



Clinical trial results: Global Registry for Long-Term Follow-up of Patients Participating in Clinical Trials with Posoleucel (ALVR105)

Summary

EudraCT number	2022-000763-45
Trial protocol	IT ES SE BE
Global end of trial date	31 January 2024

Results information

Result version number	v1 (current)
This version publication date	01 May 2024
First version publication date	01 May 2024

Trial information

Trial identification

Sponsor protocol code	P-105-401
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Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	AlloVir, Inc.
Sponsor organisation address	1100 Winter Street, Waltham, United States, MA 02451
Public contact	Clinical Trials Information Line, AlloVir, Inc., +1 617-433-2605, clinicaltrials@allovir.com
Scientific contact	Clinical Trials Information Line, AlloVir, Inc., +1 617-433-2605, clinicaltrials@allovir.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?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	31 January 2024
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	31 January 2024
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

The main objective of the study was to evaluate the long-term safety of posoleucel (PSL).

Protection of trial subjects:

This study was performed in accordance with Good Clinical Practice, including the archiving of essential documents.

Background therapy:

Physicians prescribed treatments based on usual clinical practice, and there were no restrictions on the use of medications.

Evidence for comparator: -

Actual start date of recruitment	06 January 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	Canada: 2
Country: Number of subjects enrolled	Korea, Republic of: 29
Country: Number of subjects enrolled	France: 17
Country: Number of subjects enrolled	Sweden: 1
Country: Number of subjects enrolled	Spain: 11
Country: Number of subjects enrolled	Italy: 18
Country: Number of subjects enrolled	Belgium: 2
Country: Number of subjects enrolled	United Kingdom: 6
Country: Number of subjects enrolled	United States: 151
Worldwide total number of subjects	237
EEA total number of subjects	49

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)	11
Adolescents (12-17 years)	5
Adults (18-64 years)	159
From 65 to 84 years	62
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

A total of 237 participants were enrolled at 76 sites in 11 countries between January 2022 and January 2024. Two participants with unknown age at enrollment were reported within the Adults (18-64 years) category.

Pre-assignment

Screening details:

The purpose of this registry was to provide long-term follow-up for participants in PSL clinical trials sponsored by AlloVir, Inc. Participants were eligible to enroll into this observational registry from posoleucel parent studies AVM-003-HC, P-105-201, P-105-202 and P-105-303.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	P-105-201: Placebo

Arm description:

Participants received at least one intravenous infusion of placebo in the P-105-201 parent study. Eligible participants could have had discontinued from or completed participation in the parent P-105-201 study. The maximum duration of the registry for each participant was to be 4 years after their initial dose of placebo in the P-105-201 parent study. No treatment was provided in this registry.

Arm type	No intervention
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Dispersion for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Intravenous infusion in PSL parent study. No treatment was provided in this registry.

Arm title	P-105-201: Posoleucel
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Arm description:

Participants received at least one intravenous infusion of PSL in the P-105-201 parent study. Eligible participants could have had discontinued from or completed participation in the parent P-105-201 study. The maximum duration of the registry for each participant was to be 4 years after their initial dose of PSL in the P-105-201 parent study. No treatment was provided in this registry.

Arm type	No intervention
Investigational medicinal product name	Posoleucel
Investigational medicinal product code	ALVR105
Other name	PSL, ALVR-105, Viralym-M
Pharmaceutical forms	Dispersion for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Intravenous infusion in PSL parent study. No treatment was provided in this registry.

Arm title	P-105-202: Placebo
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Arm description:

Participants received at least one intravenous infusion of placebo in the P-105-202 parent study. Eligible

participants could have had discontinued from or completed participation in the parent P-105-202 study. The maximum duration of the registry for each participant was to be 4 years after their initial dose of placebo in the P-105-202 parent study. No treatment was provided in this registry.

Arm type	No intervention
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Dispersion for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Intravenous infusion in PSL parent study. No treatment was provided in this registry.

Arm title	P-105-202: Posoleucel
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Arm description:

Participants received at least one intravenous infusion of PSL in the P-105-202 parent study. Eligible participants could have had discontinued from or completed participation in the parent P-105-202 study. The maximum duration of the registry for each participant was to be 4 years after their initial dose of PSL in the P-105-202 parent study. No treatment was provided in this registry.

Arm type	No intervention
Investigational medicinal product name	Posoleucel
Investigational medicinal product code	ALVR105
Other name	PSL, ALVR-105, Viralym-M
Pharmaceutical forms	Dispersion for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Intravenous infusion in PSL parent study. No treatment was provided in this registry.

Arm title	AVM-003-HC: Placebo
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Arm description:

Participants received at least one intravenous infusion of placebo in the AVM-003-HC parent study. Eligible participants could have had discontinued from or completed participation in the parent AVM-003-HC study. The maximum duration of the registry for each participant was to be 4 years after their initial dose of placebo in the AVM-003-HC parent study. No treatment was provided in this registry.

Arm type	No intervention
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Dispersion for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Intravenous infusion in PSL parent study. No treatment was provided in this registry.

Arm title	AVM-003-HC: Posoleucel
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Arm description:

Participants received at least one intravenous infusion of PSL in the AVM-003-HC parent study. Eligible participants could have had discontinued from or completed participation in the parent AVM-003-HC study. The maximum duration of the registry for each participant was to be 4 years after their initial dose of PSL in the AVM-003-HC parent study. No treatment was provided in this registry.

Arm type	No intervention
Investigational medicinal product name	Posoleucel
Investigational medicinal product code	ALVR105
Other name	PSL, ALVR-105, Viralym-M
Pharmaceutical forms	Dispersion for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Intravenous infusion in PSL parent study. No treatment was provided in this registry.

Arm title	P-105-303: Placebo
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Arm description:

Participants received at least one intravenous infusion of placebo in the P-105-303 parent study. Eligible participants could have had discontinued from or completed participation in the parent P-105-303 study. The maximum duration of the registry for each participant was to be 4 years after their initial dose of placebo in the P-105-303 parent study. No treatment was provided in this registry.

Arm type	No intervention
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Dispersion for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Intravenous infusion in PSL parent study. No treatment was provided in this registry.

Arm title	P-105-303: Posoleucel
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Arm description:

Participants received at least one intravenous infusion of PSL in the P-105-303 parent study. Eligible participants could have had discontinued from or completed participation in the parent P-105-303 study. The maximum duration of the registry for each participant was to be 4 years after their initial dose of PSL in the P-105-303 parent study. No treatment was provided in this registry.

Arm type	No intervention
Investigational medicinal product name	Posoleucel
Investigational medicinal product code	ALVR105
Other name	PSL, ALVR-105, Viralym-M
Pharmaceutical forms	Dispersion for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Intravenous infusion in PSL parent study. No treatment was provided in this registry.

Number of subjects in period 1	P-105-201: Placebo	P-105-201: Posoleucel	P-105-202: Placebo
Started	18	34	69
Completed	0	1	0
Not completed	18	33	69
Consent withdrawn by subject	-	-	-
Death	-	1	3
Requested discontinuation from the registry	-	-	-
Study terminated by the sponsor	18	32	66

Number of subjects in period 1	P-105-202: Posoleucel	AVM-003-HC: Placebo	AVM-003-HC: Posoleucel
Started	82	11	16
Completed	0	0	0
Not completed	82	11	16
Consent withdrawn by subject	-	1	-
Death	2	3	1
Requested discontinuation from the registry	-	-	1
Study terminated by the sponsor	80	7	14

Number of subjects in period 1	P-105-303: Placebo	P-105-303: Posoleucel
Started	4	3
Completed	0	0
Not completed	4	3
Consent withdrawn by subject	-	-
Death	-	-
Requested discontinuation from the registry	-	-
Study terminated by the sponsor	4	3

Baseline characteristics

Reporting groups

Reporting group title	P-105-201: Placebo
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Reporting group description:

Participants received at least one intravenous infusion of placebo in the P-105-201 parent study. Eligible participants could have had discontinued from or completed participation in the parent P-105-201 study. The maximum duration of the registry for each participant was to be 4 years after their initial dose of placebo in the P-105-201 parent study. No treatment was provided in this registry.

Reporting group title	P-105-201: Posoleucel
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Reporting group description:

Participants received at least one intravenous infusion of PSL in the P-105-201 parent study. Eligible participants could have had discontinued from or completed participation in the parent P-105-201 study. The maximum duration of the registry for each participant was to be 4 years after their initial dose of PSL in the P-105-201 parent study. No treatment was provided in this registry.

Reporting group title	P-105-202: Placebo
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Reporting group description:

Participants received at least one intravenous infusion of placebo in the P-105-202 parent study. Eligible participants could have had discontinued from or completed participation in the parent P-105-202 study. The maximum duration of the registry for each participant was to be 4 years after their initial dose of placebo in the P-105-202 parent study. No treatment was provided in this registry.

Reporting group title	P-105-202: Posoleucel
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Reporting group description:

Participants received at least one intravenous infusion of PSL in the P-105-202 parent study. Eligible participants could have had discontinued from or completed participation in the parent P-105-202 study. The maximum duration of the registry for each participant was to be 4 years after their initial dose of PSL in the P-105-202 parent study. No treatment was provided in this registry.

Reporting group title	AVM-003-HC: Placebo
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Reporting group description:

Participants received at least one intravenous infusion of placebo in the AVM-003-HC parent study. Eligible participants could have had discontinued from or completed participation in the parent AVM-003-HC study. The maximum duration of the registry for each participant was to be 4 years after their initial dose of placebo in the AVM-003-HC parent study. No treatment was provided in this registry.

Reporting group title	AVM-003-HC: Posoleucel
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Reporting group description:

Participants received at least one intravenous infusion of PSL in the AVM-003-HC parent study. Eligible participants could have had discontinued from or completed participation in the parent AVM-003-HC study. The maximum duration of the registry for each participant was to be 4 years after their initial dose of PSL in the AVM-003-HC parent study. No treatment was provided in this registry.

Reporting group title	P-105-303: Placebo
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Reporting group description:

Participants received at least one intravenous infusion of placebo in the P-105-303 parent study. Eligible participants could have had discontinued from or completed participation in the parent P-105-303 study. The maximum duration of the registry for each participant was to be 4 years after their initial dose of placebo in the P-105-303 parent study. No treatment was provided in this registry.

Reporting group title	P-105-303: Posoleucel
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Reporting group description:

Participants received at least one intravenous infusion of PSL in the P-105-303 parent study. Eligible participants could have had discontinued from or completed participation in the parent P-105-303 study. The maximum duration of the registry for each participant was to be 4 years after their initial dose of PSL in the P-105-303 parent study. No treatment was provided in this registry.

Reporting group values	P-105-201: Placebo	P-105-201: Posoleucel	P-105-202: Placebo
Number of subjects	18	34	69

Age categorical Units: Subjects			
<2 years	0	0	0
2 - <6 years	0	0	1
6 - <12 years	0	0	2
12 - <18 years	0	0	1
≥18 years	18	34	64
Missing	0	0	1
Age continuous Units: years			
arithmetic mean	60.3	55.8	51.2
standard deviation	± 6.87	± 14.09	± 17.35
Gender categorical Units: Subjects			
Female	4	6	25
Male	14	28	43
Missing	0	0	1
Race Units: Subjects			
American Indian or Alaskan Native	0	0	0
Asian	5	4	15
Black or African American	5	10	1
Native Hawaiian or Other Pacific Islander	0	0	1
White	8	15	44
Other, Not Listed Above	0	3	1
Not Available/Not Permitted	0	2	6
Missing	0	0	1
Ethnicity Units: Subjects			
Hispanic or Latino	1	4	10
Not Hispanic or Latino	17	29	51
Unknown	0	0	0
Not Collected or Not Reported	0	1	7
Missing	0	0	1
Region Units: Subjects			
North America	18	34	35
Other	0	0	34

Reporting group values	P-105-202: Posoleucel	AVM-003-HC: Placebo	AVM-003-HC: Posoleucel
Number of subjects	82	11	16
Age categorical Units: Subjects			
<2 years	0	0	0
2 - <6 years	0	0	0
6 - <12 years	4	0	0
12 - <18 years	2	0	0
≥18 years	75	11	16
Missing	1	0	0

Age continuous Units: years arithmetic mean standard deviation	53.2 ± 17.96	47.2 ± 19.09	45.3 ± 18.45
Gender categorical Units: Subjects			
Female	40	6	6
Male	41	5	10
Missing	1	0	0
Race Units: Subjects			
American Indian or Alaskan Native	0	0	1
Asian	15	2	4
Black or African American	3	1	2
Native Hawaiian or Other Pacific Islander	0	0	1
White	47	7	7
Other, Not Listed Above	3	0	0
Not Available/Not Permitted	13	1	1
Missing	1	0	0
Ethnicity Units: Subjects			
Hispanic or Latino	5	1	3
Not Hispanic or Latino	62	9	12
Unknown	2	0	0
Not Collected or Not Reported	12	1	1
Missing	1	0	0
Region Units: Subjects			
North America	51	6	7
Other	31	5	9

Reporting group values	P-105-303: Placebo	P-105-303: Posoleucel	Total
Number of subjects	4	3	237
Age categorical Units: Subjects			
<2 years	0	0	0
2 - <6 years	0	0	1
6 - <12 years	3	2	11
12 - <18 years	1	1	5
≥18 years	0	0	218
Missing	0	0	2
Age continuous Units: years arithmetic mean standard deviation	8.5 ± 3.32	9.0 ± 2.65	-
Gender categorical Units: Subjects			
Female	2	0	89
Male	2	3	146
Missing	0	0	2

Race			
Units: Subjects			
American Indian or Alaskan Native	0	0	1
Asian	1	0	46
Black or African American	0	0	22
Native Hawaiian or Other Pacific Islander	0	0	2
White	3	3	134
Other, Not Listed Above	0	0	7
Not Available/Not Permitted	0	0	23
Missing	0	0	2
Ethnicity			
Units: Subjects			
Hispanic or Latino	0	1	25
Not Hispanic or Latino	4	2	186
Unknown	0	0	2
Not Collected or Not Reported	0	0	22
Missing	0	0	2
Region			
Units: Subjects			
North America	0	1	152
Other	4	2	85

End points

End points reporting groups

Reporting group title	P-105-201: Placebo
Reporting group description: Participants received at least one intravenous infusion of placebo in the P-105-201 parent study. Eligible participants could have had discontinued from or completed participation in the parent P-105-201 study. The maximum duration of the registry for each participant was to be 4 years after their initial dose of placebo in the P-105-201 parent study. No treatment was provided in this registry.	
Reporting group title	P-105-201: Posoleucel
Reporting group description: Participants received at least one intravenous infusion of PSL in the P-105-201 parent study. Eligible participants could have had discontinued from or completed participation in the parent P-105-201 study. The maximum duration of the registry for each participant was to be 4 years after their initial dose of PSL in the P-105-201 parent study. No treatment was provided in this registry.	
Reporting group title	P-105-202: Placebo
Reporting group description: Participants received at least one intravenous infusion of placebo in the P-105-202 parent study. Eligible participants could have had discontinued from or completed participation in the parent P-105-202 study. The maximum duration of the registry for each participant was to be 4 years after their initial dose of placebo in the P-105-202 parent study. No treatment was provided in this registry.	
Reporting group title	P-105-202: Posoleucel
Reporting group description: Participants received at least one intravenous infusion of PSL in the P-105-202 parent study. Eligible participants could have had discontinued from or completed participation in the parent P-105-202 study. The maximum duration of the registry for each participant was to be 4 years after their initial dose of PSL in the P-105-202 parent study. No treatment was provided in this registry.	
Reporting group title	AVM-003-HC: Placebo
Reporting group description: Participants received at least one intravenous infusion of placebo in the AVM-003-HC parent study. Eligible participants could have had discontinued from or completed participation in the parent AVM-003-HC study. The maximum duration of the registry for each participant was to be 4 years after their initial dose of placebo in the AVM-003-HC parent study. No treatment was provided in this registry.	
Reporting group title	AVM-003-HC: Posoleucel
Reporting group description: Participants received at least one intravenous infusion of PSL in the AVM-003-HC parent study. Eligible participants could have had discontinued from or completed participation in the parent AVM-003-HC study. The maximum duration of the registry for each participant was to be 4 years after their initial dose of PSL in the AVM-003-HC parent study. No treatment was provided in this registry.	
Reporting group title	P-105-303: Placebo
Reporting group description: Participants received at least one intravenous infusion of placebo in the P-105-303 parent study. Eligible participants could have had discontinued from or completed participation in the parent P-105-303 study. The maximum duration of the registry for each participant was to be 4 years after their initial dose of placebo in the P-105-303 parent study. No treatment was provided in this registry.	
Reporting group title	P-105-303: Posoleucel
Reporting group description: Participants received at least one intravenous infusion of PSL in the P-105-303 parent study. Eligible participants could have had discontinued from or completed participation in the parent P-105-303 study. The maximum duration of the registry for each participant was to be 4 years after their initial dose of PSL in the P-105-303 parent study. No treatment was provided in this registry.	

Primary: Number of Participants who Experienced Adverse Drug Reactions (ARDs)

End point title	Number of Participants who Experienced Adverse Drug Reactions (ARDs) ^[1]
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End point description:

An adverse event (AE) was defined as any untoward medical occurrence in a patient or clinical trial participant administered a medicinal product and which does not necessarily have a causal relationship with this treatment. An ADR was a response to a medicinal product which is noxious and unintended. Response in this context meant that causal relationship between the medical product and an AE is at least a reasonable possibility. A serious AE or serious ADR (SADR) was an AE (or ADR) that met any of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH)-E2A Guideline criteria.

The Enrolled Population consisted of all eligible participants who had a signed informed consent.

End point type	Primary
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End point timeframe:

Up to a maximum of 4 years after the initial dose of PSL or placebo

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: No additional statistical analysis was pre-specified for this endpoint.

End point values	P-105-201: Placebo	P-105-201: Posoleucel	P-105-202: Placebo	P-105-202: Posoleucel
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	18	34	69	82
Units: participants				
Any ADRs	0	0	0	0
Any SADRs	0	0	0	0

End point values	AVM-003-HC: Placebo	AVM-003-HC: Posoleucel	P-105-303: Placebo	P-105-303: Posoleucel
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	11	16	4	3
Units: participants				
Any ADRs	0	0	0	0
Any SADRs	0	0	0	0

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants who Experienced Clinically Significant Infection with Viruses Targeted by PSL

End point title	Number of Participants who Experienced Clinically Significant Infection with Viruses Targeted by PSL
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End point description:

Clinically significant infections were defined as any of the following, regardless of relationship to PSL:

- Cytomegalovirus infection.
- Epstein-Barr virus infection.
- Adenovirus infection.
- Human herpes virus 6.
- BK virus/ Human polyomavirus 1.

- John Cunningham virus/ Human polyomavirus 2.

The Enrolled Population consisted of all eligible participants who had a signed informed consent.

End point type	Secondary
End point timeframe:	
Up to a maximum of 4 years after the initial dose of PSL or placebo	

End point values	P-105-201: Placebo	P-105-201: Posoleucel	P-105-202: Placebo	P-105-202: Posoleucel
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[2]	0 ^[3]	0 ^[4]	0 ^[5]
Units: participants				

Notes:

[2] - Data were not analyzed for this endpoint following early study termination.

[3] - Data were not analyzed for this endpoint following early study termination.

[4] - Data were not analyzed for this endpoint following early study termination.

[5] - Data were not analyzed for this endpoint following early study termination.

End point values	AVM-003-HC: Placebo	AVM-003-HC: Posoleucel	P-105-303: Placebo	P-105-303: Posoleucel
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[6]	0 ^[7]	0 ^[8]	0 ^[9]
Units: participants				

Notes:

[6] - Data were not analyzed for this endpoint following early study termination.

[7] - Data were not analyzed for this endpoint following early study termination.

[8] - Data were not analyzed for this endpoint following early study termination.

[9] - Data were not analyzed for this endpoint following early study termination.

Statistical analyses

No statistical analyses for this end point

Secondary: Rate of Mortality

End point title	Rate of Mortality
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End point description:

Overall mortality was defined as the number of participants deceased. Non-relapse mortality was defined as death without recurrent or progressive disease after transplantation. Values of "99999" indicate result was not available due to missing cause of death.

The Enrolled Population consisted of all eligible participants who had a signed informed consent.

End point type	Secondary
End point timeframe:	
Up to a maximum of 4 years after the initial dose of PSL or placebo	

End point values	P-105-201: Placebo	P-105-201: Posoleucel	P-105-202: Placebo	P-105-202: Posoleucel
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	18	34	69	82
Units: participants				
Overall Mortality (n=18, 34, 69, 82, 11, 16, 4, 3)	0	1	3	2
Non-relapse Mortality (n=0, 0, 0, 0, 1, 0, 0, 0)	0	99999	99999	99999

End point values	AVM-003-HC: Placebo	AVM-003-HC: Posoleucel	P-105-303: Placebo	P-105-303: Posoleucel
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	11	16	4	3
Units: participants				
Overall Mortality (n=18, 34, 69, 82, 11, 16, 4, 3)	3	1	0	0
Non-relapse Mortality (n=0, 0, 0, 0, 1, 0, 0, 0)	0	99999	0	0

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information^[1]

Timeframe for reporting adverse events:

Total number of deaths reported up to a maximum of 4 years after the initial dose of PSL or placebo

Adverse event reporting additional description:

Treatment-emergent AEs (TEAEs) were not applicable to this study. TEAEs associated with PSL or placebo treatment are reported in the parent study clinicaltrials.gov or [EudraCT](https://eudra.europa.eu/eudra/#!/home) results disclosure as applicable per local regulations.

The Enrolled Population consisted of all eligible participants who had a signed informed consent.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	25.0
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Reporting groups

Reporting group title	P-105-201: Placebo
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Reporting group description:

Participants received at least one intravenous infusion of placebo in the P-105-201 parent study. Eligible participants could have had discontinued from or completed participation in the parent P-105-201 study. The maximum duration of the registry for each participant was to be 4 years after their initial dose of placebo in the P-105-201 parent study. No treatment was provided in this registry.

Reporting group title	P-105-201: Posoleucel
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Reporting group description:

Participants received at least one intravenous infusion of PSL in the P-105-201 parent study. Eligible participants could have had discontinued from or completed participation in the parent P-105-201 study. The maximum duration of the registry for each participant was to be 4 years after their initial dose of PSL in the P-105-201 parent study. No treatment was provided in this registry.

Reporting group title	P-105-202: Placebo
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Reporting group description:

Participants received at least one intravenous infusion of placebo in the P-105-202 parent study. Eligible participants could have had discontinued from or completed participation in the parent P-105-202 study. The maximum duration of the registry for each participant was to be 4 years after their initial dose of placebo in the P-105-202 parent study. No treatment was provided in this registry.

Reporting group title	P-105-202: Posoleucel
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Reporting group description:

Participants received at least one intravenous infusion of PSL in the P-105-202 parent study. Eligible participants could have had discontinued from or completed participation in the parent P-105-202 study. The maximum duration of the registry for each participant was to be 4 years after their initial dose of PSL in the P-105-202 parent study. No treatment was provided in this registry.

Reporting group title	AVM-003-HC: Placebo
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Reporting group description:

Participants received at least one intravenous infusion of placebo in the AVM-003-HC parent study. Eligible participants could have had discontinued from or completed participation in the parent AVM-003-HC study. The maximum duration of the registry for each participant was to be 4 years after their initial dose of placebo in the AVM-003-HC parent study. No treatment was provided in this registry.

Reporting group title	AVM-003-HC: Posoleucel
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Reporting group description:

Participants received at least one intravenous infusion of PSL in the AVM-003-HC parent study. Eligible participants could have had discontinued from or completed participation in the parent AVM-003-HC study. The maximum duration of the registry for each participant was to be 4 years after their initial dose of PSL in the AVM-003-HC parent study. No treatment was provided in this registry.

Reporting group title	P-105-303: Placebo
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Reporting group description:

Participants received at least one intravenous infusion of placebo in the P-105-303 parent study. Eligible participants could have had discontinued from or completed participation in the parent P-105-303 study. The maximum duration of the registry for each participant was to be 4 years after their initial dose of

placebo in the P-105-303 parent study. No treatment was provided in this registry.

Reporting group title	P-105-303: Posoleucel
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Reporting group description:

Participants received at least one intravenous infusion of PSL in the P-105-303 parent study. Eligible participants could have had discontinued from or completed participation in the parent P-105-303 study. The maximum duration of the registry for each participant was to be 4 years after their initial dose of PSL in the P-105-303 parent study. No treatment was provided in this registry.

Serious adverse events	P-105-201: Placebo	P-105-201: Posoleucel	P-105-202: Placebo
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 18 (0.00%)	0 / 34 (0.00%)	0 / 69 (0.00%)
number of deaths (all causes)	0	1	3
number of deaths resulting from adverse events	0	0	0

Serious adverse events	P-105-202: Posoleucel	AVM-003-HC: Placebo	AVM-003-HC: Posoleucel
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 82 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
number of deaths (all causes)	2	3	1
number of deaths resulting from adverse events	0	0	0

Serious adverse events	P-105-303: Placebo	P-105-303: Posoleucel	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	

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

Non-serious adverse events	P-105-201: Placebo	P-105-201: Posoleucel	P-105-202: Placebo
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 18 (0.00%)	0 / 34 (0.00%)	0 / 69 (0.00%)

Non-serious adverse events	P-105-202: Posoleucel	AVM-003-HC: Placebo	AVM-003-HC: Posoleucel
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 82 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)

Non-serious adverse events	P-105-303: Placebo	P-105-303: Posoleucel	
Total subjects affected by non-serious adverse events subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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: Non-serious TEAEs were not applicable to this study. TEAEs associated with PSL or placebo treatment are reported in the parent study clinicaltrials.gov or EudraCT results disclosure as applicable per local regulations.

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
29 July 2021	Protocol Amendment 1 was created in order to: <ul style="list-style-type: none">- Revise the study objectives and endpoints.- Revise the duration of the follow-up period of the registry.- Revise the number of participants expected to be enrolled in the registry.- Revise the data collected.- Simplify some sections of the protocol.

Notes:

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.

It was planned that up to 500 participants would be enrolled; 237 participants were enrolled (135 in PSL arm and 102 in placebo arm).

Notes: