A Real-world Study to Assess Safety and Effectiveness of Xolair® in Pediatric Chronic Spontaneous Urticaria in China

Last Update: Jan 14, 2025

A Real-world, Prospective, Multicenter Study of Safety and Effectiveness of Xolair® (Omalizumab) in the Treatment of Chronic Spontaneous Urticaria (CSU) in Chinese Adolescents Inadequately Controlled With H1 Antihistamines

ClinicalTrials.gov Identifier:

NCT06053801

Novartis Reference Number:CIGE025ECN01

See if you Pre-qualify

All compounds are either investigational or being studied for (a) new use(s). Efficacy and safety have not been established. There is no guarantee that they will become commercially available for the use(s) under investigation.

Study Description

This non-interventional, multi-center, prospective post-approval study aims to provide safety and effectiveness data of Xolair® in Chinese adolescents with Chronic Spontaneous Urticaria who remain symptomatic despite H1 antihistamine treatment. The study period is 16 weeks which contains a 12-week treatment period and 4-week safety follow-up. The study period is 16 weeks which contains a 12-week treatment effect evaluation period and 4-week safety follow up. The primary objective is to evaluate the safety of Xolair® in a real-world setting in Chinese adolescent patients with Chronic Spontaneous Urticaria who remain symptomatic despite H1 antihistamine treatment over a 16-week study period. The secondary objectives are to evaluate the effectiveness (measured by ISS7, UAS7, UCT) of Xolair® and the quality of life (measured by CDLQI) of Chinese adolescent patients over a 12-week treatment period. Data will be collected in conjunction with routine care visits at the site, at Week 4, 8, 12 (recommended scheduled visits). Routine clinical assessments will be conducted, and safety information will be collected. Safety information includes AE/SAE collection, including but not limited to lab tests, vital signs, weight, physical examination etc. No extra study visits, examinations, laboratory tests or procedures other than activities performed in clinical practice will be mandated.

Condition

Chronic Spontaneous Urticaria

Overall Status

Recruiting

Number of Participants

59

Start Date

Feb 16, 2024

Completion Date

Oct 01, 2025

Gender
All
Age(s)
12 Years - 17 Years (Child)

Interventions

Other

Xolair

Prospective observational cohort study. There is no treatment allocation. Patients administered Xolair by prescription will be enrolled.

Eligibility Criteria

Inclusion Criteria:

The patient should meet all of the following criteria:

1. Diagnosed with CSU refractory to H1-AH at approved doses as defined by all of the following:

* The presence of itch and hives for ≥ 6 consecutive weeks at any time prior to enrollment despite current use of second-generation H1-AH (at locally approved doses)
* UAS7 score (range 0-42) ≥ 16 and ISS7 (range 0-21) ≥ 8 as captured in the UPDD during the 7 days prior to treatment initiation with Xolair®
2. Willing and able to complete a daily symptom Diary (UPDD) for the duration of the study, and having no more than 3 missing diary entries in the screening period.
3. Planned to receive Xolair® treatment according to the approved label in China at the time of screening.

Exclusion Criteria:

The patient should not meet any of the following criteria:

1. Use of other investigational drugs for CSU treatment within 5 half-lives, or within 30 days (for small molecules) prior to screening or until the expected pharmacodynamic effect has returned to baseline (for biologics), whichever is longer.
2. History of hypersensitivity to any of the anti-IgE drugs or their excipients or to drugs of similar classes (i.e. to murine, chimeric, or human antibodies).
3. Any other skin disease associated with chronic itching that might influence, in the investigators opinion, the study evaluations and results. (e.g. atopic dermatitis, bullous pemphigoid, dermatitis herpetiformis, senile pruritus, etc.)

Other protocol-defined inclusion/exclusion criteria may apply at the end.

China

Novartis Investigative Site

Recruiting

Nantong,Jiangsu,226000,China

Novartis Investigative Site

Recruiting

Hangzhou,Zhejiang,310001,China

Novartis Investigative Site

Recruiting

Shanghai,200443,China

Worldwide Contacts

If the location of your choosing does not feature any contact detail, please reach out using the information below.

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Source URL: *https://prod1.novartis.com/clinicaltrials/study/nct06053801*

List of links present in page

1. https://clinicaltrials.gov/ct2/show/NCT06053801
2. #trial-eligibility
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