

URTICARIA, ANGIOEDEMA

MORE PATIENTS TREATED WITH LIGELIZUMAB ARE ANGIOEDEMA-FREE COMPARED WITH OMALIZUMAB: RESULTS OF A PHASE II CLINICAL TRIAL

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Introduction: Angioedema in chronic spontaneous urticaria (CSU) can cause substantial health-related quality of life impairment. Ligelizumab, a next generation high affinity humanized monoclonal anti-IgE antibody, was examined in a Phase 2b dose-finding study in patients with CSU inadequately controlled by H1-antihistamines alone or in combination with H2-antihistamines and/or leukotriene receptor antagonists.

Objective: This analysis specifically investigated the impact of ligelizumab treatment (72 and 240 mg) versus placebo and omalizumab (300 mg) on angioedema occurrence.

Materials and Methods: Eligible patients aged 18–75 years received subcutaneous ligelizumab 72 or 240mg, omalizumab 300mg, or placebo every 4 weeks for 5 administrations, as add-on therapy to their background medication. Angioedema occurrence was recorded by patients in the Urticaria Patient Daily Diary starting 7 days before the baseline visit; at all visits it is reported for the previous 7 days.

Results: At baseline, angioedema was reported by 47.6% (n=40/84), 45.9% (n=39/85), 52.9% (n=45/85) and 58.1% (n=25/43) of patients randomized to ligelizumab 72 and 240mg, omalizumab and placebo, respectively. At Week 4, ligelizumab 72 and 240mg achieved greater changes from baseline of -30.9% and -31.1%, respectively, compared with -24.0% with omalizumab and -12.9% with placebo. At Week 12, changes from baseline were -35.1% and -40.8% for ligelizumab 72 and 240mg, respectively and -29.2% for omalizumab and -26.4% for placebo. These results are also reflected in the proportion of patients who were angioedema-free throughout the treatment period. At Week 12, 87.5%



and 94.9% of patients treated with ligelizumab 72 and 240mg were angioedema-free, respectively, compared with 76.3% for omalizumab and 68.3% for placebo.

Conclusions: Ligelizumab achieved greater reductions in the percentage of patients reporting angioedema compared with omalizumab and placebo. Ligelizumab 240mg achieved the highest percentage of angioedema-free patients and this benefit was sustained throughout the treatment period.

