Remibrutinib in real-world clinical practice: a prospective, multi-country, non-interventional, effectiveness and safety study (REASSERT)

First published: 27/01/2026

Last updated: 03/02/2026

Study Ongoing

Administrative details

EU PAS number

EUPAS1000000889

Study ID

1000000889

DARWIN EU® study

No

Study countries

- [ ] Canada
- [ ] China
- [ ] Germany

- [ ] Italy
- [ ] Japan
- [ ] Korea, Republic of
- [ ] Spain
- [ ] United States

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.

Countries will generate local protocol to be used in their country; the local study documentation will be a minimised version of the global document, modified to align with country’s evidence needs, given local disparities in treatment guidelines, access, physician type and ePROs/eDiaries used.

To achieve the core objectives the observation needs to include either the Urticaria Control Test (UCT) or Urticaria Activity Score over 7 days (UAS7) and the Dermatology Life Quality Index (DLQI). Data from all countries will be pooled and analyzed globally. In certain instances, some modifications of the global protocol may be permitted. For example, in countries where prospective monitoring of off-label antihistamines is prohibited, cohort 1 will not be enrolled.

Study status

Ongoing

Research institutions and networks

Institutions

Novartis Pharmaceuticals

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Institution

Contact details

Study institution contact

Novartis Clinical Disclosure Officer

Trialandresults.registries@novartis.com

Study contact

Trialandresults.registries@novartis.com

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: 30/01/2026

Actual: 02/02/2026

Data analysis start date
Planned: 30/10/2031

Date of final study report
Planned: 30/08/2032

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Novartis Pharma AG

Study protocol

Protocol Amendment_-_v01_Redacted_22 Dec 2025.pdf (1.25 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

CLOU064A2402

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

Study design:

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

Main study objective:

Evaluate the 12-week real-world effectiveness of remibrutinib in adult patients diagnosed with CSU who remain inadequately controlled despite sgH1-AHs (including all patients who initiate remibrutinib, regardless of prior treatment).

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 either escalate current sgH1-AHs treatment or escalate/switch current treatment to remibrutinib

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Estimated number of subjects

3277

Study design details

Setting

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, a new treatment option, covering a broader, real-world clinical practice population at a wider range of sites than in the Phase 2 and Phase 3 (REMIX) development trials.

The study employs an umbrella design which brings together the evidence needs from multiple countries under the REASSERT global program.

Countries will generate local study documentation (i.e. concept, protocol, SAP) to be applied in their country; the local study documentation will be a minimised version of the global document set, modified to align with country's evidence needs, given local disparities in treatment guidelines, access, physician type and ePROs/eDiaries used. To achieve the core objectives the observation needs to include either the Urticaria Control Test (UCT) or Urticaria Activity Score over 7 days (UAS7) and the Dermatology Life Quality Index (DLQI). These, and safety data must be observed across all participating countries.

Data from all countries will be pooled and analyzed globally. In certain instances, some modifications of the global protocol may be permitted. For example, in countries where prospective monitoring of off-label antihistamines is prohibited, cohort 1 will not be enrolled.

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)

Non-interventional study

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.