Study of the safety and tolerability of ORYLMYTE in routine practice in adolescents and adults (VORAN)

First published: 10/11/2021

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Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/44429

EU PAS number

EUPAS44205

Study ID

44429

DARWIN EU® study

No

Study countries

☐ Germany

Study description

Prospective, open-label, multicentre, non-interventional, longitudinal Post Authorization Safety Study (PASS) in adolescents (12-17 years) and adults to further describe the safety and tolerability of ORYLMYTE

Study status

Ongoing

Research institutions and networks

Institutions

Stallergenes

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Institution

Contact details

Study institution contact

Medical Department Stallergenes GmbH

Study contact

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Primary lead investigator

Medical Department Stallergenes GmbH

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 28/06/2021

Actual: 28/06/2021

Study start date
Planned: 15/10/2021

Actual: 12/11/2021

Data analysis start date
Planned: 15/01/2024

Date of final study report
Planned: 15/10/2024

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Stallergenes GmbH

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Effectiveness study (incl. comparative)

Main study objective:

To further describe the safety and tolerability of ORYLMYTE® during the first treatment year in adolescents and adults suffering from moderate to severe House Dust Mites (HDM)-induced allergic rhinitis (AR) or allergic rhinoconjunctivitis (ARC), with or without controlled asthma.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(V01AA03) house dust mites

house dust mites

Medical condition to be studied

Rhinitis allergic

Conjunctivitis allergic

Perennial allergy

Population studied

Age groups

Adolescents (12 to < 18 years)

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Estimated number of subjects

1500

Study design details

Outcomes

All adverse events (AEs) having occurred from the first intake of ORYLMYTE® until the end of the study. Effect of the treatment on the allergic symptoms and on the use of symptomatic medication, patient’s well-being, effect of the treatment on sleep, pharmacoeconomic impact of the treatment (in terms of absenteeism).

Data analysis plan

AE will be classified by Preferred Term (PT) and corresponding System Organ Class (SOC) using the current MedDRA terminology. Patients with AEs will be summarized as follows: - Patients with at least one Adverse Event (AE), at least one Adverse Drug Reaction (ADR, i.e. an event related to ORYLMYTE), at least one Serious Adverse Event (SAE), at least one Serious Adverse Drug Reaction (SADR) - Patients with at least one ADR leading to definitive discontinuation of ORYLMYTE Numbers and percentages of patients with at least one reported AE will be tabulated by MedDRA SOC and PT as follows: - All AEs, SAEs, ADRs, SADRs - All ADRs by intensity, severe ADRs, ADRs leading to definitive discontinuation of ORYLMYTE

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