



Clinical trial results:

A Randomised, Double-blind, Placebo-controlled Study to Evaluate the Effect on Urine Albumin-to-Creatinine Ratio (UACR), Pharmacodynamics, Safety, Tolerability and Pharmacokinetics of Multiple Oral Doses of MT-3995 as Add-on Therapy to ACE-I or ARB in Type II Diabetic Nephropathy Subjects with Albuminuria and an eGFR =>60 mL/min/1.73m²

Summary

| | |
|--------------------------|----------------|
| EudraCT number | 2012-002480-98 |
| Trial protocol | HU LT SK BG |
| Global end of trial date | 11 August 2014 |

Results information

| | |
|--------------------------------|--------------|
| Result version number | v1 (current) |
| This version publication date | 29 June 2016 |
| First version publication date | 29 June 2016 |

Trial information

Trial identification

| | |
|-----------------------|-------------|
| Sponsor protocol code | MT-3995-E06 |
|-----------------------|-------------|

Additional study identifiers

| | |
|------------------------------------|-------------|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | NCT01756703 |
| WHO universal trial number (UTN) | - |

Notes:

Sponsors

| | |
|------------------------------|--|
| Sponsor organisation name | Mitsubishi Tanabe Pharma Corporation |
| Sponsor organisation address | 17-10, Nihonbashi-Koamicho, Chuo-ku, Tokyo, Japan, 103-8405 |
| Public contact | General Information, Mitsubishi Tanabe Pharma Europe Ltd. , regulatory@mt-pharma-eu.com |
| Scientific contact | General Information, Mitsubishi Tanabe Pharma Europe Ltd. , regulatory@mt-pharma-eu.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 October 2014 |
| Is this the analysis of the primary completion data? | Yes |
| Primary completion date | 11 August 2014 |
| Global end of trial reached? | Yes |
| Global end of trial date | 11 August 2014 |
| Was the trial ended prematurely? | No |

Notes:

General information about the trial

Main objective of the trial:

To evaluate the safety and tolerability of multiple oral doses of MT-3995 in subjects with Type II diabetic kidney disease with protein in urine.

Protection of trial subjects:

Serum potassium algorithm

AST/ALT liver function withdrawal criteria

Serum creatinine withdrawal criteria

Background therapy:

- ACE-I or ARB treatment for at least 12 weeks prior to screening
- Stable dose of ACE-I or ARB from at least 4 weeks prior to screening until baseline visit and throughout the study period

Evidence for comparator: -

| | |
|---|------------------|
| Actual start date of recruitment | 28 November 2012 |
| 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 | Slovakia: 19 |
| Country: Number of subjects enrolled | Bulgaria: 9 |
| Country: Number of subjects enrolled | Hungary: 19 |
| Country: Number of subjects enrolled | Lithuania: 10 |
| Country: Number of subjects enrolled | Romania: 10 |
| Worldwide total number of subjects | 67 |
| EEA total number of subjects | 67 |

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) | 54 |
| From 65 to 84 years | 13 |
| 85 years and over | 0 |

Subject disposition

Recruitment

Recruitment details:

67 subjects were randomised from 57 enrolling sites in Bulgaria, Hungary, Lithuania, Romania and Slovakia. FSS was 28/11/2012; LSS was 14/03/14. FSR was 11/03/2013; LSR was 24/04/2014. The study was conducted in university/public/private hospitals and specialised diabetes/renal impairment care practices.

Pre-assignment

Screening details:

294 subjects were screened in order to randomise 67 subjects. The screening period for each subject was 2 weeks.

Period 1

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

Blinding implementation details:

UACR and PK laboratory results were not distributed to the sites in order to prevent potential unblinding. MT-3995/placebo capsules appeared the same and same number of capsules were given.

Arms

| | |
|------------------------------|---------|
| Are arms mutually exclusive? | Yes |
| Arm title | Placebo |

Arm description:

Group 1: Placebo oral capsules matching MT-3995 from Day 1 to the end of the treatment period (Week 8).

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

Dosage and administration details:

Placebo was matching the MT-3995 capsules in number and appearance.

| | |
|------------------|----------------|
| Arm title | MT-3995 - 5 mg |
|------------------|----------------|

Arm description:

Group 2: 80 mg loading dose on Day 1 and 5 mg od maintenance dose from Day 2 (Week 1) to the end of the treatment period (Week 8).

| | |
|--|--------------|
| Arm type | Experimental |
| Investigational medicinal product name | MT-3995 |
| Investigational medicinal product code | MT-3995 |
| Other name | |
| Pharmaceutical forms | Capsule |
| Routes of administration | Oral use |

Dosage and administration details:

80 mg loading dose respectively on day 1 followed by 5 mg maintenance dose from Day 2 until end of treatment period (Week 8).

| | |
|------------------|-----------------|
| Arm title | MT-3995 - 10 mg |
|------------------|-----------------|

Arm description:

Group 3: 160 mg loading dose on Day 1 and 10 mg od maintenance dose from Day 2 (Week 1) to the

end of the treatment period (Week 8).

| | |
|--|--------------|
| Arm type | Experimental |
| Investigational medicinal product name | MT-3995 |
| Investigational medicinal product code | MT-3995 |
| Other name | |
| Pharmaceutical forms | Capsule |
| Routes of administration | Oral use |

Dosage and administration details:

160 mg loading dose respectively on day 1 followed by 10 mg maintenance dose od from Day 2 until end of treatment period (Week 8).

| Number of subjects in period 1 | Placebo | MT-3995 - 5 mg | MT-3995 - 10 mg |
|---|---------|----------------|-----------------|
| Started | 22 | 23 | 22 |
| Completed | 21 | 21 | 19 |
| Not completed | 1 | 2 | 3 |
| Adverse event, non-fatal | - | - | 1 |
| Central serum potassium was high at baseline | 1 | 1 | 2 |
| Central serum potassium WD criteria fulfilled | - | 1 | - |

Baseline characteristics

Reporting groups

| | |
|--|-----------------|
| Reporting group title | Placebo |
| Reporting group description: | |
| Group 1: Placebo oral capsules matching MT-3995 from Day 1 to the end of the treatment period (Week 8). | |
| Reporting group title | MT-3995 - 5 mg |
| Reporting group description: | |
| Group 2: 80 mg loading dose on Day 1 and 5 mg od maintenance dose from Day 2 (Week 1) to the end of the treatment period (Week 8). | |
| Reporting group title | MT-3995 - 10 mg |
| Reporting group description: | |
| Group 3: 160 mg loading dose on Day 1 and 10 mg od maintenance dose from Day 2 (Week 1) to the end of the treatment period (Week 8). | |

| Reporting group values | Placebo | MT-3995 - 5 mg | MT-3995 - 10 mg |
|--|---------|----------------|-----------------|
| Number of subjects | 22 | 23 | 22 |
| 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) | 0 | 0 | 0 |
| Adults (18-64 years) | 17 | 21 | 16 |
| From 65-84 years | 5 | 2 | 6 |
| 85 years and over | 0 | 0 | 0 |
| Age continuous | | | |
| Units: years | | | |
| arithmetic mean | 56.4 | 56 | 58.2 |
| standard deviation | ± 9.8 | ± 7.3 | ± 9.4 |
| Gender categorical | | | |
| Units: Subjects | | | |
| Female | 9 | 3 | 6 |
| Male | 13 | 20 | 16 |

| Reporting group values | Total | | |
|--|-------|--|--|
| Number of subjects | 67 | | |
| Age categorical | | | |
| Units: Subjects | | | |
| In utero | 0 | | |
| Preterm newborn infants (gestational age < 37 wks) | 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) | 54 | | |
| From 65-84 years | 13 | | |
| 85 years and over | 0 | | |
| Age continuous | | | |
| Units: years | | | |
| arithmetic mean | | | |
| standard deviation | - | | |
| Gender categorical | | | |
| Units: Subjects | | | |
| Female | 18 | | |
| Male | 49 | | |

End points

End points reporting groups

| | |
|--|-----------------|
| Reporting group title | Placebo |
| Reporting group description: Group 1: Placebo oral capsules matching MT-3995 from Day 1 to the end of the treatment period (Week 8). | |
| Reporting group title | MT-3995 - 5 mg |
| Reporting group description: Group 2: 80 mg loading dose on Day 1 and 5 mg od maintenance dose from Day 2 (Week 1) to the end of the treatment period (Week 8). | |
| Reporting group title | MT-3995 - 10 mg |
| Reporting group description: Group 3: 160 mg loading dose on Day 1 and 10 mg od maintenance dose from Day 2 (Week 1) to the end of the treatment period (Week 8). | |

Primary: Not Applicable - none reported as safety is primary endpoint

| | |
|--|---|
| End point title | Not Applicable - none reported as safety is primary endpoint ^[1] |
| End point description: No primary endpoints were defined for efficacy or PD variables. Safety was the primary endpoint. | |
| End point type | Primary |
| End point timeframe: Not applicable | |

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: The primary endpoint was safety and the data are provided in the AE section.

| End point values | Placebo | MT-3995 - 5 mg | MT-3995 - 10 mg | |
|-----------------------------|------------------|------------------|------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 0 ^[2] | 0 ^[3] | 0 ^[4] | |
| Units: Not applicable | | | | |

Notes:

[2] - Not applicable as the primary endpoint was safety and the data are provided in the AE section.

[3] - Not applicable as the primary endpoint was safety and the data are provided in the AE section.

[4] - Not applicable as the primary endpoint was safety and the data are provided in the AE section.

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Start of double-blind treatment to end of 8 week follow-up period. Treatment-Emergent AEs were defined as those which started or worsened in severity after the first dose of double-blind study medication.

Adverse event reporting additional description:

During the study visits regular questioning of each subject by study staff. No leading questions were asked. Data recorded under "Non Serious Adverse Events" also includes serious adverse events.

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

Dictionary used

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

| | |
|--------------------|----|
| Dictionary version | 17 |
|--------------------|----|

Reporting groups

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

Reporting group description:

Group 1: Placebo oral capsules matching MT-3995 from Day 1 to the end of the treatment period (Week 8).

| | |
|-----------------------|---------------|
| Reporting group title | MT-3995 - 5mg |
|-----------------------|---------------|

Reporting group description:

Group 2: 80 mg loading dose on Day 1 and 5 mg od maintenance dose from Day 2 (Week 1) to the end of the treatment period (Week 8) and 8 week follow up.

| | |
|-----------------------|----------------|
| Reporting group title | MT-3995 - 10mg |
|-----------------------|----------------|

Reporting group description:

Group 3: 160 mg loading dose on Day 1 and 10 mg od maintenance dose from Day 2 (Week 1) to the end of the treatment period (Week 8) and 8 week follow up.

| Serious adverse events | Placebo | MT-3995 - 5mg | MT-3995 - 10mg |
|---|----------------|----------------|----------------|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 1 / 22 (4.55%) | 2 / 23 (8.70%) | 1 / 22 (4.55%) |
| number of deaths (all causes) | 0 | 1 | 0 |
| number of deaths resulting from adverse events | 0 | 1 | 0 |
| Injury, poisoning and procedural complications | | | |
| Contusion | | | |
| subjects affected / exposed | 1 / 22 (4.55%) | 0 / 23 (0.00%) | 0 / 22 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Nerve root injury lumbar | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 1 / 23 (4.35%) | 0 / 22 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cardiac disorders | | | |

| | | | |
|---|----------------|----------------|----------------|
| Atrial Fibrillation | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 1 / 23 (4.35%) | 0 / 22 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Myocardial infarction | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 23 (0.00%) | 1 / 22 (4.55%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Chronic Obstructive Pulmonary Disease | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 1 / 23 (4.35%) | 0 / 22 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hypercapnia | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 1 / 23 (4.35%) | 0 / 22 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 1 / 1 | 0 / 0 |

Frequency threshold for reporting non-serious adverse events: 0 %

| Non-serious adverse events | Placebo | MT-3995 - 5mg | MT-3995 - 10mg |
|---|-----------------|-----------------|-----------------|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 8 / 22 (36.36%) | 7 / 23 (30.43%) | 7 / 22 (31.82%) |
| Investigations | | | |
| Electrocardiogram QT prolonged | | | |
| subjects affected / exposed | 2 / 22 (9.09%) | 0 / 23 (0.00%) | 0 / 22 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Amylase increased | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 23 (0.00%) | 1 / 22 (4.55%) |
| occurrences (all) | 0 | 0 | 1 |
| Blood glucose increased | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 1 / 23 (4.35%) | 0 / 22 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Liver function test abnormal | | | |

| | | | |
|--|---------------------|---------------------|---------------------|
| subjects affected / exposed occurrences (all) | 0 / 22 (0.00%) 0 | 1 / 23 (4.35%) 1 | 0 / 22 (0.00%) 0 |
| Injury, poisoning and procedural complications | | | |
| Accidental overdose | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 1 / 23 (4.35%) | 0 / 22 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Contusion | | | |
| subjects affected / exposed | 1 / 22 (4.55%) | 0 / 23 (0.00%) | 0 / 22 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Nerve root injury lumbar | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 1 / 23 (4.35%) | 0 / 22 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Cardiac disorders | | | |
| Angina pectoris | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 23 (0.00%) | 1 / 22 (4.55%) |
| occurrences (all) | 0 | 0 | 1 |
| Atrial fibrillation | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 1 / 23 (4.35%) | 0 / 22 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Extrasystoles | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 1 / 23 (4.35%) | 0 / 22 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Myocardial infarction | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 23 (0.00%) | 1 / 22 (4.55%) |
| occurrences (all) | 0 | 0 | 1 |
| Nervous system disorders | | | |
| Diabetic neuropathy | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 23 (0.00%) | 1 / 22 (4.55%) |
| occurrences (all) | 0 | 0 | 1 |
| Dizziness | | | |
| subjects affected / exposed | 1 / 22 (4.55%) | 0 / 23 (0.00%) | 0 / 22 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| General disorders and administration site conditions | | | |
| Oedema peripheral | | | |
| subjects affected / exposed | 1 / 22 (4.55%) | 0 / 23 (0.00%) | 0 / 22 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |

| | | | | |
|---|---|----------------|----------------|----------------|
| Gastrointestinal disorders | Nausea | | | |
| | subjects affected / exposed | 1 / 22 (4.55%) | 0 / 23 (0.00%) | 1 / 22 (4.55%) |
| | occurrences (all) | 1 | 0 | 1 |
| | Vomiting | | | |
| | subjects affected / exposed | 0 / 22 (0.00%) | 1 / 23 (4.35%) | 1 / 22 (4.55%) |
| | occurrences (all) | 0 | 1 | 1 |
| | Abdominal pain upper | | | |
| | subjects affected / exposed | 0 / 22 (0.00%) | 0 / 23 (0.00%) | 1 / 22 (4.55%) |
| Reproductive system and breast disorders | occurrences (all) | 0 | 0 | 1 |
| | Gastrooesophageal reflux disease | | | |
| | subjects affected / exposed | 1 / 22 (4.55%) | 0 / 23 (0.00%) | 0 / 22 (0.00%) |
| | occurrences (all) | 1 | 0 | 0 |
| | Erectile dysfunction | | | |
| | subjects affected / exposed | 0 / 22 (0.00%) | 0 / 23 (0.00%) | 1 / 22 (4.55%) |
| | occurrences (all) | 0 | 0 | 1 |
| | Respiratory, thoracic and mediastinal disorders | | | |
| Respiratory, thoracic and mediastinal disorders | Chronic obstructive pulmonary disease | | | |
| | subjects affected / exposed | 0 / 22 (0.00%) | 1 / 23 (4.35%) | 0 / 22 (0.00%) |
| | occurrences (all) | 0 | 1 | 0 |
| | Cough | | | |
| | subjects affected / exposed | 0 / 22 (0.00%) | 0 / 23 (0.00%) | 1 / 22 (4.55%) |
| | occurrences (all) | 0 | 0 | 1 |
| | Hypercapnia | | | |
| | subjects affected / exposed | 0 / 22 (0.00%) | 1 / 23 (4.35%) | 0 / 22 (0.00%) |
| Musculoskeletal and connective tissue disorders | occurrences (all) | 0 | 1 | 0 |
| | Back pain | | | |
| | subjects affected / exposed | 1 / 22 (4.55%) | 0 / 23 (0.00%) | 0 / 22 (0.00%) |
| | occurrences (all) | 1 | 0 | 0 |
| | Osteoarthritis | | | |
| | subjects affected / exposed | 0 / 22 (0.00%) | 1 / 23 (4.35%) | 0 / 22 (0.00%) |
| | occurrences (all) | 0 | 1 | 0 |
| | Infections and infestations | | | |

| | | | |
|---|----------------|----------------|----------------|
| Cystitis | | | |
| subjects affected / exposed | 1 / 22 (4.55%) | 0 / 23 (0.00%) | 0 / 22 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Gastroenteritis viral | | | |
| subjects affected / exposed | 1 / 22 (4.55%) | 0 / 23 (0.00%) | 0 / 22 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Nasopharyngitis | | | |
| subjects affected / exposed | 1 / 22 (4.55%) | 0 / 23 (0.00%) | 0 / 22 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Upper respiratory tract infection | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 23 (0.00%) | 1 / 22 (4.55%) |
| occurrences (all) | 0 | 0 | 1 |
| Urinary tract infection | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 23 (0.00%) | 1 / 22 (4.55%) |
| occurrences (all) | 0 | 0 | 1 |
| Viral upper respiratory tract infection | | | |
| subjects affected / exposed | 1 / 22 (4.55%) | 0 / 23 (0.00%) | 0 / 22 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Metabolism and nutrition disorders | | | |
| Hyperglycaemia | | | |
| subjects affected / exposed | 1 / 22 (4.55%) | 1 / 23 (4.35%) | 0 / 22 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Decreased appetite | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 23 (0.00%) | 1 / 22 (4.55%) |
| occurrences (all) | 0 | 0 | 1 |
| Hyperkalaemia | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 1 / 23 (4.35%) | 0 / 22 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date | Amendment |
|-----------------|--|
| 07 January 2014 | Reduced lower limit of UACR incl. crit. from 200 to 50 mg/g; lowering of eGRF incl. crit. from 60 to 57 mL/min/1.73m ² ; incr. of > K+ incl. crit. from 5.0 to 5.2 mmol/L; error corr., further clarif. |
| 30 April 2014 | Former primary UACR objective now secondary objective and safety & tolerability now primary obj.; sample size modified accordingly |

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported