Clinical trial results:
Performance of Elucirem (gadopiclenol) in Dynamic Susceptibility Contrast Magnetic Resonance Imaging (DSC-MRI) perfusion of brain gliomas

Summary

EudraCT number	2022-002720-12
Trial protocol	HU
Global end of trial date	28 November 2024

Results information

Result version number	v1 (current)
This version publication date	31 October 2025
First version publication date	31 October 2025

Trial information

Trial identification

Sponsor protocol code	GDX-44-016

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT06057168
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Guerbet
Sponsor organisation address	15 rue Vanesses, 93420 Villepinte, France,
Public contact	Frantz Hebert, Global Head of Clinical Development, Guerbet, +33 680249334, frantz.hebert@guerbet.com
Scientific contact	Frantz Hebert, Global Head of Clinical Development, Guerbet, +33 680249334, frantz.hebert@guerbet.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	07 April 2025
Is this the analysis of the primary completion data?	Yes
Primary completion date	28 November 2024
Global end of trial reached?	Yes
Global end of trial date	28 November 2024
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To demonstrate the non-inferiority of DSC-MRI perfusion using Elucirem at 0.05 mmol/kg compared to DSC-MRI perfusion using Dotarem at 0.1 mmol/kg in terms of diagnostic quality of CBV perfusion map (off-site assessment).

Protection of trial subjects:

This trial has been conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki, that are consistent with Good Clinical Practice (GCP) according to International Conference on Harmonisation (ICH) guidelines and with the applicable regional/local regulations of the country in which the trial was conducted.
The safety data were monitored during the whole study period.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	07 September 2023
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: 17
Country: Number of subjects enrolled	Hungary: 72
Country: Number of subjects enrolled	Italy: 47
Worldwide total number of subjects	136
EEA total number of subjects	136

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)	102

From 65 to 84 years	34
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

A total of 141 patients were screened in 10 centers from three countries: 76 from four centers in Hungary, 48 from four centers in Italy and 17 from two centers in Poland.

Pre-assignment

Screening details:

Out of the 141 screened patients, 3 patients were screen failed. Therefore, 138 patients were randomized in the trial with 69 in each arm. Out of them, 2 patients prematurely discontinued the study before the injection of contrast agent. The remaining 136 patients underwent MRI examination with injection of IMP: 67 with Elucirem and 69 with Dotarem

Period 1

Period 1 title	Overall trial (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

Blinding implementation details:

Both participants and investigators (on-site readers) were aware of the contrast agent administered while the off-site image evaluations were performed by two independent blinded readers.

Arms

Are arms mutually exclusive?	Yes
Arm title	Elucirem

Arm description:

69 patients randomized in Elucirem group. Among them, 67 patients underwent a DSC-MRI perfusion using Elucirem (gadopiclenol) at 0.05 mmol/kg (safety population for Elucirem Arm). Out of them, 60 who had diagnostic CBV map and without major protocol deviation evaluated by off-site readers were included in the per-protocol primary analysis.

Arm type	Experimental
Investigational medicinal product name	gadopiclenol
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use

Dosage and administration details:

Elucirem (gadopiclenol) administered at a dose of 0.05 mmol/kg body weight in a single injection

Arm title	Dotarem

Arm description:

69 patients randomized in the Dotarem group and underwent a DSC-MRI perfusion using Dotarem (gadoterate meglumine) at 0.1 mmol/kg (safety population for Dotarem Arm). Among them, 64 who had diagnostic CBV map and without major protocol deviation evaluated by off-site readers were included in the per-protocol primary analysis.

Arm type	Active comparator
Investigational medicinal product name	gadoterate meglumine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use

Dosage and administration details:

Dotarem (gadoterate meglumine) administered at a dose of 0.1 mmol/kg body weight in a single injection.

Number of subjects in period 1	Elucirem	Dotarem
Started	67	69
Completed	67	69

Baseline characteristics

Reporting groups	
Reporting group title	Elucirem

Reporting group description:

69 patients randomized in Elucirem group. Among them, 67 patients underwent a DSC-MRI perfusion using Elucirem (gadopiclenol) at 0.05 mmol/kg (safety population for Elucirem Arm). Out of them, 60 who had diagnostic CBV map and without major protocol deviation evaluated by off-site readers were included in the per-protocol primary analysis.

Reporting group title	Dotarem

Reporting group description:

69 patients randomized in the Dotarem group and underwent a DSC-MRI perfusion using Dotarem (gadoterate meglumine) at 0.1 mmol/kg (safety population for Dotarem Arm). Among them, 64 who had diagnostic CBV map and without major protocol deviation evaluated by off-site readers were included in the per-protocol primary analysis.

Reporting group values	Elucirem	Dotarem	Total
Number of subjects	67	69	136
Age categorical			
Safety population (136 patients who received an injection of contrast agent: Elucirem or Dotarem)			
Units: Subjects			
Adults (18-64 years)	51	51	102
Adults (≥65 years)	16	18	34
Age continuous			
Safety population (136 patients who received an injection of contrast agent: Elucirem or Dotarem)			
Units: years			
arithmetic mean	54.9	54.6	
standard deviation	± 14.23	± 14.71	-
Gender categorical			
Safety population (136 patients who received an injection of contrast agent: Elucirem or Dotarem)			
Units: Subjects			
Female	23	30	53
Male	44	39	83

End points

End points reporting groups

Reporting group title	Elucirem

Reporting group description:

69 patients randomized in Elucirem group. Among them, 67 patients underwent a DSC-MRI perfusion using Elucirem (gadopiclenol) at 0.05 mmol/kg (safety population for Elucirem Arm). Out of them, 60 who had diagnostic CBV map and without major protocol deviation evaluated by off-site readers were included in the per-protocol primary analysis.

Reporting group title	Dotarem

Reporting group description:

69 patients randomized in the Dotarem group and underwent a DSC-MRI perfusion using Dotarem (gadoterate meglumine) at 0.1 mmol/kg (safety population for Dotarem Arm). Among them, 64 who had diagnostic CBV map and without major protocol deviation evaluated by off-site readers were included in the per-protocol primary analysis.

Primary: Diagnostic quality of CBV map- Off site assessment

End point title	Diagnostic quality of CBV map- Off site assessment

End point description:

Diagnostic quality of the CBV map was assessed by the two off-site blinded readers using the following scale (poor, fair, good or excellent) and by a consensus in case of discordance between the two readers. The proportion of patients with "excellent" or "good" diagnostic quality images of Elucirem group was compared to that of Dotarem group. 124 patients (60 with Elucirem and 64 with Dotarem) who had diagnostic CBV map and without protocol major deviation were included in the per-protocol analysis.

End point type	Primary

End point timeframe:

At DSC-MRI perfusion using Elucirem or Dotarem

End point values	Elucirem	Dotarem		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	60[1]	64[2]		
Units: Number	60	64		

Notes:

[1] - Patients with diagnostic CBV map and without protocol major deviation (per-protocol analysis).

[2] - Patients with diagnostic CBV map and without protocol major deviation (per-protocol analysis).

Statistical analyses

Statistical analysis title	Diagnostic quality of CBV map_off-site assessment

Statistical analysis description:

Diagnostic quality of the CBV map was assessed by the two off-site blinded readers using the following scale (poor, fair, good or excellent). The proportion of patients with "excellent" or "good" diagnostic quality images of Elucirem group was compared to that of Dotarem group. 124 patients (60 with Elucirem and 64 with Dotarem) who had diagnostic CBV map and without major protocol deviation according to the off-site evaluation were included in the per-protocol primary analysis.

Comparison groups	Elucirem v Dotarem

Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	non-inferiority[3]
Method	% confidence Interval (CI)
Parameter estimate	two-sided 95% confidence Interval (CI)
Point estimate	-0.018
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.089
upper limit	0.053

Notes:

[3] - Non-inferiority was assessed by calculating the difference in proportion of patients presenting with images of excellent or good diagnostic quality between Elucirem and Dotarem groups, and by constructing a two-sided 95% confidence Interval (CI) around this difference. If the lower bound of the two-sided 95% CI was above the pre-stated margin of non-inferiority (-12%), Elucirem was declared non-inferior to Dotarem. The Wald statistical test with a continuity correction was used for CI.

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Adverse events (AE), serious or not, related to the products of study or not, that occurred from the beginning of patient's participation in the trial (Informed Consent Form signature) were recorded until the end of the participation.

Adverse event reporting additional description:

Safety population: the patients who received an IMP
AE reporting: AEs occurring during or after IMP administration for safety population.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	27.1

Reporting groups

Reporting group title	Elucirem

Reporting group description:

Patients who received Elucirem for DSC-MRI perfusion

Reporting group title	Dotarem

Reporting group description:

Patients who received Dotarem for DSC-MRI perfusion

Serious adverse events	Elucirem	Dotarem	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 67 (0.00%)	0 / 69 (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	Elucirem	Dotarem	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3 / 67 (4.48%)	2 / 69 (2.90%)	
Injury, poisoning and procedural complications			
Incorrect dose administered			
subjects affected / exposed	2 / 67 (2.99%)	0 / 69 (0.00%)	
occurrences (all)	2	0	
Incorrect dose administered by device			

subjects affected / exposed	0 / 67 (0.00%)	1 / 69 (1.45%)	
occurrences (all)	0	1	
Nervous system disorders			
Headache			
subjects affected / exposed	0 / 67 (0.00%)	1 / 69 (1.45%)	
occurrences (all)	0	1	
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	1 / 67 (1.49%)	0 / 69 (0.00%)	
occurrences (all)	1	0	
Nausea			
subjects affected / exposed	1 / 67 (1.49%)	0 / 69 (0.00%)	
occurrences (all)	1	0	
Vomiting			
subjects affected / exposed	1 / 67 (1.49%)	0 / 69 (0.00%)	
occurrences (all)	1	0	

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

None reported