Clinical trial results:
Study of Females Exposed to Eleclazine

Summary

EudraCT number	2019-003958-86
Trial protocol	DK IT NL FR
Global end of trial date	31 January 2024

Results information

Result version number	v1 (current)
This version publication date	31 October 2024
First version publication date	31 October 2024

Trial information

Trial identification

Sponsor protocol code	GS-US-356-5413

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Gilead Sciences
Sponsor organisation address	333 Lakeside Drive, Foster City, CA, United States, 94404
Public contact	Gilead Clinical Study Information Center, Gilead Sciences, GileadClinicalTrials@gilead.com
Scientific contact	Gilead Clinical Study Information Center, Gilead Sciences, GileadClinicalTrials@gilead.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?	No

Notes:

General information about the trial

Main objective of the trial:

The main objective of this study was to find out if any female participants had signs or symptoms potentially consistent with uterine cancer after eleclazine exposure.

Protection of trial subjects:

The protocol and consent/assent forms were submitted by each investigator to a duly constituted Independent Ethics Committee (IEC) or Institutional Review Board (IRB) for review and approval before study initiation. All revisions to the consent/assent forms (if applicable) after initial IEC/IRB approval were submitted by the investigator to the IEC/IRB for review and approval before implementation in accordance with regulatory requirements.
This study was conducted in accordance with recognized international scientific and ethical standards, including but not limited to the International Conference on Harmonization guideline for Good Clinical Practice (ICH GCP) and the original principles embodied in the Declaration of Helsinki.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	24 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	Netherlands: 2
Country: Number of subjects enrolled	Denmark: 1
Country: Number of subjects enrolled	France: 6
Country: Number of subjects enrolled	Germany: 5
Country: Number of subjects enrolled	Hungary: 1
Country: Number of subjects enrolled	Italy: 8
Country: Number of subjects enrolled	United States: 46
Country: Number of subjects enrolled	New Zealand: 3
Country: Number of subjects enrolled	Poland: 3
Country: Number of subjects enrolled	Israel: 1
Country: Number of subjects enrolled	United Kingdom: 1
Worldwide total number of subjects	77
EEA total number of subjects	26

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)	62
From 65 to 84 years	15
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Participants were enrolled at study sites in the United States, Europe, New Zealand, the United Kingdom and Israel.

Pre-assignment

Screening details:

Participants who received eleclazine during prior clinical trials were enrolled in this study.

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	Eleclazine

Arm description:

Female participants who received eleclazine tablets at a dose of 1 mg, 3 mg, 6 mg, 10 mg or 60 mg in previous Gilead-sponsored studies were enrolled in this study. Participants did not receive any treatment during this study. Participants were examined to see the signs or symptoms of uterine cancer.

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

Dosage and administration details:

Administered orally

Number of subjects in period 1	Eleclazine
Started	77
Completed	68
Not completed	9
Death	8
Investigator's discretion	1

Baseline characteristics

Reporting groups	
Reporting group title	Eleclazine

Reporting group description:

Female participants who received eleclazine tablets at a dose of 1 mg, 3 mg, 6 mg, 10 mg or 60 mg in previous Gilead-sponsored studies were enrolled in this study. Participants did not receive any treatment during this study. Participants were examined to see the signs or symptoms of uterine cancer.

Reporting group values	Eleclazine	Total	
Number of subjects	77	77	
Age categorical Units: Subjects			
Adults (18-64 years)	62	62	
From 65-84 years	15	15	
Gender categorical Units: Subjects			
Female	77	77	
Male	0	0	
Race Units: Subjects			
White	66	66	
Black or African American	7	7	
Not Collected	3	3	
Asian	1	1	
Ethnicity Units: Subjects			
Not Hispanic or Latino	50	50	
Hispanic or Latino	24	24	
Not Collected	3	3	

End points

End points reporting groups

Reporting group title	Eleclazine

Reporting group description:

Female participants who received eleclazine tablets at a dose of 1 mg, 3 mg, 6 mg, 10 mg or 60 mg in previous Gilead-sponsored studies were enrolled in this study. Participants did not receive any treatment during this study. Participants were examined to see the signs or symptoms of uterine cancer.

Primary: Number of Female Participants Enrolled Who Signed the Informed Consent Form

End point title	Number of Female Participants Enrolled Who Signed the Informed Consent Form[1]

End point description:

End point type	Primary

End point timeframe:

Up to 2.8 months

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 statistical comparison was planned or performed.

End point values	Eleclazine			
Subject group type	Reporting group			
Number of subjects analysed	77			
Units: participants	69			

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Female Participants with Signs or Symptoms Potentially Consistent with Uterine Cancer After Eleclazine Exposure

End point title	Percentage of Female Participants with Signs or Symptoms Potentially Consistent with Uterine Cancer After Eleclazine Exposure[2]

End point description:

The percentage of female participants with signs or symptoms potentially consistent with uterine cancer after eleclazine exposure included participants with uterine cancer reported on the medical history form or on the adverse event form or participants with symptoms reported on the Uterine Cancer symptom and risk factor form including intermenstrual or postmenopausal bleeding, pelvic pain and unexplained weight loss.
Analysis Population Description:
Enrolled population excluding participants enrolled with waiver: All female participants included in the enrolled population excluding participants with informed consent form (ICF) waiver obtained from institutional review board / ethics committee (IRB/EC).

End point type	Primary

End point timeframe:

Up to 2.8 months

Notes:

[2] - 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 statistical comparison was planned or performed.

End point values	Eleclazine			
Subject group type	Reporting group			
Number of subjects analysed	69			
Units: percentage of participants				
number (confidence interval 95%)	8.7 (3.3 to 18.0)			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]

Timeframe for reporting adverse events:

All-Cause Mortality: Up to 2.8 months
Adverse Events: Up to 2.4 weeks

Adverse event reporting additional description:

All-cause mortality and adverse events: Enrolled Population: All females who signed the informed consent form (ICF (or whose legally authorized representatives signed the ICF)) or enrolled with ICF waiver and met all eligibility criteria for the study.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	26.1

Reporting groups

Reporting group title	Eleclazine

Reporting group description:

Female participants who received eleclazine tablets at a dose of 1 mg, 3 mg, 6 mg, 10 mg or 60 mg in previous Gilead-sponsored studies were enrolled in this study. Participants did not receive any treatment during this study. Participants were examined to see the signs or symptoms of uterine cancer.

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: The participants did not experience any non serious adverse events.

Serious adverse events	Eleclazine		
Total subjects affected by serious adverse events			
subjects affected / exposed	8 / 77 (10.39%)		
number of deaths (all causes)	8		
number of deaths resulting from adverse events			
Injury, poisoning and procedural complications			
Procedural shock			
subjects affected / exposed	1 / 77 (1.30%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Vascular disorders			
Hypotension			
subjects affected / exposed	1 / 77 (1.30%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Cardiac disorders			
Cardiac failure chronic			

subjects affected / exposed	1 / 77 (1.30%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Cardiac arrest			
subjects affected / exposed	1 / 77 (1.30%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Nervous system disorders			
Thalamus haemorrhage			
subjects affected / exposed	1 / 77 (1.30%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
General disorders and administration site conditions			
Death			
subjects affected / exposed	1 / 77 (1.30%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Hepatobiliary disorders			
Chronic hepatic failure			
subjects affected / exposed	1 / 77 (1.30%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Renal and urinary disorders			
End stage renal disease			
subjects affected / exposed	1 / 77 (1.30%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Infections and infestations			
Sepsis			
subjects affected / exposed	2 / 77 (2.60%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 2		

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

Non-serious adverse events	Eleclazine		
Total subjects affected by non-serious adverse events subjects affected / exposed	0 / 77 (0.00%)		

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 data for deaths could not be collected for participants with waiver for participants who were deceased.

Notes: