PLEASE NOTE: *This study has been imported from ClinicalTrials.gov without additional data checks.*

Trial Description

Title

A Randomized, Multicountry, Multicenter, Double-Blind, Parallel, Placebo-Controlled Study of the Effects of Atrasentan on Renal Outcomes in Subjects With Type 2 Diabetes and Nephropathy SONAR: Study Of Diabetic Nephropathy With Atrasentan

Trial Acronym

SONAR

URL of the trial

[---]*

Brief Summary in Lay Language

This study is being conducted to evaluate the effects of Atrasentan on Renal Outcomes in Subjects with Type 2 Diabetes and Nephropathy.

Brief Summary in Scientific Language

The study objective is to evaluate the effect of atrasentan compared with placebo on time to doubling of serum creatinine or the onset of end stage renal disease (ESRD) in subjects with type 2 diabetes and nephropathy who are treated with the maximum tolerated labeled daily dose (MTLDD) of a Renin Angiotensin System (RAS) inhibitor. In addition, the study will assess the effects of atrasentan compared with placebo on cardiovascular morbidity and mortality, urine albumin excretion, changes in estimated glomerular filtration rate (eGFR), as well as on the impact on quality of life in subjects with type 2 diabetes and nephropathy.

Organizational Data

- DRKS-ID: **DRKS00006389**
- Date of Registration in DRKS: **2014/11/18**

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Date of Registration in DRKS: **2014/11/18**

- Date of Registration in Partner Registry or other Primary Registry: **2013/05/17**
- Investigator Sponsored/Initiated Trial (IST/IIT): **no**
- Ethics Approval/Approval of the Ethics Committee: **[---]***
- (leading) Ethics Committee Nr.: **[---]***

Secondary IDs

- EudraCT-No.
  (for studies acc. to Drug Law): **2012-005848-21**
- Primary Registry-ID: **NCT01858532 (ClinicalTrials.gov)**
- Sponsor-ID: **M11-352 (AbbVie)**
- Other Secondary-ID: **2012-005848-21**

Health condition or Problem studied

- Free text: **Diabetic Nephropathy**

Interventions/Observational Groups

- Arm 1: **Drug: Atrasentan**
- Arm 2: **Drug: Placebo**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **patient/subject, caregiver, investigator/therapist, assessor**
- Control: **Placebo**
- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: **III**

Study Type: **Interventional**

Study Type Non-Interventional: **[---]***

Allocation: **Randomized controlled trial**

Blinding: **[---]***

Who is blinded: **patient/subject, caregiver, investigator/therapist, assessor**

Control: **Placebo**

Purpose: **Treatment**

Assignment: **Parallel**

Phase: **III**

- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **[---]***

Primary Outcome

- Time to the first occurrence of a component of the composite renal endpoint.; time frame: Approximately 48 months.; Time to the first occurrence of a component of the composite renal endpoint: doubling of serum creatinine (confirmed by a 30-day serum creatinine) or the onset of end stage renal disease (needing chronic dialysis or renal transplantation or renal death).

Secondary Outcome

- Change from baseline to Month 24 post-randomization visit on urine albumin creatinine ratio.; time frame: From Day 0 to 24 months.
- Time to a 30% estimated glomerular filtration rate reduction after 3 months post-randomization treatment.; time frame: Approximately 24 months.
- Time to cardio-renal composite endpoint: doubling of serum creatinine, end stage renal disease, cardiovascular death, nonfatal myocardial infarction, nonfatal stroke.; time frame: Approximately 48 months.
- Time to the cardiovascular composite endpoint: cardiovascular death, nonfatal myocardial infarction and nonfatal stroke.; time frame: Approximately 48 months.

Countries of recruitment

- US **United States**
- AR **Argentina**
- AU **Australia**
- AT **Austria**
- BE **Belgium**
- BR **Brazil**
-

BG **Bulgaria**

- CA **Canada**
- CL **Chile**
- CZ **Czech Republic**
- DK **Denmark**
- FI **Finland**
- FR **France**
- DE **Germany**
- GR **Greece**
- HK **Hong Kong**
- IE **Ireland**
- IL **Israel**
- IT **Italy**
- JP **Japan**
- KR **Korea, Republic of**
- MY **Malaysia**
- MX **Mexico**
- NL **Netherlands**
- NZ **New Zealand**
- PE **Peru**
- PL **Poland**
- PT **Portugal**
- PR **Puerto Rico**
- RO **Romania**
- RU **Russian Federation**
- SG **Singapore**
- SK **Slovakia**
- ZA **South Africa**
- ES **Spain**
- SE **Sweden**
- TW **Taiwan, Province of China**
- TR **Turkey**

- UA **Ukraine**
- UK **United Kingdom**

Locations of Recruitment

- **Site Reference ID/Investigator# 112075, Aachen**
- **Site Reference ID/Investigator# 100562, Berlin**
- **Site Reference ID/Investigator# 108416, Berlin**
- **Site Reference ID/Investigator# 108415, Dresden**
- **Site Reference ID/Investigator# 100559, Duesseldorf**
- **Site Reference ID/Investigator# 104235, Hamburg**
- **Site Reference ID/Investigator# 114735, Hanover**
- **Site Reference ID/Investigator# 100561, Heidelberg**
- **Site Reference ID/Investigator# 121575, Heidelberg**
- **Site Reference ID/Investigator# 125198, Hoyerswerda**
- **Site Reference ID/Investigator# 103899, Jena**
- **Site Reference ID/Investigator# 113915, Munich**
- **Site Reference ID/Investigator# 125196, Pirna**
- **Site Reference ID/Investigator# 125197, Riesa**
- **Site Reference ID/Investigator# 112076, Speyer**
- **Site Reference ID/Investigator# 112975, Stuttgart**
- **Site Reference ID/Investigator# 103900, Witten**
- **Site Reference ID/Investigator# 108895, Wuerzburg**

Recruitment

- Planned/Actual: **[---]***
- (Anticipated or Actual) Date of First Enrollment: **2013/01/31**
- Target Sample Size: **4148**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **International**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**

Gender: **Both, male and female**

Minimum Age: **18 Years**

■ Maximum Age: **85 Years**

Additional Inclusion Criteria

- Subject has type 2 diabetes and has been treated with at least one anti-hyperglycemic medication and angiotensin converting enzyme (ACE) inhibitor or angiotensin receptor blockers (ARB) (Renin Angiotensin System inhibitor) for at least 3 months prior to the Screening Period.

- Glucosylated hemoglobin A1c (HbA1c) less than or equal to 12%.

- For entry into the Run-In Period the subject must satisfy the following criteria based on the Screening laboratory values:

- Estimated glomerular filtration rate (eGFR) 25 to 75 mL/min/1.73 m2 and a urine albumin creatinine ratio (UACR) greater than or equal to 300 and less than 5,000 mg/g (The number of subjects with eGFR between 60 to 75 mL/min/1.73 m2 will be capped to 10% of the total population);

- Serum albumin greater than or equal to 3.0 g/dL (30 g/L);

- Brain natriuretic peptide (BNP) less than or equal to 200 pg/mL (200 ng/L);

- Systolic blood pressure (SBP) greater than or equal to 110 and less than or equal to 160 mmHg;

- Serum Potassium greater than or equal to 3.5 (3.5 mmol/L) and less than or equal to 5.5 mEq/L (5.5 mmol/L);

- Subjects on a maximum tolerated labeled daily dose (MTLDD) of a RAS inhibitor for greater than or equal to 4 weeks and on a diuretic at the time of screening and who satisfy the above criteria may proceed to the last visit in Run-In Period (R6);

- Subjects already on a MTLDD of a RAS inhibitor for greater than or equal to 4 weeks and not on a diuretic (unless medically contraindicated) at the time of

Screening will start with a diuretic and proceed to Run-In for at least 2 weeks.

- For entry into the Enrichment Period the subject must satisfy the following criteria based on the last visit of the Run-In Period:

- RAS inhibitor at the MTLDD for the previous 4 weeks with no adjustments of the dose;

- Subjects that were on a MTLDD RAS inhibitor and not on a diuretic (unless medically contraindicated) at the time of Screening must have been in Run-In for at least 2 weeks.

- For entry into the Double-Blind Treatment Period, the subject must satisfy the following criteria based on the last visit of the Enrichment Period:

- RAS inhibitor at the MTLDD for the previous 6 weeks during the Enrichment Period with no adjustments of the dose;

- Diuretic at any dose unless medically contraindicated or clinically intolerable in the investigator's judgement (i.e., hypotension or hypokalemia);

- Weight change less than 3 kg and absolute serum BNP less than 300 pg/mL (300 ng/L) at Enrichment Week 6 from the beginning of Enrichment;

- Subjects must not have an acute kidney injury (AKI) event at the end of the Enrichment period, as defined by an increase from baseline in serum Creatinine greater than 0.5 mg/dL and greater than 20% increase at Enrichment Week 6 (visit E5) from baseline.

Exclusion criteria

- Subject has a history of moderate or severe peripheral edema, pulmonary edema or facial edema unrelated to trauma or a history of myxedema in the prior 6 months to Screening.

- Subject has a history of pulmonary hypertension requiring oxygen therapy, and/or endothelin receptor antagonist or phosphodiesterase therapy or any lung diseases requiring oxygen therapy (e.g., chronic obstructive pulmonary disease, emphysema, pulmonary fibrosis).

- Subject has a documented diagnosis of heart failure, previous hospitalization for heart failure or current or constellation of symptoms (dyspnea on exertion, pedal edema, orthopnea, paroxysmal nocturnal dyspnea) felt to be compatible with heart failure, that was not explained by other causes, and for which there was a change in medication or other management directed at heart failure.

- Subject has known non-diabetic kidney disease (other than kidney stones).

- Subject has a history of symptomatic hypotension within the last 6 months.

Addresses

- **Primary Sponsor**

  AbbVie

  Telephone: **[---]***
  Fax: **[---]***
  E-mail: **[---]***
  URL: **[---]***
- **Contact for Scientific Queries**

  AbbVie
  Blai Coll, MD

  Telephone: **[---]***
  Fax: **[---]***
  E-mail: **[---]***
  URL: **[---]***
- **Contact for Public Queries**

  Blai Coll, MD

  Telephone: **847-937-6156**
  Fax: **[---]***
  E-mail: **blai.coll at abbvie.com**
  URL: **[---]***

Sources of Monetary or Material Support

- **[---]***

[---]*

Bitte wenden Sie sich an den Sponsor / Please refer to primary sponsor

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

Status

- Recruitment Status: **Recruiting ongoing**
- Study Closing (LPLV): **[---]***

Trial Publications, Results and other documents

The parameters in ClinicalTrials.gov and DRKS are not identical. Therefore the data import from ClinicalTrials.gov required adjustments. For full details please see the DRKS FAQs.
- Translation on version: 2
- Last processed date by ClinicalTrials.gov: 2014/11/27

** This entry means the parameter is not applicable or has not been set.*

**** This entry means that data is not displayed due to insufficient data privacy clearing.*