Open-label, Interventional, Cohort Study to Evaluate Long-term Safety of Dupilumab in Patients with Moderate to Severe Asthma who Completed the TRAVERSE-LTS12551Clinical Trial

Published: 13-02-2019
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The primary objective of this study is to describe the long-term safety of dupilumab in the treatment of patients with moderate to severe asthma who completed the previous asthma clinical trial, TRAVERSE-LTS12551.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bronchial disorders (excl neoplasms)
Study type	Interventional

Summary

ID

NL-OMON45884

Source
ToetsingOnline

Brief title
LONG-TERM FOLLOW-UP (LTFU Traverse)

Condition

- Bronchial disorders (excl neoplasms)

Synonym
Asthma; chronic inflammatory disease of the airways

Research involving
Human

Sponsors and support

Primary sponsor: Sanofi-aventis
Source(s) of monetary or material Support: Sponsor Sanofi Aventis

Intervention

Keyword: Asthma, Dupilumab, Long-Term, Safety

Outcome measures

Primary outcome

Primary safety endpoint:

Incidence rates, defined as percentage of patients with

treatment-emergent adverse events (TEAEs) and event rates per

100 patient-years.

Secondary outcome

Secondary endpoints:

* Incidence rates and event rates per 100 patient-years for

adverse events of special interest (AESIs) over the study.

* Incidence rates for serious adverse events (SAEs)/death

over the study.

* Incidence rates for adverse events (AEs) leading to study

discontinuation over the study.

Study description

Background summary

Asthma is a chronic inflammatory disease of the airways characterized by airway hyper-responsiveness, acute and chronic bronchoconstriction, airway edema, and mucus plugging. The inflammatory component of asthma involves many cell types,

including mast cells, eosinophils, T-lymphocytes, neutrophils, epithelial cells, and their biological products. For most asthma patients, a regimen of controller therapy and reliever therapy provides adequate long-term control. However, it is estimated that 5% to 10% of asthma patients have symptomatic disease despite maximum recommended treatment with combinations of anti-inflammatory and bronchodilator drugs (1).

The poor response of some patients with asthma may reflect the number of cellular and molecular mechanisms operative in asthma. There is increasing interest in distinct phenotypes because targeted therapy is more likely to be successful in patients with similar underlying pathobiologic features (2). Recent therapeutic approaches in asthma have been focused on trying to control the Type 2 T-helper cell (Th2) response. Up-regulation of interleukin(IL)-4 and IL-13 has been implicated as an important inflammatory component of asthma disease progression.

Dupilumab, a fully human monoclonal antibody that binds specifically to the shared interleukin-4 receptor alpha (IL-4R*) subunit of the IL-4 and IL 13 receptor complexes, is under development as a potential novel treatment for asthma. Dupilumab inhibits IL-4 signaling via the Type I receptor, and both IL-4 and IL-13 signaling through the Type II receptor. Dupilumab belongs to the pharmacological class of immunomodulators, IL inhibitors.

Study objective

The primary objective of this study is to describe the long-term safety of dupilumab in the treatment of patients with moderate to severe asthma who completed the previous asthma clinical trial, TRAVERSE-LTS12551.

Study design

The LPS15023 study is a Phase IIIb, open-label, interventional, outpatient, prospective, multinational, multicenter, noncomparative, single-arm, safety study.

Intervention

Study patients will be subjected to the following particular interventions/procedures or will have to undergo the below-stated physical tests and fill in questionnaires:
-Subcutaneous injections
-Safety blood tests will be performed at a local laboratory; depending on the site*s local laboratory
and facilities, either blood or urine may be assessed for pregnancy testing for WOCBP.
-Blood samples for hematology are collected from patients during the treatment

period: Blood count (erythrocytes, hemoglobin,hematocrit, and leukocytes), differential blood count (neutrophils, lymphocytes, monocytes, eosinophils, and basophils), and platelets. --Blood samples for hematology are collected from patients during the treatment period: Blood count (erythrocytes, hemoglobin,hematocrit, and leukocytes), differential blood count (neutrophils, lymphocytes, monocytes, eosinophils, and basophils), and platelets.
-For WOCBP only, blood or urine pregnancy test.
-Patients should fill out a home-dosing diary to document the administration of study IMP/NIMP
medication.

Study burden and risks

- Hypersensitivity (allergic reactions; anaphylaxis represents the most severe form thereof)
- Severe injection site reactions
- Infections (increased risk of parasitic infections).
* Infections or infestations that do not respond to medical treatment should have study IMP
discontinued until the infection is resolved.
* For any opportunistic infection, such as TB or other infections whose nature or course may
suggest an immunocompromised status (see Appendix E), patients must be permanently
discontinued from IMP.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

-Patients with asthma who completed the treatment period in the previous dupilumab asthma clinical study LTS12551.;-Signed written informed consent.

Exclusion criteria

Patients who experienced any systemic hypersensitivity reactions to the IMP in the previous dupilumab asthma study, which, in the opinion of the Investigator, could indicate that continued treatment with dupilumab may present an unreasonable risk for the patient.

Study design

Design

Study phase:	3
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	27-06-2019
Enrollment:	5
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Dupilumab
Generic name:	Dupixent

Ethics review

Approved WMO Date:	13-02-2019
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	06-05-2019
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	07-08-2019
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	04-11-2019
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	12-08-2020
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2017-002134-23-NL
CCMO	NL67927.091.18