Post-Marketing Observational Cohort Study of Patients with Inflammatory Bowel Disease (IBD) Treated with CT-P13 in Usual Clinical Practice (CONNECT-IBD)

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Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/31369

EU PAS number

EUPAS22289

Study ID

31369

DARWIN EU® study

No

Study countries

- [ ] Belgium
- [ ] Czechia
- [ ] Finland
- [ ] France
- [ ] Germany
- [ ] Greece
- [ ] Hungary
- [ ] Italy
- [ ] Netherlands
- [ ] Portugal
- [ ] Slovakia
- [ ] Spain
- [ ] United Kingdom

Study description

A multi-national, multi-centre, post-marketing observational cohort study to characterise the population, drug utilisation patterns and assess safety of patients treated with CT-P13 for Crohn’s Disease (CD) or Ulcerative Colitis (UC) in the context of standard of care (SOC) Remicade. The decision to treat with CT-P13 (or Remicade) will be made at the usual care discretion of the physician independent of and before the decision to enrol patients in the study. No specific study visits mandated per the study protocol, patients’ visit schedules will follow local SOC, typically coinciding with the schedule of infusions of CT-P13 or Remicade, with additional visits as needed at the treating physician’s discretion. Data for the study will be entered into an electronic data capture (EDC) system at enrolment and then approximately every 3 months thereafter up to a 2-year follow-up period, or until the end of the last patient 1-year follow-up period, whichever occurs first.

Study status

Finalised

Research institutions and networks

Institutions

NA

Multiple centres: 155 centres are involved in the study

Contact details

Study institution contact

Liau Katherine

Study contact

Katherine.F.Liau@pfizer.com

Primary lead investigator

Reginald Ewesuedo

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 01/12/2014

Actual: 01/12/2014

Study start date
Planned: 22/04/2015

Actual: 22/04/2015

Date of final study report
Planned: 17/06/2019

Actual: 21/08/2019

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer

Study protocol

C1231001 (ZOB INF 1402)_PROTOCOL AMENDMENT V3.0_06OCT 2017 .doc.pdf
(3.99 MB)

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Drug utilisation

Effectiveness study (incl. comparative)

Data collection methods:

Primary data collection

Main study objective:

1) To characterise the population and drug utilisation patterns of patients treated with CT-P13 for Crohn's disease (CD) or Ulcerative Colitis (UC) in the context of standard of care Remicade2) To explore the long-term safety profile of CT-P13 in the treatment of patients with CD or UC in the context of standard

of care Remicade

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Study drug International non-proprietary name (INN) or common name

INFLIXIMAB

Medical condition to be studied

Crohn's disease

Colitis ulcerative

Population studied

Short description of the study population

Patients with Crohn's disease (CD) or Ulcerative Colitis (UC), who are being treated with, or initiating treatment with, CT-P13 (or Remicade for the SOC cohort) at the time of study enrolment.

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

Other

Special population of interest, other

Crohn’s Disease (CD), Ulcerative Colitis (UC)

Estimated number of subjects

2500

Study design details

Outcomes

•Patients’ demo characteristics •Clin and diagnostic characteristics: Relevant med history of CD or UC including prior treatments •CT-P13 treatment: 1)CT-P13 & Remicade switches and reasons for switch, 2) Dose and freq, augmentation/reduction & reasons of changes•Co-therapies related to management of CD or UC•All AEs, SAEs, AESIs and special situation events (e.g. pregnancy) during study, •Clinical assessment of disease activity, data relating to: Harvey Bradshaw Index (HBI) for patients with CD, Partial Mayo Scoring System for Assessment of UC Activity, Montreal classification index for CD, Montreal classification index for UC, and fistula drainage assessment index for CD• Laboratory and imaging results related to the treatment or assessment of CD or UC

Data analysis plan

The statistical analysis for this observational study will be descriptive in nature. Given the expected heterogeneity of patients commonly seen in observational

studies, patients will be stratified (eg, UC vs. CD, by subgroup, by country) based on final data available for analysis. Data permitting, post hoc inferential analysis may be used to examine the impact of risk factors or predictors on outcomes of interest, as appropriate.

Documents

Study results

ZOB INF 1402(C1231001) CT24-GSOP-RF26 2.0 NI Study Report Abstract.pdf (1.2 MB)

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Prospective patient-based data collection

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