



Clinical trial results:

A phase II randomized, placebo-controlled, double-blinded, 2-parallel arm, clinical trial evaluating Ladarixin 400 mg twice a day as adjunctive therapy to improve glycemic control in overweight insulin-resistant patients with type 1 diabetes

Summary

EudraCT number	2022-000743-68
Trial protocol	IT
Global end of trial date	18 September 2023

Results information

Result version number	v1 (current)
This version publication date	01 March 2026
First version publication date	01 March 2026

Trial information

Trial identification

Sponsor protocol code	LDX0122
-----------------------	---------

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT05368402
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Dompé farmaceutici S.p.A.
Sponsor organisation address	Via Santa Lucia 6, Milano, Italy, 20122
Public contact	Clinical Trial Manager, Dompé farmaceutici S.p.A., +39 02583831, clinicaltrials@dompe.com
Scientific contact	Clinical Trial Manager, Dompé farmaceutici S.p.A., +39 02583831, clinicaltrials@dompe.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	28 November 2023
Is this the analysis of the primary completion data?	Yes
Primary completion date	18 September 2023
Global end of trial reached?	Yes
Global end of trial date	18 September 2023
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

The primary objective of this clinical trial was to determine whether oral ladarixin versus placebo as adjunctive therapy is efficacious in improving glycemic control in overweight, insulin-resistant adult participants with type 1 diabetes.

Protection of trial subjects:

Not Applicable

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	14 September 2022
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Italy: 2
Worldwide total number of subjects	2
EEA total number of subjects	2

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)	2
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

The present study (CONSERVA) was a randomized, placebo-controlled, double-blind, 2-parallel arm, phase II trial and the study was conducted at two sites in Italy.

Pre-assignment

Screening details:

Of 24 participants who were screened, 21 failed to meet eligibility criteria, and 3 were enrolled, of which 2 were randomized: 1 in the IMP arm and 1 in the placebo arm. The third enrolled participant was not randomized after being enrolled due to study interruption.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Ladarixin

Arm description:

Ladarixin was administered orally at the dose of 400 milligrams (mg) twice a day (b.i.d) for 7 cycles of 14 days with an interval of 14 days off, for a total duration of 26 weeks.

Arm type	Experimental
Investigational medicinal product name	Ladarixin
Investigational medicinal product code	
Other name	LDX
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

The two daily oral doses of ladarixin (400 mg each dose) were administered at about a 12-hour interval (morning and evening; ideally between 6:30/11:30 and 18:30/23:30). At each administration, 2 capsules were swallowed with a glass of water, at least 2 hours apart from breakfast or dinner.

Arm title	Placebo
------------------	---------

Arm description:

Matching placebo was administered with the same treatment schedule of the IMP.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Placebo was administered with the same schedule as Ladarixin.

Number of subjects in period 1	Ladarixin	Placebo
Started	1	1
Completed	1	1

Baseline characteristics

Reporting groups

Reporting group title	Ladarixin
-----------------------	-----------

Reporting group description:

Ladarixin was administered orally at the dose of 400 milligrams (mg) twice a day (b.i.d) for 7 cycles of 14 days with an interval of 14 days off, for a total duration of 26 weeks.

Reporting group title	Placebo
-----------------------	---------

Reporting group description:

Matching placebo was administered with the same treatment schedule of the IMP.

Reporting group values	Ladarixin	Placebo	Total
Number of subjects	1	1	2
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)	1	1	2
Adults (18-64 years)	0	0	0
From 65-84 years	0	0	0
85 years and over	0	0	0
Gender categorical			
Units: Subjects			
Female	1	1	2
Male	0	0	0

End points

End points reporting groups

Reporting group title	Ladarixin
-----------------------	-----------

Reporting group description:

Ladarixin was administered orally at the dose of 400 milligrams (mg) twice a day (b.i.d) for 7 cycles of 14 days with an interval of 14 days off, for a total duration of 26 weeks.

Reporting group title	Placebo
-----------------------	---------

Reporting group description:

Matching placebo was administered with the same treatment schedule of the IMP.

Primary: Number of Participants With an HbA1c Reduction From Baseline of $\geq 0.50\%$ (Absolute Difference) Without Episodes of Severe Hypoglycemia

End point title	Number of Participants With an HbA1c Reduction From Baseline of $\geq 0.50\%$ (Absolute Difference) Without Episodes of Severe Hypoglycemia ^[1]
-----------------	--

End point description:

The primary endpoint was defined as the proportion of participant with an HbA1c reduction from baseline of $\geq 0.50\%$ (absolute difference) without episodes of severe hypoglycemia at Week 27/28 (Visit 4). No efficacy evaluation was conducted due to the low recruitment rate (out of the 24 participants screened, only 2 participants were enrolled, 1 in the ladarixin group and 1 in the placebo group), resulting in a sample size not adequate for any formal statistical analyses. The low recruitment rate led the Sponsor decide to close enrollment on 04th August 2023 and thus to early terminate the study. No participants experienced an HbA1c reduction from baseline of at least $\geq 0.50\%$

End point type	Primary
----------------	---------

End point timeframe:

At Week 27/28 (Visit 4)

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: Not applicable

End point values	Ladarixin	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1	1		
Units: participants				
number (not applicable)	0	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants With Treatment Emergent Adverse Events (TEAEs) of Any Kind From the Beginning of Study Treatment to up to the End of Study Participation

End point title	Number of participants With Treatment Emergent Adverse Events (TEAEs) of Any Kind From the Beginning of Study Treatment to up to the End of Study Participation
-----------------	---

End point description:

This secondary endpoint was defined as the number of participants experiencing treatment emergent adverse events (TEAEs) of any kind from the beginning of study treatment administration to the end of study participation. An adverse event (AE) is any untoward medical occurrence after exposure to a medicine, which is not necessarily caused by that medicine. A serious AE (SAE) was any adverse event that results in death, is life-threatening, requires hospitalization or prolongation of existing hospitalization, results in persistent or significant disability or incapacity, or is a birth defect. A non serious AE (nSAE) is any adverse drug experience associated with the use of the Product in humans, whether or not considered drug-related, which is not a SAE. TEAEs were defined as events with onset date or worsening during the on-treatment period.

End point type	Secondary
----------------	-----------

End point timeframe:

Throughout the study, up to week 26 (day 182)

End point values	Ladarixin	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1	1		
Units: participants				
number (not applicable)	0	0		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information^[1]

Timeframe for reporting adverse events:

Throughout the study up to week 26 (day 182), for the only 2 participants with safety results.

Assessment type	Systematic
-----------------	------------

Dictionary used

Dictionary name	MedDRA
-----------------	--------

Dictionary version	25.0
--------------------	------

Reporting groups

Reporting group title	Ladarixin
-----------------------	-----------

Reporting group description:

Ladarixin was administered orally at the dose of 400 mg b.i.d. for 7 cycles of 14 days with an interval of 14 days off, for a total duration of 26 weeks.

Reporting group title	Placebo
-----------------------	---------

Reporting group description:

Matching placebo was administered with the same treatment schedule of the IMP.

Serious adverse events	Ladarixin	Placebo	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (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	Ladarixin	Placebo	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (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: Not applicable

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
30 June 2022	- Study involved a more thorough definition of pregnancy and lactation as an exclusion criterion, implementation of safety checks at week 4 and end of the study, and a better definition of hypoglycemia
28 October 2022	- Refining the definition of detectable C-peptide to facilitate recruitment.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? Yes

Date	Interruption	Restart date
04 August 2023	The Sponsor decided to close the enrollment because of a low recruitment rate. When recruitment was closed, two participants had been randomized, no SAE had occurred and therefore the safety profile of the IMP had not changed. Participants already enrolled and randomized followed the study visits and procedures as planned. The unsatisfactory recruitment was due to both a low rate of eligible participants undergoing and then passing the screening activities.	-

Notes:

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

This study was terminated early due to low recruitment rates.

Notes: