Post Authorization Safety Study (PASS) among Patients Treated with Flixabi for Rheumatoid Arthritis (RA), Ankylosing Spondylitis (AS), Other Spondyloarthropathies (SpA), and Psoriatic Arthritis (PsA) within the Swedish, Population based, Anti-Rheumatic Therapies in Sweden (ARTIS) register. (Safety of Flixabi in ARTIS)

First published: 14/08/2026

Last updated: 14/08/2026

Study Finalised

Administrative details

EU PAS number

EUPAS1000001077

Study ID

1000001077

DARWIN EU® study

No

Study countries

Sweden

Study description

To provide an assessment of pre-specified safety outcomes for Flixabi as used in the treatment of rheumatoid arthritis (RA), ankylosing spondylitis (AS) and other spondyloarthropathies (SpA), and psoriatic arthritis (PsA) in Sweden, using data from the Anti-Rheumatic Therapies In Sweden (ARTIS) system.

Study status

Finalised

Research institutions and networks

Institutions

Department of Medical Epidemiology and Biostatistics, Karolinska Institutet

Sweden

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Institution | Educational Institution | ENCePP partner

Contact details

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Primary lead investigator

Jeonghyun Lee

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 04/01/2016

Actual: 04/01/2016

Study start date

Planned: 01/01/2019

Actual: 01/01/2019

Date of final study report

Planned: 01/01/2026

Actual: 01/01/2026

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Samsung Bioepis Co., Ltd

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 topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Safety study (incl. comparative)

Data collection methods:

Primary data collection

Study design:

The study design used in this comparative safety report is an active-comparator new-user cohort design

Main study objective:

The objective of the analyses presented in this comparative safety report is to provide an assessment of pre-specified safety outcomes for Flixabi as used in the treatment of RA, AS and other spondyloarthropathies (SpA), and PsA in Sweden, using data from the ARTIS system since 2015.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

FLIXABI

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

INFLIXIMAB

Anatomical Therapeutic Chemical (ATC) code

(L04AB02) infliximab

infliximab

Medical condition to be studied

Rheumatoid arthritis

Population studied

Short description of the study population

Patients treated with Flixabi

Age groups

- **Adult and elderly population (≥18 years)**
  - Adults (18 to < 65 years)
    - Adults (18 to < 46 years)
    - Adults (46 to < 65 years)
  - Elderly (≥ 65 years)
    - Adults (65 to < 75 years)
    - Adults (75 to < 85 years)
    - Adults (85 years and over)

Study design details

Setting

The data used in the current report was extracted from Swedish registers in which information is prospectively collected (see section 9.5 Data sources and measurement). Patients treated with Flixabi entered the study from January 1st 2019 (i.e. first year of availability of Flixabi for the treatment of RA in Sweden); Patients treated with another TNFi (excluding infliximab), bionaive patients and general population comparators may entered the study from January 1st 2015, i.e. four years earlier (to optimize statistical power).

Comparators

Patients who are treated with the drug of interest are compared to patients who are treated with alternative biological or targeted synthetic disease-modifying anti-rheumatic drugs (b/tsDMARDs)(i.e., active-comparator)

Outcomes

1) All primary invasive cancers excluding non-melanoma skin cancers

2) Lymphoma

3) Tuberculosis (TB)

4) Demyelinating event/Multiple sclerosis (MS)

Summary results

This nationwide safety monitoring study identified 161 RA, 152 AS-SpA, and 65 PsA patients initiating Flixabi treatment in Sweden between 2019-2024. For all primary invasive cancers excluding non-melanoma skin cancers, standardized incidence rates were 11.3/1000 PYs (RA), 9.6/1000 PYs (AS-SpA), and 6.9/1000 PYs (PsA), which were comparable to originator-product infliximab and other TNFi cohorts . No tuberculosis or demyelinating events were observed in any Flixabi cohort across all indications, while one lymphoma event occurred in the AS-SpA cohort (3.2/1000 PYs) . Cox proportional hazards modeling was not performed due to insufficient events (<5 per cohort), limiting statistical comparisons between treatment groups.

Documents

Study report

ARTIS_PASS study_final report_final.pdf (949.97 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.

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