Retrospective Chart Review to evaluate the safety profile of ceftobiprole in patients with impaired hepatic or renal function or immunosuppression (RETRACE)

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# Administrative details

| EU PAS number    |  |
|------------------|--|
| EUPAS30444       |  |
| Study ID         |  |
| 48406            |  |
| DARWIN EU® study |  |
| No               |  |
| Study countries  |  |
| France           |  |
| Germany          |  |
| Italy            |  |

|  | Spain |
|--|-------|
|--|-------|

### **Study description**

Post-authorization safety study (PASS), retrospective chart review conducted to characterize the safety profile of ceftobiprole in patients with certain risk factors. Primary aim: To estimate the proportion and relative frequency of treatment-emergent adverse events (TEAEs) with a focus on adverse events of special interest (AESIs) including hepatic disorders, hyponatraemia, acute renal failure, hypersensitivity, pseudomembranous colitis, convulsions and haemolytic disorders in patients with immunosuppression or hepatic impairment or severe renal impairment compared to ceftobiprole - treated patients without these risk factors (control). Secondary aim: To assess the use of ceftobiprole in real-world settings with regards to treatment duration, dosage and safety in "off-label" use.

#### **Study status**

Finalised

### Research institutions and networks

### **Institutions**

### **ADVANZ Pharma**

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Institution

### Contact details

### **Study institution contact**

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Study contact

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### **Primary lead investigator**

Noëlle Jemmely

**Primary lead investigator** 

# Study timelines

### Date when funding contract was signed

Planned: 19/03/2019

Actual: 26/06/2019

#### Study start date

Planned: 09/12/2019

Actual: 30/03/2020

#### **Date of final study report**

Planned: 30/01/2024

Actual: 15/11/2023

# Sources of funding

Pharmaceutical company and other private sector

# More details on funding

ADVANZ PHARMA Switzerland SARL

# Study protocol

Correvio BPR-PAS-001 Protocol Version 4.0 20Feb18.pdf (1.17 MB)

# Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

EU RMP category 3 (required)

# Methodological aspects

Study type

Study type list

**Study type:** 

Non-interventional study

### Scope of the study:

Safety study (incl. comparative)

Main study objective:

The objective of this study is to further characterize the safety profile of ceftobiprole in patients with impaired renal or hepatic function or immunosuppression.

# Study Design

#### Non-interventional study design

Other

#### Non-interventional study design, other

**Retrospective Chart Review** 

# Study drug and medical condition

# **Study drug International non-proprietary name (INN) or common name**CEFTOLOZANE SULFATE

#### Medical condition to be studied

Renal impairment
Hepatic function abnormal
Immunosuppression

# Population studied

#### Age groups

- Adults (18 to < 46 years)
- Adults (46 to < 65 years)

- Adults (65 to < 75 years)
- Adults (75 to < 85 years)
- Adults (85 years and over)

#### Special population of interest

Renal impaired
Hepatic impaired
Immunocompromised

#### **Estimated number of subjects**

422

# Study design details

#### **Outcomes**

Primary aim: Proportion and relative frequency of Treatment-Emergent AEs in patients treated with ceftobiprole who have at least one of the following conditions: impaired renal (severe) or hepatic function or immunocompromission. The secondary aim is the assessment of ceftobiprole in the naturalistic clinical settings with respect to treatment duration and dosage as well as safety as a result of off-label use (i.e. outside labelled indications).

### Data analysis plan

Aim at detection of 2–3-fold increase in frequency of AESIs in patients with risk factors compared to patients without risk factors. Sample size was calculated using a one-sided Z-test at an alpha level of 0.05 and a power of >80% Dropout rate due to non-evaluability was estimated at 15% Per protocol a total of 422 patient charts had to be reviewed to obtain 360 evaluable charts: 180 charts from patients treated with ceftobiprole without risk factors (control group) 50 charts from patients with severe renal impairment/ ESRD 50 charts

from patients with hepatic impairment 50 charts from immunocompromised patients Proportion of AESIs observed in patients with risk factors is compared to the proportion of AESIs in patients without risk factors from RETRACE (control group) and from pooled phase 3 studies (external control) Related Risk Ratio calculation and comparison

### **Documents**

#### **Study results**

Correvio\_CO13278\_NI-PASS\_ABSTRACT Final 1.0 2023 11 15 - short.pdf (118.65 KB)

# Data management

## **ENCePP Seal**

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

### Data sources

Data sources (types)

Other

Data sources (types), other

Data source at hospitals are following patient charts depending on availability: admission notes, physician and nurse notes, consultancy reports, discharge summaries, laboratory sheets.

# Use of a Common Data Model (CDM)

#### **CDM** mapping

No

# Data quality specifications

#### **Check conformance**

Unknown

#### **Check completeness**

Unknown

### **Check stability**

Unknown

### **Check logical consistency**

Unknown

## Data characterisation

#### Data characterisation conducted

No