Long-term safety study of Rinvoq in RA patients enrolled in the Corrona RA Registry in the United States

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Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/47971

EU PAS number

EUPAS39194

Study ID

47971

DARWIN EU® study

No

Study countries

☐ United States

Study description

The overall goal of the study is to characterize the safety of Rinvoq in RA patients in the post-approval setting. The primary objective is to compare the incidence of malignancy (excluding non-melanoma skin cancer, NMSC), NMSC, MACE, VTE, SIE, and mortality in adults with RA who receive Rinvoq relative to those who are treated with biologic medications approved for the treatment of RA, in the course of routine clinical care.

Study status

Ongoing

Contact details

Study institution contact

Clinical Trial Disclosure AbbVie

Study contact

CT.Disclosures@abbvie.com

Primary lead investigator

Clinical Trial Disclosure AbbVie

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 09/01/2020

Actual: 09/01/2020

Study start date

Planned: 16/08/2019

Actual: 09/08/2021

Date of final study report
Planned: 16/02/2030

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

AbbVie

Study protocol

p19141-protocol abstract-pmos_Redacted.pdf(97.25 KB)

P19-141_protocol v3.0_abstract_Redacted.pdf(154.98 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:

Assessment of risk minimisation measure implementation or effectiveness

Main study objective:

The main objective is to compare the incidence of malignancy (excluding non-melanoma skin cancer, NMSC), NMSC, MACE, VTE, SIE, and mortality in adults with RA who receive Rinvoq relative to those who are treated with biologic medications approved for the treatment of RA, in the course of routine clinical care.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine

RINVOQ

Medical condition to be studied

Rheumatoid arthritis

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

7500

Study design details

Outcomes

To compare the incidence of malignancy (excluding non-melanoma skin cancer, NMSC), NMSC, MACE, VTE, SIE, and mortality in adults with RA who receive Rinvoq relative to those who are treated with biologic medications approved for the treatment of RA, in the course of routine clinical care. To describe the incidence rates of the following adverse events: herpes zoster (HZ), opportunistic infections (OI), active tuberculosis (TB), gastrointestinal (GI) perforations, and evidence of drug-induced liver injury (DILI) in adults with RA

who receive Rinvoq relative to those who are treated with biologic medications approved for the treatment of RA, in the course of routine clinical care.

Data analysis plan

The population of patients in the study will be characterized with respect to demographic, clinical, disease and patient-reported outcomes using descriptive statistics. The main analyses will employ propensity score methods to address confounding by indication (channeling bias) followed by estimation of incident rates as well as multivariable Cox proportional hazards modeling to estimate HRs and associated 95% CIs.

Data management

Data sources

Data sources (types)

Disease registry

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