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

Trial Description

Title

A Double-Blind, Randomized, Parallel-Group, Active-Control Study to Compare the Efficacy and Safety of CHS-0214 Versus Enbrel in Subjects With Chronic Plaque Psoriasis (RaPsOdy)

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

**This is a two part study comparing CHS-0214 to Enbrel in patients with chronic plaque PsO
who have not yet received any biologic therapy for any indication (other than insulin or
hormones).**

Brief Summary in Scientific Language

**Pt. 1 is a 12-week randomized, double-blind, active-control, parallel-group, multi-center
global study. The primary end point is 75% improvement from baseline according to the
Psoriasis Area and Severity Index (PASI-75). Comparing CHS-0214 to Enbrel for efficacy and
safety at a dosage of 50mg subcutaneous (Sc) twice weekly.**

**Pt. 2 is a 40-week randomized, double-blind, active-control, parallel-group, multi-center
global study where CHS-0214 and Enbrel dosage is reduced to 50mg Sc weekly for maintenance.**

Organizational Data

- DRKS-ID: **DRKS00008345**
- Date of Registration in DRKS: **2016/03/11**
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DRKS-ID: **DRKS00008345**
Date of Registration in DRKS: **2016/03/11**
Date of Registration in Partner Registry or other Primary Registry: **2014/05/07**

- Investigator Sponsored/Initiated Trial (IST/IIT): **no**
- Ethics Approval/Approval of the Ethics Committee: **[---]***
- (leading) Ethics Committee Nr.: **[---]***

Secondary IDs

- Primary Registry-ID: **NCT02134210 (ClinicalTrials.gov)**
- Sponsor-ID: **CHS-0214-04 (Coherus Biosciences, Inc.)**

Health condition or Problem studied

- Free text: **Plaque Psoriasis**
- ICD10: **L40 - Psoriasis**

Interventions/Observational Groups

- Arm 1: **Biological: Etanercept**
- Arm 2: **Drug: CHS-0214**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **patient/subject, caregiver, investigator/therapist, assessor**
- Control: **Active control (effective treament of control group)**
- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: **III**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **[---]***

Primary Outcome

- PASI-75; time frame: 12-weeks

Secondary Outcome

[---]*

Countries of recruitment

- US **United States**
- AU **Australia**
- CA **Canada**
- DE **Germany**
- IL **Israel**
- PL **Poland**
- ZA **South Africa**

Locations of Recruitment

- **MVZ Reichenberger Str., Aerztehaus "Rudolf Virchow, Berlin**
- **Klinische Forschung Dresden GmbH, Dresden**
- **Hautklinik Universitaetsklinikum Erlangen, Erlangen**
- **Johann Wolfgang Hospital - Goethe University, Frankfurt**
- **Dermatologikum Hamburg, Hamburg**
- **University Hospital Schleswig-Holstein - Campus Luebeck, Luebeck**

Recruitment

- Planned/Actual: **[---]***
- (Anticipated or Actual) Date of First Enrollment: **2014/06/30**
- Target Sample Size: **496**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **International**

Inclusion Criteria

- Gender: **Both, male and female**

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- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

- Male or female adults

- PsO diagnosis for 6 months

- Active disease: PASI greater than or equal to 12, Physician's Static Global Assessment (PSGA) score greater than or equal to 3 (based on a scale or 0-5),

- Body Surface Area (BSA) involved with PsO greater than or equal to 10%

- Dermatology Life Quality Index (DQLI) greater than or equal to 10

- Previously received phototherapy or systemic non-biologic therapy for PsO

Exclusion criteria

- Forms of Psoriasis other than PsO

- Drug induced Psoriasis

- Positive QuantiFERON-tuberculosis (TB) Gold Test

- Presence of significant comorbid conditions

- Chemistry and hematology values outside protocol specified range

- Major systemic infections

Addresses

- **Primary Sponsor**

Coherus Biosciences, Inc.

Telephone: **[---]***
Fax: **[---]***

Primary Sponsor

Coherus Biosciences, Inc.

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

- **Contact for Scientific Queries**

Coherus Biosciences, Inc.
Barbara K Finck, M.D.

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

- **Contact for Public Queries**

Regan Burns

Telephone: **650-649-3582**
Fax: **[---]***
E-mail: **rburns at coherus.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: 1

- Last processed date by ClinicalTrials.gov: 2015/05/04

** 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.*