A 10-Year, Post-marketing, Observational Study to Assess Long Term Safety of HUMIRA® (Adalimumab) in Adult Patients With Chronic Plaque Psoriasis (PS) (ESPRIT)

First published: 13/08/2019

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Study Finalised

Administrative details

EU PAS number

EUPAS30560

Study ID

48814

DARWIN EU® study

No

Study countries

- ☐ Austria
- ☐ Canada
- ☐ Denmark

- [ ] France
- [ ] Germany
- [ ] Greece
- [ ] Ireland
- [ ] Netherlands
- [ ] Puerto Rico
- [ ] Spain
- [ ] Sweden
- [ ] United Kingdom
- [ ] United States

Study description

The purpose of this study is to evaluate the long-term safety of Humira® in Adult Patients with Chronic Plaque Psoriasis (Ps).

Study status

Finalised

Contact details

Study institution contact

Clinical Trial Disclosure AbbVie CT.Disclosures@abbvie.com

Study contact

CT.Disclosures@abbvie.com

Primary lead investigator

Clinical Trial Disclosure AbbVie

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 01/02/2008

Study start date
Actual: 26/09/2008

Date of final study report
Planned: 23/10/2023

Actual: 16/01/2024

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

AbbVie

Study protocol

p10023-protocol-amendment3_Redacted_13Aug2019.pdf(539.66 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 3 (required)

Other study registration identification numbers and links

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Safety study (incl. comparative)

Main study objective:

The primary objective of this registry is to evaluate the long-term safety of HUMIRA® inadult Ps patients who are treated as recommended in the product label.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Prospective Observational Study

Study drug and medical condition

Name of medicine

HUMIRA

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

ADALIMUMAB

Anatomical Therapeutic Chemical (ATC) code

(L04AB04) adalimumab

adalimumab

Medical condition to be studied

Psoriasis

Additional medical condition(s)

Chronic Plaque Psoriasis

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)

Estimated number of subjects

6082

Study design details

Outcomes

- Incidence of Serious Adverse Events-Incidence of Adverse Events of Special Interest
- Adverse Events that lead to permanent discontinuation of HUMIRA®,
- Health Care Utilization-Work Productivity and Activity Impairment Questionnaire: Specific Health Problem-Patient Global Assessment
- Patient Health Question-9
- Medical Outcomes Social Activities Scale
- Patient reported outcome
- Census-Psoriasis Impact and Experience
- Illness Cognition
- Insurance Status
- Rosenberg Self-Esteem Scale-Physician's Global Assessment

Data analysis plan

The number and percent of patients experiencing SAEs, AEs of Special Interest and AEsthat lead to permanent discontinuation of HUMIRA® during the registry, regardless ofwhether the AEs are reported during or after the HUMIRA® treatment, will be tabulatedby body system and Medical Dictionary for Drug Regulatory Activities (MedDRA) preferred term. Rates (event per 100 patient-year of observation) of SAEs and AEs ofSpecial Interest and the 95% confidence interval will be provided. The analysis will beperformed using data from first day in the registry to the date of last contact for the AllTreated Patient Population. The last contact date is defined as the last date of registry ordirect to HCP process participation, whichever occurs later. Standardized incidence ratios(SIRs) will be used to compare the rates of events in this registry to the general population.

Documents

Study report

P10-023-CSR Abstract_Redacted.pdf(247.07 KB)

Data management

Data sources

Data sources (types)

Disease registry

Spontaneous reports of suspected adverse drug reactions

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Yes

Check completeness

Yes

Check stability

Yes

Check logical consistency

Yes

Data characterisation

Data characterisation conducted

Yes