An Active Surveillance, Post Authorization Safety Study (PASS) to Investigate Relevant Safety Outcomes among Patients Treated with Flixabi for Rheumatoid Arthritis (RA) within the German Registry Rheumatoide Arthritis: Beobachtung der Biologika-Therapie (RABBIT)

First published: 06/08/2026

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Study Finalised

Administrative details

EU PAS number

EUPAS1000001076

Study ID

1000001076

DARWIN EU® study

No

Study countries

Germany

Study description

To investigate relevant safety outcomes in patients with rheumatoid arthritis by evaluating and comparing unadjusted incidence rates of pre-defined outcomes in patients exposed to Flixabi (index drug group) and patients treated with infliximab (biologic original and biosimilar) except Flixabi (comparator group), and estimating and comparing the risk of pre-defined outcomes in patients exposed to the index drug in comparison to patients exposed to drugs from the comparator group by applying multivariable adjusted analyses.

Study status

Finalised

Research institutions and networks

Institutions

Epidemiology Unit, Deutsches Rheuma-Forschungszentrum Berlin (DRFZ)

Germany

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Institution | Educational Institution

Contact details

Study institution contact

Jeonghyun Lee jhyun94.lee@samsung.com

Study contact

jhyun94.lee@samsung.com

Primary lead investigator

Jeonghyun Lee

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/01/2023

Actual: 01/01/2023

Study start date

Planned: 01/01/2023

Actual: 01/01/2023

Date of final study report

Planned: 31/03/2026

Actual: 10/06/2026

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Samsung Bioepis

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:

Non-interventional prospective observational cohort study

Main study objective:

The objectives were to compare patients exposed to Flixabi (index group) and patients treated with any other
infliximab except Flixabi (comparator group). The pre-defined outcomes comprised tuberculosis, serious
infections (excluding tuberculosis) / sepsis, congestive heart failure, myocardial infarction, central
demyelination / demyelinating disorders, serious hematologic disorders, neoplasms / malignancies, death,
serious systemic hypersensitivity reactions / serious infusion reactions, hepatic failure, serious gastrointestinal
ulcer / perforation, stroke, venous thromboembolism, pregnancy and pregnancy outcomes, and immunogenicity.
Events are classified as serious or non-serious by the reporting physician.

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 with rheumatoid arthritis enrolled in the RABBIT register who initiated treatment with Flixabi (index drug group) or other infliximab products including Remicade, Zessly, Remsima, and Inflectra (comparator group) after at least one prior csDMARD failure. Patients must have a rheumatologist-confirmed diagnosis of RA and be at least 18 years of age at initiation of treatment.

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

Patients with RA enrolled and observed in RABBIT between 01 January 2017 and 30 June 2025 were analysed
according to their exposure groups and described both at the time of enrolment and at each start of therapy using
summary measures.

Comparators

Any other infliximab except Flixabi

Outcomes

Events of interest were defined in the RABBIT study protocol and comprise outcomes of tuberculosis (incident and reactivated), other serious infections, myocardial infarction, heart failure, stroke, venous thromboembolism, central demyelination, hepatic failure, serious systemic hypersensitivity reactions/serious infusion reactions, serious gastrointestinal ulcer/perforation, serious hematologic disorders, malignancies and deaths. In case of an event of interest or in case of an SAE which had been assigned to be possibly related to a DMARD, the treating physician is asked to complete a query for additional information. For all events of interest, as well as for pregnancies and pregnancy-related outcomes, additional event-specific queries are used. For SAEs with a possible relation to DMARD use, a general additional query is used without event-specific questions. All additional queries comprise details for greater specification of the event, related diagnostic and therapeutic procedures, as well as
the course of DMARD therapy. In addition, all other medications the patient had been treated with at the time of the event are reported.

Summary results

A total of 215 treatment episodes were eligible for the analyses, including 32 episodes based on 32 patients for
Flixabi and 183 episodes based on 174 patients for the comparator group. Mean age at index date was 56.7 years
in the Flixabi versus 57.0 years in the comparator group. Most patient characteristics were comparable for both
groups.No events occurred in the Flixabi group for several pre-defined safety outcomes where events were
observed in the comparator group, including serious infections/sepsis, myocardial infarction,
neoplasms/malignancies, serious hematologic disorders, demyelinating disorders, serious gastrointestinal
ulcer/perforation, stroke, and death.One case of venous thromboembolism (VTE) was observed in the Flixabi
treatment group. No VTE events were recorded in the comparator group. The unadjusted IR of VTE in the
Flixabi group was 34.75 (95% CI: 0.44–97.63). For immunogenicity, five events were observed in the Flixabi
group, corresponding to an unadjusted IR of 96.65 (95% CI: 31.38–225.54). In the comparator group, 14 events
were observed, resulting in an unadjusted IR of 57.9 (95% CI: 31.65–97.14).The fully adjusted Cox regression
model for immunogenicity shows a numerically increased, but statistically not significant risk in the Flixabi
group compared with the comparator group (HR: 2.16, 95% CI: 0.59–7.87).

Documents

Abstract of study report

Flixabi_Final Study Report_RABBIT_final.pdf (1.21 MB)

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.

Data sources

Data source(s), other

biologics registry RABBIT

Data sources (types)

Drug 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