NOVARTIS

Xolair SAA - Efficacy - HCP

Prescribing information

Image

Image

Xolair® (omalizumab) efficacy

Indications in severe allergic asthma (SAA):[1]

Xolair is indicated in adults, adolescents and children (6 to <12 years of age).

Xolair treatment should only be considered for patients with convincing immunoglobulin E (IgE) mediated asthma.

Adults and adolescents (12 years of age and older)
Xolair is indicated as add-on therapy to improve asthma control in patients with severe persistent allergic asthma who have a positive skin test or in vitro reactivity to a perennial aeroallergen and who have reduced lung function (FEV_1 <80%) as well as frequent daytime symptoms or night-time awakenings and who have had multiple documented severe

asthma exacerbations despite daily high-dose inhaled corticosteroids, plus a long-acting inhaled beta2-agonist.

Children (6 to <12 years of age)
Xolair is indicated as add-on therapy to improve asthma control in patients with severe persistent allergic asthma who have a positive skin test or in vitro reactivity to a perennial aeroallergen and frequent daytime symptoms or night-time awakenings and who have had multiple documented severe asthma exacerbations despite daily high-dose inhaled corticosteroids, plus a long-acting inhaled beta2-agonist.

Please refer to the Xolair Summary of Product Characteristics (SmPC) for the full therapeutic indications.[1]

Xolair exacerbation reduction in SAA

In a systematic review of 42 real-world studies:[2]

Image

Xolair was observed to reduce the frequency of exacerbations vs baseline up to and **beyond 4 years**[2]

Image

Xolair was observed to reduce the number of exacerbations per year by **71%** vs baseline at ≥36 months (n=95). At baseline, the weighted mean number of exacerbations per patients in the preceding year was 4.0 (n=25 studies)[2]

Xolair has demonstrated a reduction in exacerbations across clinical trials and real-world studies:[2-6]

Data are from studies with different designs and cannot be directly compared.

Image

INNOVATE primary endpoint[4]

Rate of clinically significant asthma exacerbations (defined as a worsening of asthma symptoms requiring treatment with systemic corticosteroids) during the 28-week double-blind treatment phase:

- Post-hoc primary ITT analysis (with adjustment for baseline exacerbation history): 0.68 for Xolair versus 0.91 for placebo (p=0.042)
- Rate ratio without adjustment for baseline exacerbation history was not statistically significant (0.806 [95% CI: 0.552–0.998]; p=0.153).

Xolair response rates

Xolair is intended for long-term use; clinical trials have demonstrated that it takes at least 12–16 weeks for Xolair treatment to show effectiveness.[1]

In the **INNOVATE** RCT (N=419):[4]

Image

60.5% of patients treated with Xolair (n=209) had a **good or excellent investigators' global evaluation of treatment effectiveness (GETE) rating** vs 42.8% of patients who received placebo (n=210) at Week 28 (p<0.001)[4]

Image

64.3% of patients treated with Xolair (n=209) had a **good or excellent patients' global evaluation of treatment effectiveness rating** vs 43.3% of patients who received placebo (n=210) at Week 28 (p<0.001)[4]

Xolair response by eosinophil level

A retrospective, real-world study of 872 SAA patients aged ≥6 years (**STELLAIR**) demonstrated:[7]

Image

Xolair effectiveness was similar in patients with 'high' and 'low' eosinophil levels[7]

Proportion of combined responders in 'low' and 'high' blood eosinophil groups:[7]

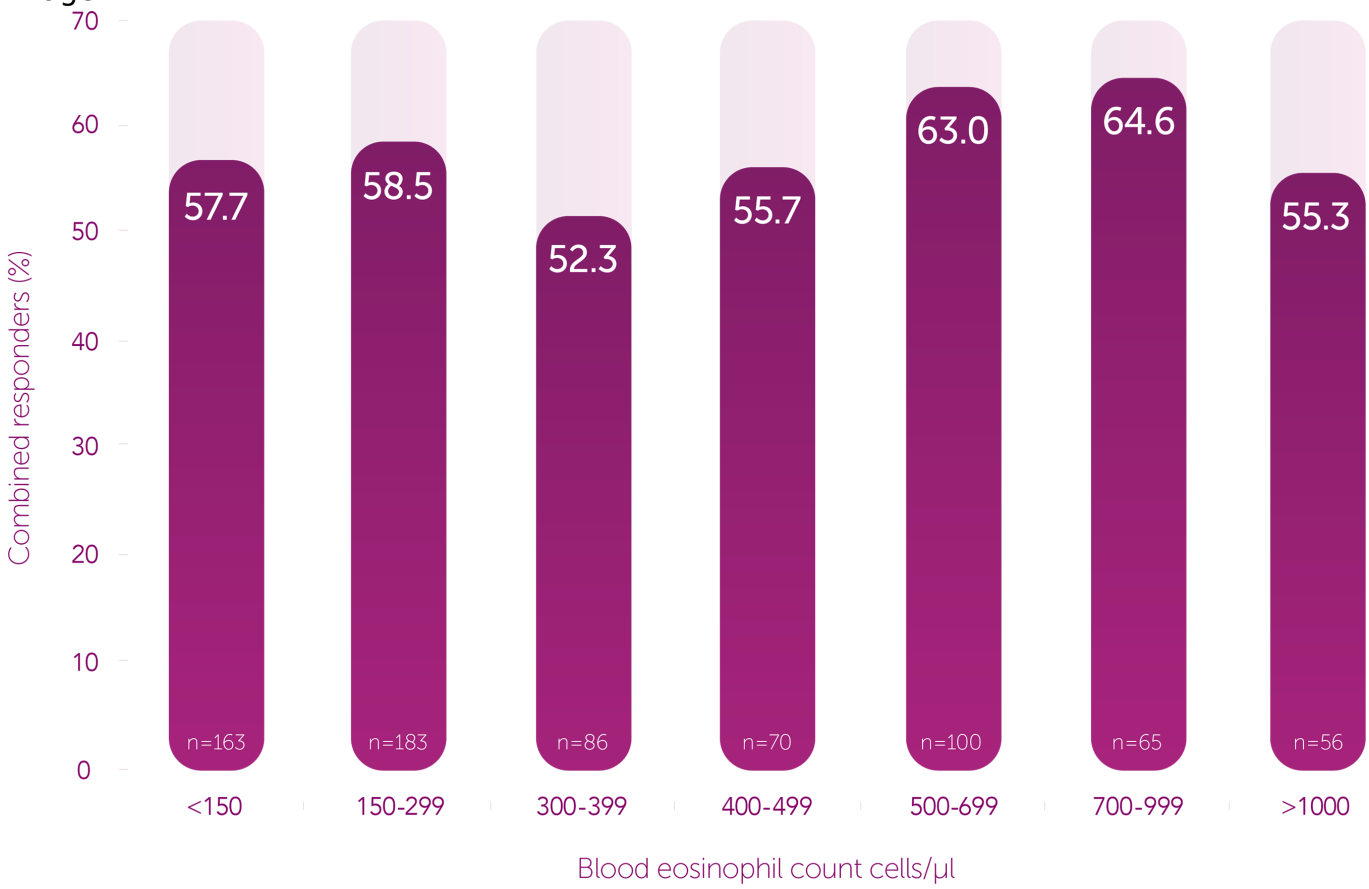
- Low (eosinophil count <300 cells/µl): **58.1%** (95% CI: 52.7–63.4%) (n=346)
- High (eosinophil count ≥300 cells/µl): **58.4%** (95% CI: 53.2–63.4%) (n=377)

Combined response

A combination of GETE evaluation and a ≥40% reduction in the annual exacerbation rate[7]

Combined responders to Xolair in adults (aged ≥18 years) according to blood eosinophil count[7]

Image



Adapted from Humbert M, et al. 2018.[7]

In rare cases, patients on therapy with anti-asthma medicinal products, including Xolair, may present or develop systemic eosinophilia and vasculitis. These events are commonly associated with the reduction of oral corticosteroid therapy. In these patients, physicians should be alert to the development of marked eosinophilia, vasculitic rash, worsening pulmonary symptoms, paranasal sinus abnormalities, cardiac complications, and/or neuropathy. Discontinuation of omalizumab should be considered in all severe cases with the above-mentioned immune system disorders.[1]

Oral corticosteroid (OCS) use in Xolair patients

In a retrospective, real-world study of 872 SAA patients aged ≥6 years (**STELLAIR**):[7]

Image

Xolair was observed to reduce OCS burden from baseline[7]

For patients requiring OCS maintenance (n=195), within a year of Xolair initiation:[7]

Image

49.2% were able to **discontinue OCS** (n=96)

Image

62.1% decreased their median daily dose by 10 mg/day, representing a 50% **median reduction** in daily OCS dose

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For information on Xolair's safety profile

Click here

PERSIST study design[3]

A prospective, open-label, observational, multicentre 52-week study in 158 patients (aged ≥12 years) with severe persistent allergic asthma despite treatment with an ICS and a LABA.

Primary objectives:

- Describe the patients who, in the treating physician’s best clinical judgement, were being treated with Xolair

- Determine the 16- and 52-week effectiveness of Xolair as an add-on therapy by measuring the proportion of patients:

    - improving in 2005 GINA classification
    - with good/excellent GETE rating
    - achieving ≥0.5 point improvement in total AQLQ score
    - severe exacerbation-free (severe exacerbation defined as exacerbation during which the patient required a systemic corticosteroid, or emergency room visit or hospitalisation for the exacerbation
    - improving in EQ-5D utility (52 weeks only)

- Describe the treatment patterns involving add-on Xolair treatment
- Describe the safety and tolerability of treatment with Xolair when used in a pragmatic trial

INNOVATE study design[4]

A randomised, multicentre, placebo-controlled, double-blind, parallel-group study in 419 patients (aged 12–75 years) with severe persistent allergic asthma who were inadequately controlled despite treatment with a high-dose ICS plus LABA, and additional controller medication if required.

The primary efficacy variable analysis included a post-hoc adjustment for baseline exacerbation history. After adjustment for the primary ITT population, the clinically significant asthma exacerbation rate showed a statistically significant between-group difference (0.68 with Xolair vs 0.91 with placebo; p=0.042).

Primary endpoint:

- Rate of clinically significant asthma exacerbations (defined as a worsening of asthma

symptoms requiring treatment with systemic corticosteroids) during the 28-week double-blind treatment phase

Secondary endpoints included:

- Severe exacerbation rate (severe exacerbation defined as PEF or FEV_1 <60% of personal best, requiring treatment with systemic corticosteroids)
- Rate of hospitalisation, emergency room visits, and unscheduled doctor's visits for exacerbations
- Symptoms, morning PEF, rescue medication use and FEV_1
- Quality of life at weeks 0, 12 and 28 of the treatment phase (assessed using AQLQ)
- Treatment effectiveness at treatment end

APEX II study design[5]

Observational, retrospective, mixed-methodology study assessing the real-life effectiveness of Xolair in 258 patients (aged ≥16 years) with severe persistent allergic asthma.

Primary endpoint:

Change in mean daily dose of OCS prescribed per patient between the 12-month pre-Xolair and post-Xolair initiation periods

Secondary endpoints included:

- Proportion of patients stopping and/or reducing OCS by ≥20%

- Exacerbation rate (exacerbations requiring either hospitalisation or increase in OCS dose ≥10 mg at any point for at least 3 days)
- Hospital resource use
- Lung function
- Patient-reported outcomes

Tzortzaki study design[6]

Four-year non-interventional, retrospective, observational, multicentre study in 60 patients

(aged ≥12 years) with poorly controlled severe persistent allergic asthma despite treatment with a high-dose ICS and a LABA according to the GINA guidelines.

Endpoints:

Effectiveness of Xolair, at 4 months, 1 year and 4 years, as add-on therapy in relation to:

- Lung function (FEV_1 and FVC)
- Number of severe exacerbations (patient required a systemic corticosteroid, required an ER visit or was hospitalised for the exacerbation)
- Level of asthma control
- Daily dose of ICS

STELLAIR study design[7]

A multicentre, non-interventional, retrospective, observational study using data from medicinal records of of 872 patients with SAA treated with Xolair.

Primary endpoint:

- Response to Xolair at T4–6 compared with T–12 using GETE, ≥40% reduction in annual exacerbation rate and a combined response of both

- Response was analysed according to blood eosinophil count (cells/µL) measured in the year prior to Xolair initiation.

A&E, accident and emergency; AQLQ, asthma quality of life questionnaire; ARR; absolute rate reduction; EQ-5D, EuroQol 5-Dimensions; ER, emergency room; GETE, global evaluation of treatment effectiveness; ICS, inhaled corticosteroid; IgE, immunoglobulin E; ITT, intent-to-treat; FEV_1, forced expiratory volume in 1 second; FVC, forced expiratory volume; GINA, Global Initiative for Asthma; LABA, long-acting beta2-agonist; OCS, oral corticosteroid; PEF, peak expiratory flow; RCT, randomised controlled trial; SAA, severe allergic asthma; SmPC, summary of product characteristics.

References

1. Xolair® (omalizumab) Summary of Product Characteristics.

2. MacDonald KM, et al. *Expert Rev Clin Immunol* 2019;15(5):553–569.

3. Brusselle G, et al. *Respir Med* 2009;103(11):1633–1642.

4. Humbert M, et al. *Allergy* 2005;60(3):309–316.

5. Niven RM, et al. *BMJ Open* 2016;6:e011857.

6. Tzortzaki EG, et al. *Pulm Pharmacol Ther* 2012;25(1):77–82.

7. Humbert M, et al. *Eur Respir J* 2018;51(5):1702523.

Xolair® (omalizumab) quality of life

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Xolair® (omalizumab) safety profile

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