# BOSSA Study: Bosentan for the treatment of Steroid-resistant Pulmonary Sarcoidosis

Submission date Recruitment status Prospectively registered 31/08/2010 No longer recruiting [ ] Protocol [ ] Statistical analysis plan Registration date Overall study status 27/09/2010 Completed [X] Results [ ] Individual participant data **Last Edited** Condition category 01/11/2018 Haematological Disorders

# Plain English summary of protocol

Not provided at time of registration

# **Contact information**

# Type(s)

Scientific

#### Contact name

**Prof Michael Tamm** 

#### Contact details

University Hospital Basel Petersgraben 4 Basel Switzerland 4031

# Additional identifiers

#### Protocol serial number

N/A

# Study information

#### Scientific Title

Randomised placebo-controlled, double-blind, exploratory trial of Bosentan for Steroid-resistant Pulmonary Sarcoidosis: the BOSSA Study

#### **Acronym**

**BOSSA** 

#### **Study objectives**

To assess the safety and efficacy of a treatment with bosentan in steroid-resistant sarcoidosis.

## Ethics approval required

Old ethics approval format

### Ethics approval(s)

The Ethics Committee of University Hospital Basel approved on the 29th May 2007 (ref: Nr. 71 /07)

## Study design

Randomised placebo controlled phase II study

#### Primary study design

Interventional

## Study type(s)

**Treatment** 

# Health condition(s) or problem(s) studied

Sarcoidosis with pulmonary involvement

#### **Interventions**

Patients will be randomised to receive

- 1. Bosentan
- 2. Placebo

62.5 mg Twice daily (BID) for 4 weeks followed by 125 mg BID for 11 months.

## Intervention Type

Drug

#### Phase

Phase II

# Drug/device/biological/vaccine name(s)

Bosentan

# Primary outcome(s)

- 1. Safety as measured by severe adverse events (SAEs) and necessity to stop bosentan due to increases liver enzymes
- 2. Efficacy at 12 months as measured by:
- 2.1. Overall response rate as defined by a 10% improvement of either TLC, DLCO, VO2 peak, endurance time at 75% of VO2 peak or 6-min walk distance (6MWD) or
- 2.2. A decrease in the HRCT-score greater than or equal to and absence of worsening by at least 10% in any functional parameters and absence of an increase in the HRCT-score greater than or equal to 2

## Key secondary outcome(s))

- 1. Overall adverse events, reported during the regular visits of the patients at the centres
- 2. Changes in QoL, measured by SF-36 questionnaire
- 3. Decrease in expression of genes associated with firbroproliferation
- 4. Efficacy at 3, 6 and 9 months

## Completion date

31/12/2012

# **Eligibility**

#### Key inclusion criteria

- 1. Biopsy-proven sarcoidosis with pulmonary involvement stages II, III, (IV) according to Silzbach
- 2. Persistant symptoms on long-term oral corticosteroids (greater than 2 months; 5 mg prednisone or equivalent and/or other immunosuppressive agents
- 3. Aged greater than 18 years
- 4. Informed written consent
- 5. Impaired exercise capacity (oxygen uptake [VO2] peak less than 80%) or resting lung functions (forced expiratory volume in one second [FEV1], forced vital capacity [FVC] or diffusing capacity of the lung for carbon monoxide [DLCO] less than 80%)

#### Participant type(s)

Patient

## Healthy volunteers allowed

No

#### Age group

Adult

## Lower age limit

18 years

#### Sex

Αll

#### Key exclusion criteria

- 1. Systemic illness other than sarcoidosis requiring immunosuppressive therapy
- 2. Honey combing greater than 10% on High Resolution Computed Tomography [HRCT] scan
- 3. Marked disturbance of liver enzymes at baseline
- 4. Pregnancy
- 5. Relevant psychiatric illness or addictive disorder
- 6. Previous or current treatment with bosentan
- 7. Therapry with cyclosporine A

#### Date of first enrolment

01/10/2007

#### Date of final enrolment

31/12/2012

# Locations

#### Countries of recruitment

Switzerland

Study participating centre University Hospital Basel

Basel Switzerland 4031

# Sponsor information

# Organisation

University Hospital Basel (Switzerland)

#### **ROR**

https://ror.org/04k51q396

# Funder(s)

## Funder type

Industry

#### Funder Name

Actelion Pharma Schweiz AG (Germany)

# **Results and Publications**

Individual participant data (IPD) sharing plan

# IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type Details Date created Date added Peer reviewed? Patient-facing?

Results article results 28/10/2018 Yes No

Participant information sheet