



Clinical trial results:

A Phase 3 Randomized, Double-blind, Placebo-controlled, Multi-center Study to Evaluate the Efficacy and Safety of Pimodivir in Combination With the Standard-of-care Treatment in Adolescent, Adult, and Elderly Non-hospitalized Subjects With Influenza A Infection who Are at Risk of Developing Complications

Summary

EudraCT number	2017-002217-59
Trial protocol	SE GB LV EE LT FR DE ES NL SK HU BE BG CZ PL AT IT
Global end of trial date	24 August 2020

Results information

Result version number	v1 (current)
This version publication date	13 March 2021
First version publication date	13 March 2021
Summary attachment (see zip file)	63623872FLZ3002 (2017-002217-59)_Limited Results (63623872FLZ3002_Redacted CSR Synopsis.pdf)

Trial information

Trial identification

Sponsor protocol code	63623872FLZ3002
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03381196
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Janssen Research & Development, LLC
Sponsor organisation address	920 Route 202, Raritan, United States, NJ 08869
Public contact	Clinical Registry Group, Janssen Research & Development, LLC, ClinicalTrialsEU@its.jnj.com
Scientific contact	Clinical Registry Group, Janssen Research & Development, LLC, ClinicalTrialsEU@its.jnj.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	Yes
EMA paediatric investigation plan number(s)	EMA-001975-PIP01-16
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	24 August 2020
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	24 August 2020
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

The primary objective is to evaluate superiority of pimodivir (Pi) in combination with standard-of-care (SOC) treatment (tmt) compared to placebo in combination with SOC treatment, with respect to the time to resolution of influenza-related symptoms.

Protection of trial subjects:

Safety assessments included AE, laboratory parameters, electrocardiogram [ECG], and vital signs.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	20 December 2017
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Poland: 3
Country: Number of subjects enrolled	Spain: 2
Country: Number of subjects enrolled	Sweden: 1
Country: Number of subjects enrolled	United Kingdom: 1
Country: Number of subjects enrolled	Austria: 3
Country: Number of subjects enrolled	Belgium: 4
Country: Number of subjects enrolled	Bulgaria: 10
Country: Number of subjects enrolled	Estonia: 1
Country: Number of subjects enrolled	France: 2
Country: Number of subjects enrolled	Germany: 4
Country: Number of subjects enrolled	Hungary: 2
Country: Number of subjects enrolled	Italy: 3
Country: Number of subjects enrolled	Latvia: 1
Country: Number of subjects enrolled	Lithuania: 11
Country: Number of subjects enrolled	Argentina: 25
Country: Number of subjects enrolled	Brazil: 1
Country: Number of subjects enrolled	Canada: 4
Country: Number of subjects enrolled	India: 8

Country: Number of subjects enrolled	Korea, Republic of: 2
Country: Number of subjects enrolled	Mexico: 7
Country: Number of subjects enrolled	Malaysia: 1
Country: Number of subjects enrolled	Russian Federation: 2
Country: Number of subjects enrolled	South Africa: 58
Country: Number of subjects enrolled	Taiwan: 6
Country: Number of subjects enrolled	Thailand: 13
Country: Number of subjects enrolled	Turkey: 4
Country: Number of subjects enrolled	Ukraine: 10
Country: Number of subjects enrolled	United States: 355
Worldwide total number of subjects	544
EEA total number of subjects	47

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)	17
Adults (18-64 years)	395
From 65 to 84 years	132
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Study started on 24 January 2018 and completed on 24 August 2020.

Period 1

Period 1 title	Overall Period (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes
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Arm title	Pimodivir + SOC
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Arm description:

Subjects received pimodivir 600 milligram (mg), orally, twice daily, for 5 days (on Days 1 through 5; for subjects who received only 1 dose of pimodivir on Day 1 [evening], dosing continued until the morning of Day 6) along with Standard-of-Care (SOC) treatment.

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

Dosage and administration details:

Pimodivir tablet was administered.

Arm title	Placebo + SOC
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Arm description:

Subjects received placebo matching to pimodivir orally, twice daily, for 5 days (on Days 1 through 5; for subjects who received only 1 dose of placebo on Day 1 [evening], dosing continued until the morning of Day 6) along with SOC treatment.

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

Dosage and administration details:

Placebo was administered.

Number of subjects in period 1	Pimodivir + SOC	Placebo + SOC
Started	273	271
Completed	261	263
Not completed	12	8
Consent withdrawn by subject	7	6
Other	5	2

Baseline characteristics

End points

End points reporting groups

Reporting group title	Pimodivir + SOC
Reporting group description: Subjects received pimodivir 600 milligram (mg), orally, twice daily, for 5 days (on Days 1 through 5; for subjects who received only 1 dose of pimodivir on Day 1 [evening], dosing continued until the morning of Day 6) along with Standard-of-Care (SOC) treatment.	
Reporting group title	Placebo + SOC
Reporting group description: Subjects received placebo matching to pimodivir orally, twice daily, for 5 days (on Days 1 through 5; for subjects who received only 1 dose of placebo on Day 1 [evening], dosing continued until the morning of Day 6) along with SOC treatment.	

Primary: Time to Resolution of 7 Primary Influenza-related Symptoms

End point title	Time to Resolution of 7 Primary Influenza-related Symptoms
End point description:	
End point type	Primary
End point timeframe: Up to Day 28	

End point values	Pimodivir + SOC	Placebo + SOC		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	223	223		
Units: hours				
median (confidence interval 95%)	92.62 (77.60 to 104.20)	105.13 (92.73 to 128.63)		

Statistical analyses

Statistical analysis title	Statistical Analysis
Comparison groups	Pimodivir + SOC v Placebo + SOC
Number of subjects included in analysis	446
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.0216
Method	Gehan-Wilcoxon test

Adverse events

Adverse events information^[1]

Timeframe for reporting adverse events:

Up to Day 28

Adverse event reporting additional description:

The limited results for this early terminated trial are available in the attached CSR synopsis.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	21.1
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Reporting groups

Reporting group title	Pimodivir + SOC
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Reporting group description: -

Reporting group title	Placebo+SOC
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Reporting group description: -

Serious adverse events	Pimodivir + SOC	Placebo+SOC	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 273 (0.00%)	0 / 271 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events			

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

Non-serious adverse events	Pimodivir + SOC	Placebo+SOC	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 273 (0.00%)	0 / 271 (0.00%)	

Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.

Justification: No adverse events reported.

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

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

The limited results for this early terminated trial are available in the attached CSR synopsis.

Notes: