An observational post-approval safety study of golimumab in treatment of polyarticular Juvenile Idiopathic Arthritis (pJIA) using the German Biologics JIA Registry (BiKeR) (MK-8259-050)

First published: 30/01/2018

Last updated: 14/03/2024

Study Ongoing

Administrative details

EU PAS number

EUPAS20781

Study ID

47271

DARWIN EU® study

No

Study countries

☐ Germany

Study description

Simponi® (golimumab, GLM) received European marketing authorization for the treatment of polyarticular juvenile idiopathic arthritis (pJIA) on 24 June 2016. In connection with the approval in this indication, the Sponsor is committed to conduct a required postauthorization safety study (PASS) to monitor long-term safety of GLM in the treatment of pJIA in regular clinical practice setting. This is an observational PASS and will monitor safety and effectiveness of GLM use in the treatment of pJIA in usual clinical practice using data from the German Biologics JIA Registry (Biologika in der Kinderrheumatologie, BiKeR). The study will comprise four study cohorts: GLM cohort, contemporary anti-tumor necrosis factor (anti-TNF) control cohort (including adalimumab ADA, etanercept ETA, or their biosimilars when available), contemporary methotrexate (MTX) control cohort, and historic anti-TNF control cohort (ADA or ETA). The primary objectives are to describe the baseline clinical and demographic characteristics of the four study cohorts, to evaluate long-term safety of GLM in treatment of pJIA, and to compare the risks of primary safety endpoints in GLM cohort with those in contemporary anti-TNF cohort (primary comparison) and with those in contemporary MTX cohort (secondary comparison), adjusted for baseline characteristics.

Study status

Ongoing

Research institutions and networks

Institutions

Merck & Co.

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Institution

Centre for Pediatric Rheumatology Sankt Augustin

Sankt Augustin, Germany

Contact details

Study institution contact

Clinical Trials Disclosure Merck Sharp & Dohme LLC

ClinicalTrialsDisclosure@merck.com

Study contact

ClinicalTrialsDisclosure@merck.com

Primary lead investigator

Gerd Horneff

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 03/05/2017

Study start date
Planned: 31/01/2018

Actual: 31/01/2018

Data analysis start date
Planned: 01/12/2026

Date of final study report
Planned: 30/06/2027

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Merck Sharp & Dohme/Janssen Biologics B.V.

Study protocol

8259-050-v1_final-redaction.pdf(518.35 KB)

MK-8259-050-02-V2-JANSSEN-Prot_Final Redaction.pdf(683.14 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

MK-8259-050

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Disease epidemiology

Effectiveness study (incl. comparative)

Main study objective:

To evaluate long-term GLM safety in treatment of pJIA by describing risk of primary safety endpoints for 4 cohorts: serious infections, malignancy, autoimmune processes, exposure during pregnancy, and to compare the risks in GLM vs. other cohorts.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(L04AB06) golimumab

golimumab

Medical condition to be studied

Juvenile idiopathic arthritis

Population studied

Age groups

Children (2 to < 12 years)

Adolescents (12 to < 18 years)

Adults (18 to < 46 years)

Estimated number of subjects

3258

Study design details

Outcomes

Serious infections (including opportunistic infections, TB and hepatitis B reactivation), malignancy, autoimmune processes (including thyroiditis, autoimmune diabetes, uveitis, psoriasis, IBD, celiac disease, demyelinating disorders, as well as SLE), exposure during pregnancy. Incidence of demyelinating disorders, serious depression including suicidality, PedACR 30/50/70/90 & JADAS-10 scores, treatment duration/discontinuation.

Data analysis plan

For primary safety endpoints, frequency/incidence rate will be calculated for each cohort. Subgroup analyses stratified by history of prior anti-TNF use will be done if data permit. For secondary safety endpoints, frequency/incidence rate will be calculated for the GLM cohort, and two contemporary comparator cohorts. For historic anti-TNF cohort, frequencies/incidence rates will be calculated only for those secondary endpoints systematically collected during the historic observation period. For GLM cohort, treatment response will be described at months 3, 6, 12, and 24 compared to baseline. For GLM cohort, treatment duration and reasons for GLM discontinuation will be described. Comparative analyses between GLM and two contemporary comparator cohorts may be done for primary safety outcomes adjusting for potential confounders in the final report.

Data management

Data sources

Data source(s)

Biologika in der Kinderrheumatologie

Data sources (types)

Disease registry

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