Assessing Long-Term Outcomes of DUPIXENT® Treatment in Patients with Chronic Rhinosinusitis with Nasal Polyposis (AROMA)

First published: 11/08/2021

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Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/42822

EU PAS number

EUPAS41565

Study ID

42822

DARWIN EU® study

No

Study countries

- [ ] Canada
- [ ] France
- [ ] Germany
- [ ] Italy
- [ ] Japan
- [ ] Netherlands
- [ ] United States

Study description

The primary objectives of the study are: • To longitudinally characterize the long-term effectiveness of DUPIXENT® through assessment of patient-reported symptoms, Health-Related Quality of Life (HRQoL) related to chronic rhinosinusitis with nasal polyposis (CRSwNP) and other type 2 comorbidities, and their change over-time. • To characterize patients who receive DUPIXENT® for CRSwNP in a real-world setting with respect to their medical history, demographic and disease characteristics, and type 2 comorbidities The secondary objectives of the study are: • To characterize real-world utilization of DUPIXENT® for patients with CRSwNP • To collect patient and physician global assessment of disease severity and treatment satisfaction for patients receiving DUPIXENT® for CRSwNP • To collect long-term safety data for patients receiving DUPIXENT® for CRSwNP

Study status

Ongoing

Research institutions and networks

Institutions

Regeneron Pharmaceuticals

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Institution

Contact details

Study institution contact

Study Director Regeneron

Study contact

clinicaltrialdisclosureteam@regeneron.com

Primary lead investigator

Study Director Regeneron

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 09/06/2021

Study start date

Planned: 13/08/2021

Actual: 12/08/2021

Data analysis start date
Planned: 15/09/2026

Date of final study report
Planned: 12/02/2027

Sources of funding

- Other
- Pharmaceutical company and other private sector

More details on funding

Regeneron Pharmaceuticals, Inc., Sanofi

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

R668-cSNP-2072,NCT04959448

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Other

If ‘other’, further details on the scope of the study

Characterization of population receiving therapy

Main study objective:

• To longitudinally characterize the long-term effectiveness of DUPIXENT® through assessment of patient-reported symptoms, HRQoL related to CRSwNP and other type 2 comorbidities and their change over-time. • To characterize patients who receive DUPIXENT® for CRSwNP in a real-world setting with respect to their medical history, demographic and disease characteristics, and type 2 comorbidities

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Observational prospective product registry

Study drug and medical condition

Medical condition to be studied

Chronic rhinosinusitis with nasal polyps

Population studied

Age groups

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Estimated number of subjects

1000

Study design details

Outcomes

• Baseline Patient Characteristics • Baseline Disease Characteristics, • Descriptive summaries of DUPIXENT and other CRSwNP treatments used during the study as defined in the protocol • Reasons for initiation of new CRSwNP treatments, concomitant therapies, treatment durations, and reasons for discontinuation and/or switching • Global assessment of disease severity and treatment satisfaction • Descriptive summary of adverse events See add'l info NCT04959448

Data analysis plan

Data collected in this registry will be analyzed descriptively.

Data management

Data sources

Data sources (types)

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