Clinical trial results:
A Multicenter, Randomized, Double Blind, Placebo Controlled, Proof of Concept, Phase 2 Study to Evaluate the Efficacy and Safety of Weekly Subcutaneous MLN1202, in Improving Diabetic Nephropathy in Subjects With Macroalbuminuria

Summary

EudraCT number	2014-005142-21
Trial protocol	SK AT DK
Global end of trial date	17 November 2015

Results information

Result version number	v1 (current)
This version publication date	26 July 2020
First version publication date	26 July 2020

Trial information

Trial identification

Sponsor protocol code	MLN1202-2005

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02410499
WHO universal trial number (UTN)	U1111-1168-1426

Notes:

Sponsors

Sponsor organisation name	Takeda
Sponsor organisation address	One Takeda Parkway, Deerfield, United States, 60015
Public contact	Medical Director, Clinical Science, Takeda Development Centre Europe Limited, 001 224-554-6500, trialdisclosures@takeda.com
Scientific contact	Medical Director, Clinical Science, Takeda Development Centre Europe Limited, 001 224-554-6500, trialdisclosures@takeda.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	17 November 2015
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	17 November 2015
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

The purpose of this study is to characterize the effects of 85 days treatment with MLN1202 on urinary albumin-to-creatinine ratio (UACR) in participants with type 2 diabetes, advanced kidney disease/diabetic nephropathy (DN) and macroalbuminuria (UACR>300 mg/g) based on average of 3 consecutive first morning voids sample collection.

Protection of trial subjects:

N/A

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	20 May 2015
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	Slovakia: 99999
Worldwide total number of subjects	99999
EEA total number of subjects	99999

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)	99999
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

99999 is "Not applicable" value or 0 participants, this trial was discontinued with no participants enrolled in the trial.

Pre-assignment

Screening details:

N/A

Period 1

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

Arms

Arm title	Overall

Arm description:

MLN1202 solution for SC injection

Arm type	Experimental
Investigational medicinal product name	MLN1202
Investigational medicinal product code	MLN1202
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Dosage would have been one subcutaneous injection weekly.

Number of subjects in period 1	Overall
Started	99999
Completed	99999

Baseline characteristics

Reporting groups	
Reporting group title	Overall
Reporting group description:	
MLN1202 solution for SC injection	

Reporting group values	Overall	Total	
Number of subjects	99999	99999	
Age Categorical Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	99999	99999	
From 65-84 years	0	0	
85 years and over	0	0	
Age Continuous Units: years			
arithmetic mean	0		
standard deviation	± 0	-	
Gender Categorical Units: Subjects			
Female	99999	99999	
Male	0	0	

End points

End points reporting groups

Reporting group title	Overall
Reporting group description:	
MLN1202 solution for SC injection	

Primary: Change from Baseline in Urinary Albumin-to-Creatinine Ratio (UACR) at Day 85

End point title	Change from Baseline in Urinary Albumin-to-Creatinine Ratio (UACR) at Day 85[1]
End point description:	
99999 is "Not applicable" value or 0 participants, this trial was discontinued with no participants enrolled in the trial.	
End point type	Primary
End point timeframe:	
N/A	

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: N/A

End point values	Overall			
Subject group type	Reporting group			
Number of subjects analysed	99999[2]			
Units: number	99999			

Notes:

[2] - No subjects were enrolled in the trial hence results are not available

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]

Timeframe for reporting adverse events:

All adverse events occurring during the course of the clinical trial were to be collected.

Adverse event reporting additional description:

N/A

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	0

Reporting groups

Reporting group title	MLN1202

Reporting group description:

MLN1202 solution for SC injection

Serious adverse events	MLN1202		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 99999 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

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

Non-serious adverse events	MLN1202		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 99999 (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: N/A

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.

99999 is "Not applicable" value or 0 participants, this trial was discontinued with no participants enrolled in the trial.

Notes: