

Effect of ligelizumab on complete symptom control and quality of life in chronic spontaneous urticaria

Full abstract title: Complete symptom control in patients with chronic spontaneous urticaria is associated with an improvement in health-related quality of life: Data from the phase 2b ligelizumab study

Authors: Bernstein J, Giménez-Arnau A, Maurer M, et al.

Date: September 2021

Please note that this summary only contains information from the full EADV 2021 scientific abstract and selected supporting references. The results of this study may not reflect those of other studies. This summary is not intended to provide medical advice.

Why was this study done?

Chronic spontaneous urticaria (CSU) is an unpredictable skin condition characterized by the development of hives and/or angioedema (sudden painful swelling under the skin surface) that persists for more than six weeks,^{1,2} in the absence of an identified external cause.¹⁻³ It can persist for up to five years and in some cases decades.^{4,5}

Hives, also known as wheals, are swellings of the skin, persistently itchy, sometimes painful and often accompanied by a burning sensation;⁶ they can affect any area of the body. As well as hives, the presence of angioedema is often painful and disfiguring. This can appear on the face (swollen lips or eyelids), hands, feet and genitalia,⁶ adding to the physical burden of CSU and negatively impacting quality of life.⁷

CSU is a distressing disease, with unpredictable symptoms, which can cause anxiety and depression.^{5,8}

Many people with CSU do not achieve complete control of signs and symptoms despite using standard of care treatments (antihistamines and omalizumab).^{1,5}

What did this study look at?

Ligelizumab is being investigated as a potential treatment for CSU. It is a type of medication called a biologic. Ligelizumab binds to IgE, an antibody, in a unique way that prevents the activation of cells involved in the inflammatory process (mast cells) responsible for the signs and symptoms of CSU.^{9,10}

This study looked at the relationship between complete urticaria control (measured using a weekly 7-day Urticaria Activity Score [UAS7]) and various patient-reported outcomes. A UAS7 score of 0 is defined as complete urticaria control (wheal and itch free).

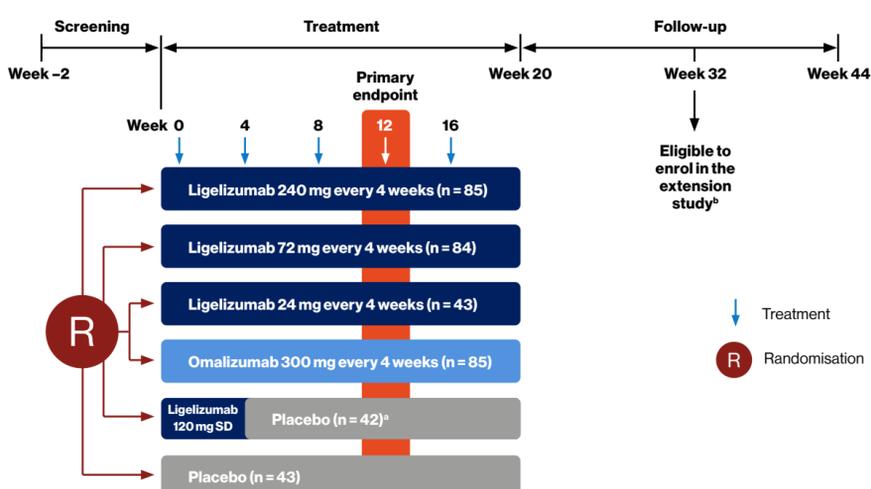
Patients whose symptoms were not well controlled with antihistamines were administered treatment with ligelizumab, omalizumab or placebo over 20 weeks with 12 weeks of follow up (n=382).

The objective was to assess if an improvement in signs and symptoms of CSU would correlate with improved quality of life, as reported by patients.

Participants reported the impact of treatment on sleep, work, daily activities and overall quality of life by completing four questionnaires:



Design of the study

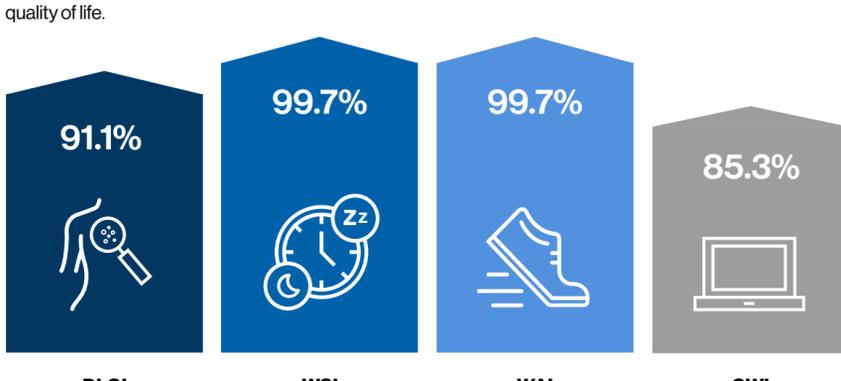


*The 120 mg single-dose (SD) arm was chosen to characterize the pharmacokinetics/pharmacodynamics. Data from this arm assesses the duration of the response and correlates this with the concentration of drug in the serum at the time when symptoms reappear. *Patients who remained in the follow-up period for at least 12 weeks and had active disease (UAS7 ≥ 12), could enter the extension study from Week 32 onwards.

n, number of patients in the corresponding category; SD, single dose; UAS7, 7-day Urticaria Activity Score.

What did the study find?

Looking at all treatment groups combined, a UAS7 score of 0 (complete urticaria control and wheal and itch free) was strongly associated with low scores of patient-reported outcomes, meaning minimal impact on quality of life.



Percentage of people with low scores on quality-of-life measurements who also achieved complete urticaria control.

Safety

Ligelizumab was well-tolerated with no new or unexpected side effects, consistent with previous studies.

Why does this matter?

Prevention of the signs and symptoms of CSU improves overall quality of life. Patients achieving complete urticaria control are less likely to have an impact on sleep, work productivity or daily activities.

Currently there are limited therapies approved for inadequately controlled CSU. Ligelizumab could potentially be a treatment option and help more people with CSU achieve complete control of their symptoms.

Glossary

Angioedema:

sudden, painful swelling of the skin.

Biologic medicine:

a treatment made using living organisms, rather than being chemically synthesized.

Dermatology Life Quality Index (DLQI):

a ten-question questionnaire used to measure the impact of skin disease on the quality of life of an affected person.

Overall Work Impairment (OWI):

a PRO measure that assesses the impact of disease on the patient's work life.

Patient-reported outcome (PRO):

a report from a patient about how they feel or function in relation to a health condition without interpretation by healthcare professionals or anyone else.

Placebo:

a "dummy" treatment; a substance with no active component that has no therapeutic effect.

7-day Urticaria Activity Score (UAS7):

a method used for assessing disease severity. Patients score their number of hives (0 to 3) and itch severity (0 to 3) for 7 days.

Weekly Activity Interference (WAI):

a PRO measure that assesses the impact of disease on the patient's general activities over the past 7 days.

Weekly Sleep Interference (WSI):

a PRO measure that assesses the impact of disease on the patient's sleep.

Who sponsored this study?

Novartis Pharma AG, Basel, Switzerland sponsored both this study and the writing of this plain language media summary.

Further information

More on the study can be found here: <https://clinicaltrials.gov/ct2/show/NCT02477332>

References

- Zuberbier T, Aberer W, Asero R, et al. The EAACI/GA²LEN/EDF/WAO guideline for the definition, classification, diagnosis and management of urticaria. *Allergy*. 2018;73:1393-1414.
- Kolkhir P, Altrichter S, Munoz M, et al. New treatments for chronic urticaria. *Ann Allergy Asthma Immunol*. 2020;124:2-12.
- Kaplan AP. Diagnosis, pathogenesis, and treatment of chronic spontaneous urticaria. *Allergy Asthma Proc*. 2018;39:184-190.
- Ghazanfar MN, Kibsgaard L, Thomsen SF, et al. Risk of comorbidities in patients diagnosed with chronic urticaria: A nationwide registry-study. *World Allergy Organ J*. 2020;13:100097.
- Maurer M, Weller K, Bindslev-Jensen C, et al. Unmet clinical needs in chronic spontaneous urticaria. A GA²LEN task force report. *Allergy*. 2011;66:317-330.
- DermNet NZ. *Chronic spontaneous urticaria* [online] December 2018. Available from: <https://dermnetz.org/topics/chronic-spontaneous-urticaria/> [Last accessed: September 2021].
- Grob JJ, Revuz J, Ortonne JP, et al. Comparative study of the impact of chronic urticaria, psoriasis and atopic dermatitis on the quality of life. *Br J Dermatol*. 2005;152:289-295.
- Balp MM, Khalil S, Tian H, et al. Burden of chronic urticaria relative to psoriasis in five European countries. *J Eur Acad Dermatol Venereol*. 2018;32:282-290.
- Arm JP, Bottoli I, Skerjanec A, et al. Pharmacokinetics, pharmacodynamics and safety of QGE031 (ligelizumab), a novel high-affinity anti-IgE antibody, in atopic subjects. *Clin Exp Allergy*. 2014;44:1371-1385.
- Gasser P, Tarchevskaya SS, Guntern P, et al. The mechanistic and functional profile of the therapeutic anti-IgE antibody ligelizumab differs from omalizumab. *Nat Commun*. 2020;11:165.