URTICARIA, ANGIOEDEMA

EFFECT OF OMALIZUMAB TREATMENT ON DISEASE ACTIVITY IN CHRONIC SPONTANEOUS/IDIOPATHIC URTICARIA: RESULTS FROM XTEND-CIU, A LONGITUDINAL PERSPECTIVE

M Maurer [1] - T Murphy [2] - M Holden [3] - A Iqbal [3] - B Yoo [3] - T Casale [4]

Charité - Universitätsmedizin Berlin, Department Of Dermatology And Allergy, Berlin, Germany [1] - Charleston Ent And Allergy, Charleston Ent And Allergy, Charleston, United States [2] - Genentech, Inc., Us Medical Affairs, South San Francisco, United States [3] - University Of South Florida, Morsani College Of Medicine / Department Of Internal Medicine (allergy And Immunology), Tampa, United States [4]

Introduction: Omalizumab was approved for the treatment of chronic spontaneous/idiopathic urticaria (CSU/CIU) based on pivotal studies that demonstrated efficacy/safety through 24 weeks of treatment.

Objective: We examined the effect of omalizumab treatment and withdrawal on CSU/CIU disease activity longitudinally over the 60-week duration of the XTEND-CIU study.

Materials and Methods: XTEND-CIU included a 24-week open-label (omalizumab 300mg Q4W), 24-week double-blind (open-label responders [UAS7 ≤6] randomized to omalizumab: placebo), and 12-week follow-up (off-treatment) phase. Among the outcomes, changes in urticaria control (assessed by the urticaria control test [UCT]), in urticaria activity (assessed by the urticaria activity score [UAS7], and the weekly itch score), and in quality of life impairment (assessed by the Dermatological Life Quality Index [DLQI]) were included in this analysis.

Results: At baseline (open-label), 205 omalizumab-treated patients reported severe impairment by their disease (mean [SD] scores): UCT: (2.5[2.51]); UAS7: (32.2[6.98]); weekly itch: (15.47[3.58]); DLQI (14.8[6.89]). Substantial improvements were observed at Weeks 12/24; (mean change [SD]) UCT: 9.6[4.78]/11.1[4.39]); UAS7: (-23.7[12.25]/-26.1[12.45]); weekly itch: (□12.0[5.82]/□13.3[5.73]); DLQI: (□11.5[7.48]/-12.6[7.06]). Of 205 open-label patients, 81/53 responders were randomized to omalizumab/placebo in the double-blind phase. In omalizumab-treated patients, improvements were maintained from Week 24 to Week 48 (mean change [95%CI]) UCT: □1.7[□2.6,-0.7]); UAS7: (3.5[1.51-5.54]); weekly itch: (1.9[0.8-2.9]); DLQI: (1.5[0.3-2.6]).

Placebo-treated patients, in contrast, experienced worsening disease activity (mean change [95%CI]) UCT: -7.8[-9.6,-6.0]); UAS7: (16.3[12.30-20.35]); weekly itch: (8.1[6.1-10.1]); DLQI: (8.2[5.5-10.9]). Changes in UAS7 from Week 48 to Week 60 were similar in omalizumab-/placebo-treated patients. No new safety issues were identified.

Conclusions: Omalizumab was associated with rapid, substantial improvements in disease activity during open-label treatment with no new safety concerns identified. Benefits were maintained to the end of the double-blind phase to a greater extent among patients randomized to continue omalizumab versus placebo-treated patients, who generally experienced disease worsening after omalizumab discontinuation at Week 24.