



Clinical trial results:

A Randomized, Double masked, Parallel group, Dose-finding study to evaluate SYL1801 in patients with neovascular AMD

Summary

EudraCT number	2022-000214-34
Trial protocol	SK CZ HU
Global end of trial date	19 December 2024

Results information

Result version number	v1 (current)
This version publication date	20 March 2026
First version publication date	20 March 2026

Trial information

Trial identification

Sponsor protocol code	SYL1801_II
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Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Sylentis S.A.U
Sponsor organisation address	C. Progreso, 3, Getafe, Spain, 28906
Public contact	Clinical Trials Information, Sylentis S.A.U, 34 918047667,
Scientific contact	Clinical Trials Information, Sylentis S.A.U, 34 918047667,

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	19 December 2024
Is this the analysis of the primary completion data?	Yes
Primary completion date	19 December 2024
Global end of trial reached?	Yes
Global end of trial date	19 December 2024
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective is to evaluate effect on visual acuity of SYL1801 sodium at three doses (5 mg/mL, 25 mg/mL and 50 mg/mL) when administered as 1 drop once a day for 42 days in subjects with neovascular AMD.

Protection of trial subjects:

During the treatment period, subjects will perform self-assessment of visual acuity via smartphone app. Results were reviewed by investigators' staff.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	22 November 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	Poland: 50
Country: Number of subjects enrolled	Slovakia: 1
Country: Number of subjects enrolled	Czechia: 24
Country: Number of subjects enrolled	Hungary: 24
Worldwide total number of subjects	99
EEA total number of subjects	99

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)	6
From 65 to 84 years	86

85 years and over	7
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Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Subjects were randomized in a 1:1:1 ratio to one of three treatment groups using a block randomization design

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	5 mg/mL SYL1801 ophthalmic solution

Arm description: -

Arm type	Experimental
Investigational medicinal product name	SYL1801
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Eye drops
Routes of administration	Ophthalmic use

Dosage and administration details:

1 drop q.d for 42 days

Arm title	25 mg/mL SYL1801 ophthalmic solution
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Arm description: -

Arm type	Experimental
Investigational medicinal product name	SYL1801
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Eye drops
Routes of administration	Ophthalmic use

Dosage and administration details:

1 drop q.d for 42 days

Arm title	50 mg/mL SYL1801 ophthalmic solution
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Arm description: -

Arm type	Experimental
Investigational medicinal product name	SYL1801
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Eye drops
Routes of administration	Ophthalmic use

Dosage and administration details:

1 drop q.d for 42 days

Number of subjects in period 1	5 mg/mL SYL1801 ophthalmic solution	25 mg/mL SYL1801 ophthalmic solution	50 mg/mL SYL1801 ophthalmic solution
Started	35	30	34
Completed	35	28	34
Not completed	0	2	0
Consent withdrawn by subject	-	1	-
Lost to follow-up	-	1	-

Baseline characteristics

Reporting groups

Reporting group title	5 mg/mL SYL1801 ophthalmic solution
Reporting group description: -	
Reporting group title	25 mg/mL SYL1801 ophthalmic solution
Reporting group description: -	
Reporting group title	50 mg/mL SYL1801 ophthalmic solution
Reporting group description: -	

Reporting group values	5 mg/mL SYL1801 ophthalmic solution	25 mg/mL SYL1801 ophthalmic solution	50 mg/mL SYL1801 ophthalmic solution
Number of subjects	35	30	34
Age categorical			
Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	3	1	2
From 65-84 years	30	27	29
85 years and over	2	2	3
Gender categorical			
Units: Subjects			
Female	16	18	18
Male	19	12	16

Reporting group values	Total		
Number of subjects	99		
Age categorical			
Units: Subjects			
In utero	0		
Preterm newborn infants (gestational age < 37 wks)	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)	6		
From 65-84 years	86		
85 years and over	7		
Gender categorical			
Units: Subjects			
Female	52		
Male	47		

Subject analysis sets

Subject analysis set title	FAS
Subject analysis set type	Full analysis

Subject analysis set description:

All randomized subjects who received at least one dose of the study drug and had at least one post-baseline efficacy assessment

Subject analysis set title	PP
Subject analysis set type	Per protocol

Subject analysis set description:

Subjects in the FAS who completed the study without major protocol deviations which might affect the evaluation of the primary endpoint measures

Reporting group values	FAS	PP	
Number of subjects	98	96	
Age categorical Units: Subjects			
In utero Preterm newborn infants (gestational age < 37 wks) Newborns (0-27 days) Infants and toddlers (28 days-23 months) Children (2-11 years) Adolescents (12-17 years) Adults (18-64 years) From 65-84 years 85 years and over			
Gender categorical Units: Subjects			
Female	52	50	
Male	46	46	

End points

End points reporting groups

Reporting group title	5 mg/mL SYL1801 ophthalmic solution
Reporting group description: -	
Reporting group title	25 mg/mL SYL1801 ophthalmic solution
Reporting group description: -	
Reporting group title	50 mg/mL SYL1801 ophthalmic solution
Reporting group description: -	
Subject analysis set title	FAS
Subject analysis set type	Full analysis
Subject analysis set description:	
All randomized subjects who received at least one dose of the study drug and had at least one post-baseline efficacy assessment	
Subject analysis set title	PP
Subject analysis set type	Per protocol
Subject analysis set description:	
Subjects in the FAS who completed the study without major protocol deviations which might affect the evaluation of the primary endpoint measures	

Primary: Change from baseline in BCVA score based on ETDRS visual acuity chart

End point title	Change from baseline in BCVA score based on ETDRS visual acuity chart
End point description:	
End point type	Primary
End point timeframe:	
Baseline to Day 42	

End point values	5 mg/mL SYL1801 ophthalmic solution	25 mg/mL SYL1801 ophthalmic solution	50 mg/mL SYL1801 ophthalmic solution	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	35	30	34	
Units: letters				
least squares mean (confidence interval 95%)	1.44 (-1.17 to 4.04)	0.90 (-1.94 to 3.74)	0.96 (-1.73 to 3.64)	

Statistical analyses

Statistical analysis title	Differences between groups
Comparison groups	5 mg/mL SYL1801 ophthalmic solution v 25 mg/mL SYL1801 ophthalmic solution v 50 mg/mL SYL1801 ophthalmic solution

Number of subjects included in analysis	99
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.953
Method	Mixed models analysis

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Overall period

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	25
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Reporting groups

Reporting group title	5 mg/mL SYL1801 ophthalmic solution
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Reporting group description: -

Reporting group title	25 mg/mL SYL1801 ophthalmic solution
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Reporting group description: -

Reporting group title	50 mg/mL SYL1801 ophthalmic solution
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Reporting group description: -

Serious adverse events	5 mg/mL SYL1801 ophthalmic solution	25 mg/mL SYL1801 ophthalmic solution	50 mg/mL SYL1801 ophthalmic solution
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 35 (2.86%)	2 / 30 (6.67%)	1 / 34 (2.94%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Adenocarcinoma of colon			
subjects affected / exposed	1 / 35 (2.86%)	0 / 30 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gallbladder adenocarcinoma			
subjects affected / exposed	0 / 35 (0.00%)	0 / 30 (0.00%)	1 / 34 (2.94%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Traumatic intracranial haemorrhage			
subjects affected / exposed	0 / 35 (0.00%)	1 / 30 (3.33%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suture rupture			

subjects affected / exposed	0 / 35 (0.00%)	0 / 30 (0.00%)	1 / 34 (2.94%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Cardiac failure			
subjects affected / exposed	0 / 35 (0.00%)	1 / 30 (3.33%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Frequency threshold for reporting non-serious adverse events: 2 %

Non-serious adverse events	5 mg/mL SYL1801 ophthalmic solution	25 mg/mL SYL1801 ophthalmic solution	50 mg/mL SYL1801 ophthalmic solution
Total subjects affected by non-serious adverse events			
subjects affected / exposed	10 / 35 (28.57%)	10 / 30 (33.33%)	8 / 34 (23.53%)
Investigations			
Blood urea increased			
subjects affected / exposed	2 / 35 (5.71%)	0 / 30 (0.00%)	0 / 34 (0.00%)
occurrences (all)	2	0	0
C-reactive protein increased			
subjects affected / exposed	1 / 35 (2.86%)	1 / 30 (3.33%)	0 / 34 (0.00%)
occurrences (all)	1	1	0
Vascular disorders			
Blood pressure fluctuation			
subjects affected / exposed	0 / 35 (0.00%)	1 / 30 (3.33%)	2 / 34 (5.88%)
occurrences (all)	0	0	2
Eye disorders			
Neovascular age-related macular degeneration			
subjects affected / exposed	7 / 35 (20.00%)	9 / 30 (30.00%)	6 / 34 (17.65%)
occurrences (all)	8	10	6
Visual acuity reduced			
subjects affected / exposed	3 / 35 (8.57%)	0 / 30 (0.00%)	2 / 34 (5.88%)
occurrences (all)	3	0	2
Infections and infestations			
Upper respiratory tract infection			
subjects affected / exposed	1 / 35 (2.86%)	0 / 30 (0.00%)	1 / 34 (2.94%)
occurrences (all)	1	0	1

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
02 September 2022	Updated endpoints and scape criteria
04 May 2023	Updated inclusion criteria and concomitant medication clarification

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported