



Clinical trial results:

An open-label, multicentre, single arm study to assess the efficacy and safety of triptorelin 6-month formulation administered subcutaneously in participants with locally advanced and/or metastatic prostate cancer previously treated and castrated with a GnRH analogue

Summary

EudraCT number	2021-005719-29
Trial protocol	FR BE ES LT NL CZ
Global end of trial date	08 July 2024

Results information

Result version number	v1 (current)
This version publication date	20 July 2025
First version publication date	20 July 2025

Trial information

Trial identification

Sponsor protocol code	D-FR-52014-245
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT05458856
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Ipsen Pharma SAS
Sponsor organisation address	70 rue Balard, PARIS, France, 75015
Public contact	Medical Director, Ipsen Pharma SAS, clinical.trials@ipsen.com
Scientific contact	Medical Director, Ipsen Pharma SAS, clinical.trials@ipsen.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	08 July 2024
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	08 July 2024
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate the efficacy of triptorelin embonate 22.5 milligrams (mg) 6-month formulation administered subcutaneously (SC) in maintaining serum testosterone castrate levels in participants with advanced prostate cancer previously treated and castrated with a gonadotropin-releasing hormone (GnRH) analogue.

Protection of trial subjects:

The study was conducted under the provisions of the Declaration of Helsinki, in accordance with the International Conference on Harmonisation Consolidated Guideline on Good Clinical Practice and in compliance with independent ethics committees and informed consent regulations.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	30 August 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	Czechia: 8
Country: Number of subjects enrolled	France: 31
Country: Number of subjects enrolled	Germany: 7
Country: Number of subjects enrolled	Lithuania: 51
Country: Number of subjects enrolled	Netherlands: 20
Country: Number of subjects enrolled	Spain: 30
Worldwide total number of subjects	147
EEA total number of subjects	147

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)	24
From 65 to 84 years	116
85 years and over	7

Subject disposition

Recruitment

Recruitment details:

This Phase III, multicenter, open-label, single arm study was conducted at 26 investigational sites in 6 countries from 30-Aug-2022 to 08-Jul-2024 in participants with locally advanced and/or metastatic prostate cancer previously treated and castrated with a GnRH analogue.

Pre-assignment

Screening details:

The study consisted of a screening period (Day -28 to Day -1), study treatment administration on Days 1 and 169 (with visits on Days 3, 7, 29, 85, 141, 171, 175, 253, 309) and an end of study/early discontinuation visit on Day 337. A total of 147 participants were enrolled in the 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	Triptorelin Embonate 22.5 mg
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Arm description:

Participants received triptorelin embonate 22.5 mg SC injection on Days 1 and 169.

Arm type	Experimental
Investigational medicinal product name	Triptorelin embonate
Investigational medicinal product code	
Other name	Decapeptyl®, Pamorelin®, Diphereline®
Pharmaceutical forms	Powder and solvent for suspension for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Triptorelin embonate 22.5 mg was administered as an SC injection on Days 1 and 169.

Number of subjects in period 1	Triptorelin Embonate 22.5 mg
Started	147
Received treatment	145
Completed	134
Not completed	13
Consent withdrawn by subject	5
Physician decision	1
Death	4
Protocol deviation	3

Baseline characteristics

Reporting groups

Reporting group title	Triptorelin Embonate 22.5 mg
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Reporting group description:

Participants received triptorelin embonate 22.5 mg SC injection on Days 1 and 169.

Reporting group values	Triptorelin Embonate 22.5 mg	Total	
Number of subjects	147	147	
Age categorical Units: Subjects			
Age continuous Units: years arithmetic mean standard deviation	71.8 ± 8.43	-	
Gender categorical Units: Subjects			
Female	0	0	
Male	147	147	
Ethnicity Units: Subjects			
Hispanic or Latino	4	4	
Not Hispanic or Latino	104	104	
Unknown or Not Reported	39	39	
Race Units: Subjects			
White	109	109	
Other	2	2	
Not Reported	36	36	

End points

End points reporting groups

Reporting group title	Triptorelin Embonate 22.5 mg
Reporting group description:	
Participants received triptorelin embonate 22.5 mg SC injection on Days 1 and 169.	

Primary: Percentage of Participants who Maintained Castrate Levels of Serum Testosterone During the Study

End point title	Percentage of Participants who Maintained Castrate Levels of Serum Testosterone During the Study ^[1]
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End point description:

Blood samples were collected for the measurement of serum testosterone concentrations using a validated, specific and sensitive liquid chromatography tandem mass spectrometry method. Maintenance of castration during the study was defined as testosterone <1.735 nanomoles per liter (nmol/L) (<50 nanograms/deciliter [ng/dL]) at Days 29, 85, 141, 169, 253, 309 and 337. The full analysis set (FAS) included all participants who signed an informed consent form (ICF) and received 2 administrations of study treatment and completed all visits for testosterone measurement (Days 29, 85, 141, 169, 253, 309 and 337).

End point type	Primary
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End point timeframe:

Up to Day 337

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: As the endpoint is descriptive in nature, no statistical analysis is provided.

End point values	Triptorelin Embonate 22.5 mg			
Subject group type	Reporting group			
Number of subjects analysed	120			
Units: percentage of participants				
number (confidence interval 95%)	95.0 (89.4 to 98.1)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Castrated on Days 29, 85, 141, 169, 253, 309 and 337

End point title	Percentage of Participants Castrated on Days 29, 85, 141, 169, 253, 309 and 337
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End point description:

Blood samples were collected for the measurement of serum testosterone concentrations using a validated, specific and sensitive liquid chromatography tandem mass spectrometry method. Castration was defined as testosterone <1.735 nmol/L (<50 ng/dL). The FAS included all participants who signed an ICF and received 2 administrations of study treatment and completed all visits for testosterone measurement (Days 29, 85, 141, 169, 253, 309 and 337).

End point type	Secondary
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End point timeframe:

Days 29, 85, 141, 169, 253, 309 and 337

End point values	Triptorelin Embonate 22.5 mg			
Subject group type	Reporting group			
Number of subjects analysed	120			
Units: percentage of participants				
number (confidence interval 95%)				
Day 29	100.0 (97.0 to 100.0)			
Day 85	100.0 (97.0 to 100.0)			
Day 141	98.3 (94.1 to 99.8)			
Day 169	97.5 (92.9 to 99.5)			
Day 253	100.0 (97.0 to 100.0)			
Day 309	99.2 (95.4 to 100.0)			
Day 337	99.2 (95.4 to 100.0)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With a Serum Testosterone Level <0.694 nmol/L (<20 ng/dL) During the Study

End point title	Percentage of Participants With a Serum Testosterone Level <0.694 nmol/L (<20 ng/dL) During the Study
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End point description:

Blood samples were collected for the measurement of serum testosterone concentrations using a validated, specific and sensitive liquid chromatography tandem mass spectrometry method. The FAS included all participants who signed an ICF and received 2 administrations of study treatment and completed all visits for testosterone measurement (Days 29, 85, 141, 169, 253, 309 and 337).

End point type	Secondary
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End point timeframe:

Up to Day 337

End point values	Triptorelin Embonate 22.5 mg			
Subject group type	Reporting group			
Number of subjects analysed	120			
Units: percentage of participants				
number (confidence interval 95%)	83.3 (75.4 to 89.5)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With a Serum Testosterone Level <0.694 nmol/L (<20 ng/dL) on Days 29, 85, 141, 169, 253, 309 and 337

End point title	Percentage of Participants With a Serum Testosterone Level <0.694 nmol/L (<20 ng/dL) on Days 29, 85, 141, 169, 253, 309 and 337
End point description:	
Blood samples were collected for the measurement of serum testosterone concentrations using a validated, specific and sensitive liquid chromatography tandem mass spectrometry method. The FAS included all participants who signed an ICF and received 2 administrations of study treatment and completed all visits for testosterone measurement (Days 29, 85, 141, 169, 253, 309 and 337).	
End point type	Secondary
End point timeframe:	
Days 29, 85, 141, 169, 253, 309 and 337	

End point values	Triptorelin Embonate 22.5 mg			
Subject group type	Reporting group			
Number of subjects analysed	120			
Units: percentage of participants				
number (confidence interval 95%)				
Day 29	92.5 (86.2 to 96.5)			
Day 85	92.5 (86.2 to 96.5)			
Day 141	92.5 (86.2 to 96.5)			
Day 169	94.2 (88.4 to 97.6)			
Day 253	95.8 (90.5 to 98.6)			
Day 309	95.8 (90.5 to 98.6)			
Day 337	98.3 (94.1 to 99.8)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Castrated on Days 3 and 7 After Each Injection Administered on Days 1 and 169

End point title	Percentage of Participants Castrated on Days 3 and 7 After Each Injection Administered on Days 1 and 169
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End point description:

Blood samples were collected for the measurement of serum testosterone concentrations using a validated, specific and sensitive liquid chromatography tandem mass spectrometry method. Castration was defined as testosterone <1.735 nmol/L (<50 ng/dL). Percentages are rounded off to the tenth decimal place. The FAS included all participants who signed an ICF and received 2 administrations of study treatment and completed all visits for testosterone measurement (Days 29, 85, 141, 169, 253, 309 and 337).

End point type	Secondary
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End point timeframe:

On Days 3, 7, 171, and 175

End point values	Triptorelin Embonate 22.5 mg			
Subject group type	Reporting group			
Number of subjects analysed	120			
Units: percentage of participants				
number (confidence interval 95%)				
Day 3	92.5 (86.2 to 96.5)			
Day 7	98.3 (94.1 to 99.8)			
Day 171	95.0 (89.4 to 98.1)			
Day 175	95.8 (90.5 to 98.6)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percent Change From Baseline in Prostate Specific Antigen (PSA) at Days 169 and 337

End point title	Percent Change From Baseline in Prostate Specific Antigen (PSA) at Days 169 and 337
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End point description:

Blood samples were collected for the measurement of plasma PSA concentrations. Percent change in PSA was defined as the absolute value of the difference between the PSA values at Days 169 and 337 and the baseline value divided by the baseline value. The baseline value was the last sample prior to the first injection. The FAS included all participants who signed an ICF and received 2 administrations of study treatment and completed all visits for testosterone measurement (Days 29, 85, 141, 169, 253, 309 and 337). Only those participants with data collected at specified timepoints are reported. Here, n=number of participants with data collected for each specified category.

End point type	Secondary
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End point timeframe:

Baseline (prior to injection on Day 1), Days 169 and 337

End point values	Triptorelin Embonate 22.5 mg			
Subject group type	Reporting group			
Number of subjects analysed	118			
Units: percent change				
median (inter-quartile range (Q1-Q3))				
Day 169 (n=115)	0.00 (-35.60 to 0.00)			
Day 337 (n=118)	0.00 (-46.90 to 14.30)			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants With Treatment-Emergent Adverse Events (TEAEs) and TEAEs of Local Intolerance

End point title	Number of Participants With Treatment-Emergent Adverse Events (TEAEs) and TEAEs of Local Intolerance
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End point description:

An adverse event (AE) was any untoward medical occurrence in clinical study participant, temporally associated with use of study treatment, whether or not considered related to study treatment. TEAEs were AEs that started or worsened on or after the first study treatment administration and within 168 days after the last dose of study treatment, or up to Day 337, whichever was later. Local tolerance was assessed 2 hours after each injection by examination of injection site for signs such as but not limited to tenderness, redness, bruising, erythema, swelling, rash, pain, itching, induration, hematoma, ulceration or necrosis. The safety set included all participants who received at least 1 dose of study treatment.

End point type	Secondary
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End point timeframe:

From first dose of study treatment (Day 1) up to end of study visit (Day 337)

End point values	Triptorelin Embonate 22.5 mg			
Subject group type	Reporting group			
Number of subjects analysed	145			
Units: participants				
TEAEs	88			
TEAEs of Local Intolerance	19			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Serious AEs, non-serious AEs and deaths were collected from screening (Day -28) up to end of study visit (Day 337), up to maximum of 365 days

Adverse event reporting additional description:

The safety set included all participants who received at least 1 dose of study treatment.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	27.0
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Reporting groups

Reporting group title	Triptorelin Embonate 22.5 mg
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Reporting group description:

Participants received triptorelin embonate 22.5 mg SC injection on Days 1 and 169.

Serious adverse events	Triptorelin Embonate 22.5 mg		
Total subjects affected by serious adverse events			
subjects affected / exposed	26 / 145 (17.93%)		
number of deaths (all causes)	4		
number of deaths resulting from adverse events	4		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Squamous cell carcinoma of skin			
subjects affected / exposed	2 / 145 (1.38%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Clear cell renal cell carcinoma			
subjects affected / exposed	1 / 145 (0.69%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Metastases to central nervous system			
subjects affected / exposed	1 / 145 (0.69%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Injury, poisoning and procedural complications			

Foot fracture			
subjects affected / exposed	1 / 145 (0.69%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Head injury			
subjects affected / exposed	1 / 145 (0.69%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Peroneal nerve injury			
subjects affected / exposed	1 / 145 (0.69%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Road traffic accident			
subjects affected / exposed	1 / 145 (0.69%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Skin laceration			
subjects affected / exposed	1 / 145 (0.69%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Vascular disorders			
Hypertension			
subjects affected / exposed	1 / 145 (0.69%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cardiac disorders			
Acute myocardial infarction			
subjects affected / exposed	1 / 145 (0.69%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
Cerebral haematoma			

subjects affected / exposed	1 / 145 (0.69%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cerebral ischaemia			
subjects affected / exposed	1 / 145 (0.69%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Generalised tonic-clonic seizure			
subjects affected / exposed	1 / 145 (0.69%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Syncope			
subjects affected / exposed	1 / 145 (0.69%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
Disease progression			
subjects affected / exposed	2 / 145 (1.38%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 2		
Death			
subjects affected / exposed	1 / 145 (0.69%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
General physical health deterioration			
subjects affected / exposed	1 / 145 (0.69%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 145 (0.69%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	1 / 145 (0.69%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Inguinal hernia			
subjects affected / exposed	1 / 145 (0.69%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Pneumothorax spontaneous			
subjects affected / exposed	1 / 145 (0.69%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Renal and urinary disorders			
Nephrolithiasis			
subjects affected / exposed	1 / 145 (0.69%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal and connective tissue disorders			
Osteonecrosis			
subjects affected / exposed	1 / 145 (0.69%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
COVID-19			
subjects affected / exposed	4 / 145 (2.76%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Anal abscess			
subjects affected / exposed	1 / 145 (0.69%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Appendicitis			

subjects affected / exposed	1 / 145 (0.69%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Lyme disease			
subjects affected / exposed	1 / 145 (0.69%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pneumonia			
subjects affected / exposed	1 / 145 (0.69%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	Triptorelin Embonate 22.5 mg		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	38 / 145 (26.21%)		
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	9 / 145 (6.21%)		
occurrences (all)	9		
Vascular disorders			
Hot flush			
subjects affected / exposed	17 / 145 (11.72%)		
occurrences (all)	18		
Hypertension			
subjects affected / exposed	14 / 145 (9.66%)		
occurrences (all)	15		
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	8 / 145 (5.52%)		
occurrences (all)	8		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
13 September 2022	Objectives and endpoints were modified to add clarification on the primary and secondary estimands for the primary endpoint. Number of participants was revised from 153 to 145, to account for decrease in dropout rate from 15% to 10%. An exclusion criteria related to the use of other therapy for prostate cancer during the study was modified to avoid exclusion of eligible participants. The list of prohibited medications during the study was modified to include abiraterone. Clarification on withdrawal of participants with lack of efficacy during the study was added to the protocol. Blood volume collection during the study was increased from 65 milliliter (mL) to 153 mL, to accommodate blood samples needed for central laboratory testing. Primary objective was modified to include definition of "maintenance of castration". Definition of FAS was modified to include the participants who received 2 administrations of study intervention and completed all visits for testosterone measurement. Administrative changes resulting due to changes in sponsor signatory and medical monitor were made. Minor inconsistencies and typographical mistakes were corrected.
04 December 2023	Reporting of Coronavirus disease 2019 (COVID-19) cases was modified. This meant that COVID-19 was no longer to be reported as an SAE unless the occurrence of COVID-19 met the defined seriousness criteria. Reason for temporary discontinuation of study treatment was updated to comply with protocol template guidance. Definition of a lost to follow-up participant was updated to comply with protocol template guidance. Administrative changes resulting due to changes in sponsor signatory and medical monitor were made. Minor inconsistencies and typographical mistakes were corrected.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported