Open-label extension study to evaluate the long-term safety and tolerability of dupilumab in patients with asthma who participated in a previous dupilumab asthma clinical study

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Primary:Evaluate the long-term safety and tolerability of dupilumab in patients with asthma who participated in a previous dupilumab asthma study.Secondary:Evaluate the efficacy of dupilumab in patients with asthma who participated in a previous...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Allergic conditions
Study type	Interventional

Summary

ID

NL-OMON45794

Source
ToetsingOnline

Brief title
TRAVERSE

Condition

- Allergic conditions
- Lower respiratory tract disorders (excl obstruction and infection)

Synonym
Asthma

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Asthma, Dupilumab, Extension study, Open-label

Outcome measures

Primary outcome

Number of participants with adverse events

Secondary outcome

- Assessment of safety parameters (laboratory data, ECG and vital signs) -

clinically significant changes from baseline

- FEV1 - clinically significant changes from baseline

- Asthma control questionnaire - clinically significant changes from baseline

- Asthma symptom scores - clinically significant from baseline

- Asthma Quality of Life Questionnaire (AQLQS) - clinically significant from

baseline

- Anti-drug antibodies - changes from baseline

- Biomarkers - changes from baseline

Study description

Background summary

Dupilumab is under development as a potential novel treatment for asthma. It blocks the downstream signaling initiated by IL-4 and IL-13, both known as important inflammatory components of asthma disease progression. Recently published clinical data from a Phase 2 clinical trial, demonstrated that dupilumab had a significant clinical effect in reducing asthma exacerbations,

improving lung function and asthma control in patients with moderate to severe uncontrolled asthma in comparison with placebo.

Study objective

Primary:
Evaluate the long-term safety and tolerability of dupilumab in patients with asthma who participated in a previous dupilumab asthma study.

Secondary:
Evaluate the efficacy of dupilumab in patients with asthma who participated in a previous dupilumab asthma clinical study.
Evaluate dupilumab in patients with asthma who participated in a previous dupilumab asthma clinical study, with regards to:
- Systemic exposure
- Anti-drug antibodies
- Biomarkers

Study design

Phase 2/3, open-label, single arm.

Intervention

Subcutaneous injection with dupilumab, every 2 weeks.

Study burden and risks

Risks and burdens related to blood collection and possible adverse events of study medication.

Contacts

Public
Sanofi-aventis

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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 a previous dupilumab asthma clinical study (ie, PDY14192, EFC13579 or EFC13691) or patients with asthma who completed the treatment and follow-up periods in pervious dupilumab asthma study DRI12544
- Patient is on a stable background dose of moderate or high dose inhaled ICS [(fluticasone propionate greater than 250 *g twice daily (or equipotent)] for ><= 1 month prior to V1)
- Signed written informed consent

Exclusion criteria

** Exclusion criteria related to study methodology **
E 01. Patients who have not completed the treatment period in PDY14192, EFC13579, or EFC13691 studies or the treatment and follow up periods in DRI12544 study
E 02. Chronic obstructive pulmonary disease (COPD) or other lung diseases (e.g., emphysema,
idiopathic pulmonary fibrosis, Churg-Strauss syndrome, allergic bronchopulmonary aspergillosis) which impair pulmonary function tests
E 03. Current smoker (smoking history >10 pack-years) or previous smoker (within 6 months prior to V1)
E 04. Clinically significant comorbidity/lung disease other than asthma
E 05. Alcohol abuse or drug abuse
E 06. Inability to follow the procedures of the study/noncompliance (eg, due to language problems or psychological disorders)
E 07. Reversal of sleep pattern (eg, night shift workers)
E 08. Patients requiring beta-adrenergic receptor blockers (beta blockers) for any reason
E 09. Anti-immunoglobulin E (IgE) therapy (omalizumab) within 130 days prior to Visit 1;

biologic therapy within 6 months prior to Visit 1 (not including parent dupilumab study)
E 10. Patient receiving concomitant treatment prohibited in the study (see Protocol section 8.8.1)
E 11. Exposure to another investigative antibody within a time period prior to Visit 1 that is less
than 5 half-lives of the antibody (if known). In case the half-life is not known, then the minimum interval since exposure to the prior investigative antibody is 6 months. The minimum interval since exposure to any other (non-antibody) investigative study medication is 30 days prior to Visit 1
E 12. Patient is Investigator or any Sub-Investigator, research assistant, pharmacist, study coordinator, other staff or relative thereof directly involved in the conduct of the protocol
E 13. Concomitant severe disease;** Exclusion criteria related to the active comparator and/or mandatory background therapies **
E 14. Diseases for which the use of background therapies are contraindicated, e.g., ICS (active
and inactive pulmonary tuberculosis) or LABA
E 15. Treatment with drugs associated with clinically significant QTc interval prolongation/ Torsades de Pointes ventricular tachycardia;** Exclusion criteria related to the current knowledge of Sanofi compound **
E 16. Patients with any event or laboratory abnormality per investigator judgment, would adversely affect participation of the patient in this study
E 17. Pregnant or breastfeeding women
E 18. (A) Women of childbearing potential (pre-menopausal female biologically capable of becoming pregnant) who:
* Do not have a confirmed negative serum *-hCG test at Visit 1
* Who are not protected by acceptable forms of effective contraception during the study, including the 16-week follow-up period as stated in the Protocol
(B) Male participant with a female partner of childbearing potential not protected by acceptable method(s) of birth control (as defined in the Protocol).
E 19. Diagnosed active parasitic infection; suspected or high risk of parasitic infection, unless clinical and (if necessary) laboratory assessments have ruled out active infection before enrolment
E 20. History of human immunodeficiency virus (HIV) infection or positive HIV screen (Anti-HIV-1 and HIV-2 antibodies) at Visit 1
E 21. Known or suspected history of immunosuppression, including history of invasive opportunistic infections (e.g., tuberculosis, histoplasmosis, listeriosis, coccidioidomycosis, pneumocystosis, aspergillosis), despite infection resolution; or unusually frequent, recurrent, or prolonged infections, per Investigator judgment
E 22. Evidence of acute or chronic infection requiring treatment with antibacterials, antivirals, antifungals, antiparasitics or antiprotozoals within 4 weeks before Visit 1; significant viral infections within 4 weeks before Visit 1 that may not have received antiviral treatment (e.g., influenza receiving only symptomatic treatment)
E 23. Live, attenuated vaccinations within 12 weeks prior to Visit 1 or planned live, attenuated
vaccinations during the study (see Appendix A)
E 24. Patients with active autoimmune disease or patients using immunosuppressive therapy for

autoimmune disease (e.g. Hashimoto*s thyroiditis, Graves* disease, inflammatory bowel disease, primary biliary cirrhosis, systemic lupus erythematous, multiple sclerosis, psoriasis vulgaris)
E 25. Patients with positive or indeterminate hepatitis B surface antigen (HBs Ag), hepatitis B core antibody (HBc Ab), or hepatitis C antibody at Visit 1.
E 26. Patients who experienced any hypersensitivity reactions to IMP in the previous dupilumab
asthma study (including *allergic* injection site reactions) which, in the opinion of the investigator, could indicate that continued treatment with dupilumab may present an unreasonable risk for the patient
E 27. Patients who have traveled to parasitic endemic area within 6 months prior to screening.;** Additional exclusion criteria during or at the end of screening period before study enrollment **
E 28. Patient who has withdrawn consent during the screening (patients who are not willing to
continue or fail to return)
E 29. Patient who develops a new medical condition, suffered a change in status of an established medical condition, developed a laboratory abnormality, or required a new treatment or medication during the screening period which meets any previously described study exclusion criterion

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):	05-09-2016
Enrollment:	5
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	n.v.t.
Generic name:	dupilumab

Ethics review

Approved WMO Date:	30-03-2016
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	11-08-2016
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	06-12-2016
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	01-03-2017
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	03-04-2017
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	14-09-2017
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	17-10-2017
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Approved WMO Date:	11-05-2018
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	22-05-2018
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	EUCTR2013-003856-19-NL
Other	IND105379
CCMO	NL57214.091.16