
SYNOPSIS OF FINAL REPORT

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| TITLE OF THE STUDY: | A Continued Access Protocol to Provide Xolair® (Omalizumab) to Subjects with Severe Allergic Asthma Who Have Received Xolair Treatment in a Previous Investigational Study |
| SPONSOR: | Genentech, Inc. 1 DNA Way South San Francisco, CA 94080-4990 U.S.A. |
| INDICATION: | Severe allergic asthma |
| INVESTIGATORS: | Twelve investigators participated in the study. |
| STUDY CENTERS: | There were 12 study centers in the United States. |
| PUBLICATIONS: | No publications resulted from this study. |
| STUDY DESIGN: | This was a continued access protocol to provide subjects who have completed Genentech, Inc. Studies Q2143g, Q2195g, Q2461g, or Novartis Pharmaceuticals Corporation Study CIGE025 0010E1 with continued Xolair treatment. Subject eligibility was based on disease severity and asthma deterioration upon withdrawal of Xolair treatment. Subjects whose last Xolair dose was <9 months prior to the screening visit were to continue with the same Xolair dosing regimen that they received in the previous Genentech or Novartis clinical study. For subjects whose last Xolair dose was ≥9 months prior to the screening visit, an IgE re-test was required. These subjects were dosed according to IgE level and weight at screening using the Xolair dosing schedule. |
| OBJECTIVES: | The primary objectives of this study were to provide continued Xolair treatment to subjects with severe allergic asthma who deteriorated upon withdrawal of Xolair and to collect serious adverse event (SAE) data on subjects who have received continued Xolair treatment for up to an additional 24 weeks. |
| CLINICAL PHASE: | III |
| PERIOD OF STUDY: | 2 May 2003 to 19 September 2003 |
| NO. OF PATIENTS: | Of the 24 subjects who enrolled in this study, 23 subjects received study drug. |
| DEMOGRAPHIC DATA: | In the Q2wk group, the majority of subjects were male (58.3%), White (75.0%), with a mean age of 41 years (range, 9–71 years). In the Q4wk group, the majority of subjects were male (72.7%), White (90.9%), with a mean age of 30 years (range, 9–51 years). |
| REFERENCE DRUG: | Xolair® (omalizumab) |
| CRITERIA FOR EVALUATION: | Analyses were conducted on subjects who received at least one dose of Xolair (safety-evaluable population). |
| STATISTICAL METHODS: | This study was designed to provide ongoing Xolair treatment; therefore, statistical analyses were limited to descriptive summaries of baseline characteristics and SAEs reported during the study. |

PROCEDURES:

Subjects whose last Xolair dose was <9 months prior to the screening visit continued with the same Xolair dosing regimen that they received in the previous Genentech or Novartis clinical study. For subjects whose last Xolair dose was ≥9 months prior to the screening visit, dosing was to be based on IgE level and weight at screening using the Xolair dosing schedule.

PATIENT POPULATION:

All subjects who completed Genentech Studies Q2143g, Q2195g, Q2461g, or Novartis Study CIGE025 0010E1 and whose disease deteriorated upon withdrawal of Xolair were eligible to enroll in this study.

SAFETY RESULTS:

No deaths occurred during the study. One serious adverse event was reported, an unintended pregnancy in the partner of a subject, that was judged by the investigators to be unrelated to treatment with Xolair.

CONCLUSIONS:

Based on this open-label study of subjects with severe allergic asthma, continued treatment with Xolair appears to be safe and well tolerated.
