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

Trial Description

Title

Investigation of Pharmacokinetics, Pharmacodynamics, Safety, and Tolerability of Single Oral Doses of 75 mg Molidustat in Male and Female Subjects With Renal Impairment Requiring Hemo- or Peritoneal Dialysis Compared to Age- and Weight-matched Healthy Subjects in a Single-center, Non-controlled, Non-blinded Study With Group Stratification

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

The study investigates the pharmacokinetics (absorption, distribution, elimination) of molidustat after intake of a single 75 mg tablet in subjects with renal impairment requiring hemo- or peritoneal dialysis compared to age-and gender-matched healthy subjects. In addition, the effect of molidustat on the hormone erythropoietin will be evaluated as well as the safety and tolerability of molidustat.

Brief Summary in Scientific Language

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Organizational Data

- DRKS-ID: **DRKS00008817**
- Date of Registration in DRKS: **2015/08/12**
- Date of Registration in Partner Registry or other Primary Registry: **2014/12/05**
- 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): **2014-003292-31**
- Primary Registry-ID: **NCT02312973 (ClinicalTrials.gov)**
- Sponsor-ID: **17767 (Bayer)**
- Other Secondary-ID: **2014-003292-31**

Health condition or Problem studied

- Free text: **Renal Insufficiency, Chronic**
- ICD10: **N18.9 - Chronic kidney disease, unspecified**

Interventions/Observational Groups

- Arm 1: **Drug: Molidustat(BAY85-3934)**
- Arm 2: **Drug: Molidustat(BAY85-3934)**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Non-randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **[---]***
- Purpose: **[---]***
- Assignment: **Crossover**
- Phase: **I**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **[---]***

Primary Outcome

- Pharmacokinetics characterized by Cmax of Molidustat; time frame: Up to 96 hours post dose; Cmax: maximum drug concentration in plasma after single dose administration
- Pharmacokinetics characterized by AUC of Molidustat; time frame: Up to 96 hours post dose; AUC: area under the plasma concentration vs time curve from zero to infinity

- Pharmacokinetics characterized by Cmax,norm of Molidustat; time frame: Up to 96 hours post dose; Cmax,norm;maximum drug concentration in plasma after single dose administration divided by dose (milligrams) per kilogram body weight
- Pharmacokinetics characterized by (AUCnorm) of Molidustat; time frame: Up to 96 hours post dose; AUCnorm; area under the plasma concentration vs time curve divided by dose per kg body weight

Secondary Outcome

- Pharmacokinetics characterized by Cmax of erythropoietin; time frame: Up to 48 hours post dose; Cmax: maximum drug concentration in plasma after single dose administration
- Pharmacokinetics characterized by AUC (0-tlast) of erythropoietin; time frame: Up to 48 hours post dose; AUC(0-tlast): AUC from time 0 to the last data point above lower limit of quantification
- Pharmacokinetics characterized by tmax of erythropoietin; time frame: Up to 48 hours post dose; tmax: time to reach maximum drug concentration in plasma after single (first) dose
- Number of subjects with Treatment Emergent Adverse Event (TEAE); time frame: Up to 7 days post dose

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- **Kiel**

Recruitment

- Planned/Actual: **[---]***
- (Anticipated or Actual) Date of First Enrollment: **2014/12/31**
- Target Sample Size: **32**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **79 Years**

Additional Inclusion Criteria

- Male and female (without childbearing potential)

- Age: ≥18 and ≤79 years of age

- Body mass index (BMI): ≥18 and ≤34 kg/m2

- Ethnicity: White

- Subjects with severe renal impairment on hemodialysis or peritoneal dialysis, and

- Healthy subjects

Exclusion criteria

- Women of childbearing potential, pregnant or lactating women

- Use of medication within the 2 weeks preceding the study which could interfere with the investigational product

- Positive results for hepatitis B virus surface antigen (HBsAg), hepatitis C virus antibodies (HCV Ab), human immune deficiency virus 1 and 2 antibodies (HIV 1/2 Ab)

- Exclusion periods from other studies or simultaneous participation in other clinical studies

Addresses

■ **Primary Sponsor**

Bayer

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

■ **Contact for Scientific Queries**

Bayer
Bayer Study Director

Contact for Scientific Queries

Bayer
Bayer Study Director

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

- **Contact for Public Queries**

Bayer Clinical Trials Contact

Telephone: **[---]***
Fax: **[---]***
E-mail: **clinical-trials-contact at bayerhealthcare.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

- Further trial documents **Click here and search for drug information provided by the FDA.**
- Further trial documents **Click here and search for information on any recalls, market or product safety alerts by the FDA which might have occurred with this product.**

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: 2015/06/17

** 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.*