 2022
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	Colombia: 1
Country: Number of subjects enrolled	Egypt: 10
Country: Number of subjects enrolled	Peru: 13
Country: Number of subjects enrolled	Türkiye: 17
Country: Number of subjects enrolled	Viet Nam: 260
Worldwide total number of subjects	301
EEA total number of subjects	0

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)	10
Adolescents (12-17 years)	14

Adults (18-64 years)	265
From 65 to 84 years	12
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Participants took part in 10 investigative sites in 5 countries.

Pre-assignment

Screening details:

The study consisted of a screening up to 3 days to assess eligibility.

Period 1

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

Arms

Arm title	Triclabendazole
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Arm description:

Triclabendazole was administered as two 10 mg/kg doses given approximately 12 hours apart. Both doses were administered orally with food.

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

Dosage and administration details:

Triclabendazole was administered as two 10 mg/kg doses given approximately 12 hours apart. Both doses were administered orally with food.

Number of subjects in period 1	Triclabendazole
Started	301
Completed	296
Not completed	5
Subject decision	2
Lost to follow-up	3

Baseline characteristics

Reporting groups

Reporting group title	Triclabendazole
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Reporting group description:

Triclabendazole was administered as two 10 mg/kg doses given approximately 12 hours apart. Both doses were administered orally with food.

Reporting group values	Triclabendazole	Total	
Number of subjects	301	301	
Age categorical			
Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	10	10	
Adolescents (12-17 years)	14	14	
Adults (18-64 years)	265	265	
From 65-84 years	12	12	
85 years and over	0	0	
Age Continuous			
Units: years			
arithmetic mean	37.3		
standard deviation	± 14.81	-	
Sex: Female, Male			
Units: participants			
Female	185	185	
Male	116	116	
Race/Ethnicity, Customized			
Units: Subjects			
White	27	27	
Asian	260	260	
American Indian or Alaska Native	14	14	
Types of Fascioliasis			
Units: Subjects			
Acute fascioliasis participants	246	246	
Chronic fascioliasis participants	39	39	
Undetermined participants	16	16	

End points

End points reporting groups

Reporting group title	Triclabendazole
Reporting group description: Triclabendazole was administered as two 10 mg/kg doses given approximately 12 hours apart. Both doses were administered orally with food.	

Primary: Number of participants with treatment emergent adverse events (AEs) and serious adverse events (SAEs)

End point title	Number of participants with treatment emergent adverse events (AEs) and serious adverse events (SAEs) ^[1]
End point description: Number of participants with treatment emergent adverse events (any AE regardless of seriousness), and SAEs.	
End point type	Primary
End point timeframe: Adverse events were reported from the first dose of study treatment until approximately 90 days thereafter.	
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: Statistical analyses are not applicable for this endpoint.	

End point values	Triclabendazole			
Subject group type	Reporting group			
Number of subjects analysed	301			
Units: participants				
Adverse Events	139			
Serious Adverse Events	7			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of acute and chronic fascioliasis participants who achieved Clinical Response

End point title	Percentage of acute and chronic fascioliasis participants who achieved Clinical Response
End point description: Clinical Response at Day 10 was defined as improvement or resolution of baseline signs and symptoms. 95% confidence interval (CI) is calculated based on Clopper-Pearson method. The Number of Subjects Analyzed differs as stated on the category column, in case of difference from Number of subjects that started the Arm.	
End point type	Secondary
End point timeframe: Baseline, Day 10	

End point values	Triclabendazole			
Subject group type	Reporting group			
Number of subjects analysed	269			
Units: percentage of participants				
number (confidence interval 95%)				
Acute fascioliasis (n=233)	95.7 (92.2 to 97.9)			
Chronic fascioliasis (n=36)	75.0 (57.8 to 87.9)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of acute fascioliasis participants who achieved Clinical Cure

End point title	Percentage of acute fascioliasis participants who achieved Clinical Cure
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End point description:

A participant was considered to achieve clinical cure if all of the following criteria were met.

- Resolution of all sign and symptoms present at baseline
- Improvement in ultrasound findings:
Abdomen – for hepatic lesions and/or biliary tract blockage caused by Fasciola worm(s)
- Improvement in the lab parameter from baseline:
Eosinophil count: $\geq 50\%$ reduction from baseline value or reaching normal range if baseline value was above normal range

95% confidence interval (CI) is calculated based on Clopper-Pearson method.

End point type	Secondary
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End point timeframe:

Baseline, Day 30, Day 60 and Day 90

End point values	Triclabendazole			
Subject group type	Reporting group			
Number of subjects analysed	242			
Units: percentage of participants				
number (confidence interval 95%)				
Day 30	78.5 (72.8 to 83.5)			
Day 60	83.5 (78.2 to 87.9)			
Day 90	93.8 (90.0 to 96.5)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of chronic fascioliasis participants who achieved Clinical Cure

End point title	Percentage of chronic fascioliasis participants who achieved Clinical Cure
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End point description:

A participant was considered to achieve clinical cure if all of the following criteria were met.

- Resolution of all sign and symptoms present at baseline
- Improvement in ultrasound findings: Abdomen – for hepatic lesions and/or biliary tract blockage caused by Fasciola worm(s)
- Improvement in the lab parameter from baseline:
 - Eosinophil count: $\geq 50\%$ reduction from baseline or reaching normal range if baseline value was above normal range
 - Hemoglobin: ≥ 1 g/dL increase from baseline value or reaching normal range if baseline value was below normal range
 - Liver function test: ≥ 1 grade improvement from baseline or reaching normal range for each test if baseline value was above normal range
 - Erythrocyte sedimentation rate: $\geq 50\%$ reduction from baseline or reaching normal range if baseline value was above normal range

95% CI is calculated based on Clopper-Pearson method.

End point type	Secondary
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End point timeframe:

Baseline, Day 30, Day 60 and Day 90

End point values	Triclabendazole			
Subject group type	Reporting group			
Number of subjects analysed	36			
Units: percentage of participants				
number (confidence interval 95%)				
Day 30	12.8 (4.3 to 27.4)			
Day 60	17.9 (7.5 to 33.5)			
Day 90	17.9 (7.5 to 33.5)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of chronic fascioliasis participants who achieved parasitological cure

End point title	Percentage of chronic fascioliasis participants who achieved parasitological cure
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End point description:

The parasitological cure rate in chronic fascioliasis participants was measured by the proportion of participants with absence of fasciola eggs confirmed by stool examination. In case of missing assessments at post baseline visits, parasitological cure is imputed as cured if two consecutive prior visits are negative, else parasitological cure is imputed as not cured. 95% confidence interval (CI) is

calculated based on Clopper-Pearson method.

End point type	Secondary
End point timeframe:	
At Day 10, Day 30, Day 60 and Day 90	

End point values	Triclabendazole			
Subject group type	Reporting group			
Number of subjects analysed	26			
Units: percentage of participants				
number (confidence interval 95%)				
Day 10	80.8 (60.6 to 93.4)			
Day 30	84.6 (65.1 to 95.6)			
Day 60	84.6 (65.1 to 95.6)			
Day 90	84.6 (65.1 to 95.6)			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Adverse events were reported from the first dose of study treatment until approximately 90 days thereafter.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	29.0
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Reporting groups

Reporting group title	EGATEN 10 mg BID
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Reporting group description:

EGATEN 10 mg BID

Serious adverse events	EGATEN 10 mg BID		
Total subjects affected by serious adverse events			
subjects affected / exposed	7 / 301 (2.33%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Uterine leiomyoma			
subjects affected / exposed	1 / 301 (0.33%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Injury, poisoning and procedural complications			
Spinal column injury			
subjects affected / exposed	1 / 301 (0.33%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Gastritis			
subjects affected / exposed	1 / 301 (0.33%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastrooesophageal reflux disease			

subjects affected / exposed	1 / 301 (0.33%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Hepatobiliary disorders			
Cholecystitis			
subjects affected / exposed	1 / 301 (0.33%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	1 / 301 (0.33%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	1 / 301 (0.33%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal and connective tissue disorders			
Intervertebral disc degeneration			
subjects affected / exposed	1 / 301 (0.33%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Gastrointestinal infection			
subjects affected / exposed	1 / 301 (0.33%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Liver abscess			
subjects affected / exposed	2 / 301 (0.66%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Pneumonia			

subjects affected / exposed	1 / 301 (0.33%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Sepsis			
subjects affected / exposed	1 / 301 (0.33%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	EGATEN 10 mg BID		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	84 / 301 (27.91%)		
Investigations			
Gamma-glutamyltransferase increased			
subjects affected / exposed	16 / 301 (5.32%)		
occurrences (all)	16		
Alanine aminotransferase increased			
subjects affected / exposed	28 / 301 (9.30%)		
occurrences (all)	29		
Aspartate aminotransferase increased			
subjects affected / exposed	21 / 301 (6.98%)		
occurrences (all)	22		
Gastrointestinal disorders			
Abdominal pain upper			
subjects affected / exposed	34 / 301 (11.30%)		
occurrences (all)	37		
Skin and subcutaneous tissue disorders			
Urticaria			
subjects affected / exposed	34 / 301 (11.30%)		
occurrences (all)	37		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
10 May 2021	The primary purpose of this amendment was to incorporate safety ECG monitoring for a subset of patients enrolling into the study who may be at increased risk of QT prolongation.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported