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

Trial Description

Title

Phase 3, Prospective, Randomized, Double-blind, Placebo-controlled Multicenter Study to Evaluate the Pharmacokinetics, Safety and Efficacy of Paricalcitol Capsules in Decreasing Serum Intact Parathyroid Hormone Levels in Pediatric Subjects Ages 10 to 16 Years With Moderate to Severe Chronic Kidney Disease

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

Safety and efficacy study using Paricalcitol capsules to decrease parathyroid hormone levels in children ages 10 to 16 with Chronic Kidney Disease.

Brief Summary in Scientific Language

The study consists of two parts. Part I is an open-label single-dose, non-fasting, multicenter study to evaluate the pharmacokinetics of paricalcitol capsules in 12 pediatric subjects ages 10 to 16 years with Chronic Kidney Disease Stages 3 and 4. Part II of this study will be conducted as a 12 week randomized double-blind, placebo-controlled study, followed by 12 weeks open-label treatment. Subjects active or enrolled under amendment 5 will enter a Follow-Up period and have study visits every 4 weeks until the final subject reaches Week 24. The objective of this multicenter study is to evaluate the safety and efficacy of paricalcitol capsules in decreasing serum intact parathyroid hormone levels to the National Kidney Foundation's Kidney Disease Outcomes Quality Initiative target goals in 36 pediatric subjects ages 10 to 16 years with Chronic Kidney Disease Stages 3 and 4.

Organizational Data

- DRKS-ID: **DRKS00006499**
- Date of Registration in DRKS: **2015/01/19**
- Date of Registration in Partner Registry or other Primary Registry: **2009/11/13**
- 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): **2010-019439-37**
- Primary Registry-ID: **NCT01020487 (ClinicalTrials.gov)**
- Sponsor-ID: **M10-149 (AbbVie (prior sponsor, Abbott))**
- Other Secondary-ID: **2010-019439-37**

Health condition or Problem studied

- Free text: **Chronic Kidney Disease Stage 3 and 4**

Interventions/Observational Groups

- Arm 1: **Drug: Zemplar (paricalcitol) Capsules**
- Arm 2: **Drug: Placebo capsules**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **patient/subject, investigator/therapist**
- 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, investigator/therapist**

Control: **Placebo**

Purpose: **Treatment**

Assignment: **Parallel**

Phase: **III**

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

Primary Outcome

- The primary efficacy-endpoint is the proportion of subjects who achieve two consecutive greater than or equal to 30 percent reductions from baseline in intact parathyroid hormone levels.; time frame: 12 Weeks; The primary efficacy measure for intact parathyroid hormone in pediatric Chronic Kidney Disease subjects is determined by the stage of Chronic Kidney Disease. The data is collected via blood draws.

Secondary Outcome

- The proportion of subjects who achieve a final intact parathyroid hormone values within Kidney Disease Outcomes Quality Initiative intact parathyroid hormone target ranges will be evaluated within each Chronic Kidney Disease stage.; time frame: 12 Weeks
- The proportion of subjects who achieve a final value within the applicable Kidney Disease Outcomes Quality Initiative target ranges for calcium.; time frame: 12 Weeks
- The proportion of subjects who achieve a final value within the applicable Kidney Disease Outcomes Quality Initiative target ranges for phosphorus.; time frame: 12 Weeks
- The mean percent change in intact parathyroid hormone from baseline to each post baseline visit (Weeks 2, 4, 8 and 12).; time frame: 2 Weeks
- The mean percent change in intact parathyroid hormone from baseline to each post baseline visit (Weeks 2, 4, 8 and 12).; time frame: 4 Weeks
- The mean percent change in intact parathyroid hormone from baseline to each post baseline visit (Weeks 2, 4, 8 and 12).; time frame: 8 Weeks
- The mean percent change in intact parathyroid hormone from baseline to each post baseline visit (Weeks 2, 4, 8 and 12).; time frame: 12 Weeks
- The mean change in First Morning Void Urine Albumin/Creatinine Ratio from baseline to each post baseline visit (Weeks 4, 8 and 12).; time frame: 4 Weeks
- The mean change in First Morning Void Urine Albumin/Creatinine Ratio from baseline to each post baseline visit (Weeks 4, 8 and 12).; time frame: 8 Weeks
- The mean change in First Morning Void Urine Albumin/Creatinine Ratio from baseline to each post baseline visit (Weeks 4, 8 and 12).; time frame: 12 Weeks

- The proportion of subjects who achieve a final intact parathyroid hormone values within Kidney Disease Outcomes Quality Initiative intact parathyroid hormone target ranges will be evaluated within each Chronic Kidney Disease stage.; time frame: 12 Weeks
- The proportion of subjects who achieve a final value within the applicable Kidney Disease Outcomes Quality Initiative target ranges for calcium.; time frame: 12 Weeks
- The proportion of subjects who achieve a final value within the applicable Kidney Disease Outcomes Quality Initiative target ranges for phosphorus.; time frame: 12 Weeks
- The mean percent change in intact parathyroid hormone from baseline to each post baseline visit (Weeks 2, 4, 8 and 12).; time frame: 2 Weeks
- The mean percent change in intact parathyroid hormone from baseline to each post baseline visit (Weeks 2, 4, 8 and 12).; time frame: 4 Weeks
- The mean percent change in intact parathyroid hormone from baseline to each post baseline visit (Weeks 2, 4, 8 and 12).; time frame: 8 Weeks
- The mean percent change in intact parathyroid hormone from baseline to each post baseline visit (Weeks 2, 4, 8 and 12).; time frame: 12 Weeks
- The mean change in First Morning Void Urine Albumin/Creatinine Ratio from baseline to each post baseline visit (Weeks 4, 8 and 12).; time frame: 4 Weeks
- The mean change in First Morning Void Urine Albumin/Creatinine Ratio from baseline to each post baseline visit (Weeks 4, 8 and 12).; time frame: 8 Weeks
- The mean change in First Morning Void Urine Albumin/Creatinine Ratio from baseline to each post baseline visit (Weeks 4, 8 and 12).; time frame: 12 Weeks

Countries of recruitment

- US **United States**
- DE **Germany**
- PT **Portugal**
- PR **Puerto Rico**
- SG **Singapore**
- ES **Spain**
- UK **United Kingdom**

Locations of Recruitment

- **Site Reference ID/Investigator# 38562, Berlin**
- **Site Reference ID/Investigator# 38363, Cologne**
- **Site Reference ID/Investigator# 39968, Hamburg**
- **Site Reference ID/Investigator# 38563, Hannover**

- **Site Reference ID/Investigator# 38964, Marburg**
- **Site Reference ID/Investigator# 38362, Munich**

Recruitment

- Planned/Actual: **[---]***
- (Anticipated or Actual) Date of First Enrollment: **2010/02/27**
- Target Sample Size: **48**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **International**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **10 Years**
- Maximum Age: **16 Years**

Additional Inclusion Criteria

- Subject has Chronic Kidney Disease Stage 3 or 4 as determined by estimated Glomerular Filtration Rate (15 to 59 mL/min/1.73 m2) at Screening.

- Subject is not expected to begin dialysis for at least 6 months (in the opinion of the investigator).

- For entry into the Washout Period (for subjects who are currently on a VDRA and need to complete a 2 to 4 week washout), the subject must satisfy the following criteria based on the Screening laboratory values:

- estimated Glomerular Filtration Rate between 15 to 59 mL/min/1.73 m2 (estimate by the Schwartz formula as outlined in Section 5.3.1.2).

- iPTH measurement that is greater than or equal to 60 pg/mL (Stage 3 subjects) or greater than or equal to 90 pg/mL (Stage 4 subjects).

- An adjusted serum calcium value greater than or equal to 8.2 mg/dL (2.05 mmol/L) to less than or equal to 10.5 mg/dL (2.63 mmol/L).

- A serum phosphorus value greater than or equal to 2.0 mg/dL (0.65 mmol/L but less than or equal to 6.0 mg/dL (1.94 mmol/L).

- For entry into the Treatment Phase (Vitamin D Receptor Activator naïve

**subjects and
those that have completed a 4 week washout), the subject must have:**

**- iPTH measurement that is greater than or equal to 75 pg/mL (Stage 3 subjects) or
greater than or equal to 110 pg/mL (Stage 4 subjects).**

**- An adjusted serum calcium value greater than or equal to 8.4 mg/dL (2.10 mmol/L)
but less than or equal to 10.2 mg/dL (2.55 mmol/L).**

**- A serum phosphorus value greater than or equal to 2.5 mg/dL (0.81 mmol/L) but
less than or equal to 5.8 mg/dL (1.87 mmol/L).**

**- Must have 25-hydroxyvitamin D levels ≥ 30 ng/mL prior to washout, if not VDRA
naïve, or treatment in Part II of the study.**

Exclusion criteria

- All subjects that have had a small bowel transplant will be excluded from the study.

**- Subject has had acute kidney failure within 12 weeks of the Screening Phase (defined
as an acute rise in serum creatinine).**

**- Subject has had symptomatic or significant hypocalcemia requiring active Vitamin D
therapy (for example, calcitriol, paricalcitol, doxercalciferol or alfacalcidol)
within 6 months prior to the Screening Phase.**

- Subject has a history of active kidney stones (6 months prior to screening).

**- Subject has chronic gastrointestinal disease, which in the investigator's opinion may
cause significant gastrointestinal malabsorption.**

**- Subject is taking maintenance calcitonin, bisphosphonates, cinacalcet,
glucocorticoids in an equivalent dose of greater than 5 mg prednisone daily, or other
drugs known to affect calcium or bone metabolism within 4 weeks prior to Treatment.**

Addresses

■ **Primary Sponsor**

AbbVie (prior sponsor, Abbott)

Primary Sponsor

AbbVie (prior sponsor, Abbott)

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

- **Contact for Scientific Queries**

AbbVie
Ann Eldred, MD

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

- **Contact for Public Queries**

AbbVie
Ann Eldred, MD

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
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 complete, follow-up continuing**
- Study Closing (LPLV): **[---]***

Trial Publications, Results and other documents

■ Further trial 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: 1
- Last processed date by ClinicalTrials.gov: 2014/07/16

* *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.*