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Human Medicines Evaluation 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/P46/055

Note

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

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1. Introduction

The MAH has completed the study CIGE025AEG01 i.e. an observational study to evaluate efficacy and safety of omalizumab in severe persistent, IgE mediated asthma paediatric and adult patients. This study was conducted in Egypt, and enrolled male and female patients 6 to 82 years.

2. Scientific discussion

2.1. Information on the development program

The MAH stated that the study (CIGE025AEG01) is a stand-alone study.

2.2. Information on the pharmaceutical formulation used in the study

Xolair, as commercially available in Egypt.

2.3. Clinical aspects

2.3.1. Introduction

The MAH submitted a clinical overview and final study report for CIGE025AEG01 which is an observational study to evaluate efficacy and safety of omalizumab in severe persistent, IgE mediated asthma paediatric and adult patient The study was conducted in Egypt and enrolled male and female patients (≥6 years of age). Seven patients were younger than 18 years of age at randomisation.

Purpose

The purpose of this open label, non-comparative, study was to evaluate the efficacy and safety of omalizumab in the day-to-day clinical practice in an Egyptian population with IgE mediated asthma.

Objectives

Primary objectives

To evaluate the reduction in OCS use in patients requiring oral steroids as asthma maintenance therapy. Following screening for two weeks, eligible patients received omalizumab for 16 weeks.

Demographics

A total of 59 patients were enrolled. Enrolled patients had moderate-to-severe persistent allergic asthma inadequately controlled despite high-dose ICS plus LABA and OCS maintenance therapy. Of these 7 were children.

Results

Efficacy

In the overall population, the use of OCS dropped from 81.1% of patients (43 out of 53 patients) at baseline to 52.8% of patients (28 out of 53 patients) at the end of the study ($p<0.001$). Data for the children are listed in Table 3-1 below (quoted from the MAHs clinical overview):

Table 3-1 Change from Baseline in the use of OCS (CIGE025AEG01: aged 6 to less than 18 years)

Center No – Patient No	Age, gender	Baseline	Visit 6 (after 16 weeks treatment)
2-1	6.9, male	Dexaphen syrup 5 mg, b.i.d.	No OCS treatment
8-1	13.7, male	Prednisolone 5 mg, o.d.	No OCS treatment
11-1	9.8, female	Predsol syrup 8 mg, b.i.d.	Predsol 2.6 mg, o.d.
11-2	8,6 female	Predsol forte syrup 8 mg, b.i.d.	Predsol forte syrup 2 mg, PRN
11-3	7.3, male	Silone syrup 5 mg, o.d.	No OCS treatment
12-7	6.4, male	No OCS treatment	No OCS treatment
14-7	10.0, male	Prednisolone 10 mg, o.d.	No OCS treatment

b.i.d.: twice daily, o.d.: once daily, PRN: pro re nata (when needed)

Safety

One out of seven patients experienced AEs. This patient experienced epistaxis, shortness of breath, and productive cough, which were all mild in intensity and not suspected to be related to omalizumab. No deaths, SAEs and AEs leading to treatment discontinuation were reported.

Discussion

Considering the low number of patients, the results of this single armed study is difficult to interpret. In addition, as there was no run-in period where the dose of OCS was optimised it cannot be concluded to what extent the lowered doses taken by the end of the study reflects an unnecessary overuse of OCS at study start.

3. Overall conclusion

Seven patients 9-14 years of age were included in this study. The efficacy pattern previously known for Xolair was confirmed. No adverse events warranting further investigation were recorded.

B/R remains unchanged.

4. Recommendation

☒ Fulfilled:

No regulatory action required.