Remibrutinib in real-world clinical practice: a prospective, multi-country, non-interventional, effectiveness and safety study (REASSERT) - Local adaptation in Germany from global umbrella protocol (CLOU064A2402)

First published: 29/05/2026

Last updated: 29/05/2026

Study Planned

Administrative details

EU PAS number

EUPAS1000001003

Study ID

1000001003

DARWIN EU® study

No

Study countries

Germany

Study description

This is a prospective, multi-country, non-interventional study in patients with CSU where the treatment decision prior enrolment has been made to either escalate current sgH1-AHs treatment or escalate/switch current treatment to remibrutinib.
The primary aim of this study is to gather real-world effectiveness and safety data for remibrutinib, covering a broader, real-world clinical practice population. The study employs an umbrella design which brings the evidence needs from multiple countries under the REASSERT global program.

This version of the protocol has been tailored to meet the specific requirements of Germany; the local study documentation is a minimized version of the global document set, modified to align with local evidence needs, given local disparities in treatment guidelines, access, legal requirements, physician type and electronic patient-reported outcomes (ePROs)/electronic diaries (eDiaries) used.

The major protocol adaption for Germany from the umbrella protocol is the exclusion of cohort 1:
• Cohort 1 (Inadequate control of CSU despite licensed dose of sgH1-AH and decision to escalate sgH1-AH treatment.) will not be addressed as this is considered off-label in Germany.

The study has 2 periods:
• Early frequent observational period (Phase 1): Baseline to week 12
• Long-term observational period (Phase 2): From Month 3 to 24

Study status

Planned

Research institutions and networks

Institutions

Novartis Pharmaceuticals

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

Novartis Clinical Disclosure Officer

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Study contact

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Primary lead investigator

Novartis Clinical Disclosure Officer

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 24/03/2025

Study start date

Planned: 01/06/2026

Data analysis start date
Planned: 31/05/2029

Date of interim report, if expected
Planned: 30/09/2027

Date of final study report
Planned: 31/01/2030

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Novartis Pharma AG

Study protocol

REASSERT_German Protocol_ v00_04-Feb-2026_signed_Redacted.pdf (1.58 MB)

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Other study registration identification numbers and links

CLOU064ADE02

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Effectiveness study (incl. comparative)

Evaluation of patient-reported outcomes

Healthcare resource utilisation

Safety study (incl. comparative)

Data collection methods:

Primary data collection

Study design:

Prospective, multi-country, non-interventional study in patients with CSU where the treatment decision prior enrolment has been made to escalate/switch current treatment to remibrutinib

Main study objective:

Evaluate the 12-week real-world effectiveness of remibrutinib in adult patients diagnosed with CSU who remain symptomatic despite sgH1-AHs.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(L04AA60) remibrutinib

remibrutinib

Medical condition to be studied

Chronic spontaneous urticaria

Population studied

Short description of the study population

Patients with CSU where the treatment decision prior enrolment has been made to escalate/switch current treatment to remibrutinib

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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)

Estimated number of subjects

470

Study design details

Setting

The study is conducted in various healthcare system settings, office- and hospital-based.

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 sources (types)

Electronic healthcare records (EHR)

Non-interventional study

Patient surveys

Use of a Common Data Model (CDM)

CDM mapping

Yes

CDM Mappings

CDM name

CDISC SDTM

CDM website

https://www.cdisc.org/standards/foundational/sdtm

CDM version

SDTM v2.0 and SDTM IG v3.4

Data quality specifications

Check conformance

Yes

Check completeness

Yes

Check stability

Yes

Check logical consistency

Yes

Data characterisation

Data characterisation conducted

Yes

Data characterisation moment

after data extraction

after extract-transform-load to a common data model

after creation of study variables

Data characterisation details

The study will collect participant-level data including demographics, medical history, concomitant medications, and laboratory results along with variables required by the protocol. Data will be captured at baseline and at each scheduled follow-up visit as mentioned in schedule of assessment . Variables will include both categorical (e.g., sex, adverse event categories) and continuous measures (e.g., lab values).

For data collection and quality : The study will collect data in an EDC applications. The forms will checks in place to ensure data quality and completeness. The applicable SOPs will be followed to ensure compliance with data collection and reporting process.