18 August 2016
EMA/611553/2016
Procedure Management and Committees Support Division

Assessment report for paediatric studies submitted according to Article 46 of the Regulation (EC) No 1901/2006

Xolair

omalizumab

Procedure no: EMEA/H/C/000606/P46/054

Note

Assessment report as adopted by the CHMP with all information of a commercially confidential nature deleted.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8613
E-mail info@ema.europa.eu **Website** www.ema.europa.eu
An agency of the European Union

1. Introduction

On 17 February 2016, the MAH completed the study CIGE025E2306 i.e. a multicentre, randomized, double-blind, placebo-controlled phase III study to evaluate the efficacy and safety of omalizumab in patients with chronic spontaneous urticaria (CSU) who remain symptomatic despite H1 antihistamine (H1AH) therapy. This study population included paediatric patients (≥12 years of age) and thus the data are submitted in accordance with Article 46 of Regulation (EC) No1901/2006, as amended.

2. Scientific discussion

2.1. Information on the development program

The MAH stated that the study (CIGE025E2306) is a stand-alone study.

2.2. Information on the pharmaceutical formulation used in the study

Commercially available Xolair in Japan and Korea indicated for chronic idiopathic urticaria:

Adults and adolescents (12 years of age and older)

Xolair is indicated as add-on therapy for the treatment of CSU in adults and adolescents (12 years and above) with inadequate response to H1 antihistamine treatment.

2.3. Clinical aspects

2.3.1. Introduction

The MAH submitted a clinical overview and final study report for CIGE025E2306 which is a multicentre, randomized, double-blind, placebo-controlled phase III study to evaluate the efficacy and safety of omalizumab in patients with chronic spontaneous urticaria (CSU) who remain symptomatic despite H1 antihistamine (H1AH) therapy. The study was conducted in Japan and Korea, and enrolled male and female patients (≥12 years of age). Four patients were younger than 18 years of age at randomisation.

2.3.2. Clinical study

Purpose

The purpose of this study was to demonstrate the efficacy and safety of omalizumab compared with placebo, as an add-on to H1AH therapy in Japanese and Korean patients with CSU who remain symptomatic despite H1AH therapy.

Objectives

Primary objectives

The primary objective was to demonstrate the superiority of omalizumab 300 mg and/or 150 mg injected subcutaneously every 4 weeks in patients with refractory CSU receiving concomitant H1AH therapy with respect to a reduction from baseline in an itch severity score at Week 12, compared to placebo.

Secondary objectives included:

Urticaria Activity Score-7, weekly hives score, Dermatology Life Quality Index, and safety.

Demographics

A total of 218 patients were randomized (73 patients to omalizumab 300 mg, 71 patients to omalizumab 150 mg, and 74 patients to placebo). In the age group 12 to <18 years, four patients were randomized (2 patients to omalizumab 300 mg, 1 patient to omalizumab 150 mg, and 1 patient to placebo). The three patients treated with omalizumab completed the study. The patient who received placebo discontinued from the study after Week 4 due to "Subject/guardian decision."

CHMP comment:

Details about the demographics for these three patients are not given.

Results

Efficacy

There was a decrease in all three patients treated with omalizumab in the itch severity score at Week 12:

Weekly itch severity score at Week 12 in patients aged 12 to less than 18 years (Study IGE025E2306)

Treatment	Score at baseline	Score at Week 12 (Change from baseline)
IGE025 150 mg	14.0	0.0 (-14.0)
IGE025 300 mg	12.5	0.5 (-12.0)
Placebo	16.5	NA: discontinued
IGE025 300 mg	17.0	0.0 (-17.0)

Safety

All AEs recorded in the paediatric patients were mild or moderate in severity and patients recovered without any specific actions taken. No AEs leading to treatment discontinuation were reported in these patients. Causality was stated as "not suspected" in all cases.

3. Rapporteur's overall conclusion and recommendation

Overall conclusion

Four patients 12-18 years of age were included in this study. Two of these were administered the therapeutic dose (300 mg by subcutaneous injection every 4 weeks), one a lower dose (150 mg) and the fourth placebo. A clear decrease in itch severity score was recorded for all patients treated with Xolair whereas the patient treated with placebo withdrew at week 4 due to "Subject/guardian decision". The adverse events recorded were mild (moderate in one case of sinusitis during the follow up period) and not regarded treatment related.

B/R remains unchanged.

Recommendation

☒ **Fulfilled:**

No regulatory action required.