1311 | Design and rationale of the optima study: retreatment or step-up therapy with omalizumab in patients with chronic idiopathic/spontaneous urticaria (CIU/CSU)

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Introduction: Pivotal Phase 3 studies have demonstrated that subcutaneous administration of Omalizumab 150 or 300 mg every 4 weeks for 24 weeks is safe and effective in treating symptoms associated with CIU/CSU. OPTIMA (NCT02161562) is a novel study addressing remaining gaps in the knowledge of optimal CIU/CSU treatment.

Objectives: OPTIMA is a Phase 3b, international, multicenter, randomized, open-label, non-comparator trial. The purpose of the study is to gather data on: (i) retreatment efficiency upon return of symptoms once omalizumab treatment is withdrawn from well controlled patients (UAS7≤6) and symptoms have returned (UAS7≥16); (ii) dose step-up from 150 mg if patients are not well controlled after ≥8 and ≤24 weeks of treatment to 300 mg; (iii) treatment extension beyond 24 weeks in patients who are not well-controlled with 300 mg at 24 weeks. Patients with CIU/CSU and symptomatic despite H_1-antihistamine treatment are randomized 4:3 to 150 or 300 mg omalizumab for 24 weeks of initial treatment and then enter one of the following phases: (i) withdrawal phase (if UAS7 ≤ 6 at either dose); (ii) step-up to 300 mg (if 150 mg initially and UAS7 > 6); (iii) extended treatment for 12 more weeks (if 300 mg initially and UAS7 > 6). Patients in the withdrawal phase are monitored and retreated at the randomized initial dose if relapse occurs (UAS7 ≥ 16). The entire study is 53 weeks, including the final follow-up. There are six distinct treatment groups as a result of this treatment optimization design. Three hundred and fourteen patients were required to observe a sufficient number of relapses after initial dosing with 150 or 300 mg.

Results: Endpoints/Analysis: The primary endpoint is the proportion of patients who were clinically well controlled (UAS7 ≤ 6) after the initial dosing phase, relapsed (UAS7 ≥ 16) when treatment was discontinued, and who achieved a UAS7 score ≤6 at the end of the second dosing Phase. Key secondary endpoints include: change in UAS7 score and proportion of patients UAS7 ≤ 6 in those who step-up from 150 to 300 mg; change in UAS7 score in patients who extend 300 mg treatment; time to relapse in both doses.

Conclusions: The OPTIMA study will allow better characterization of appropriate omalizumab treatment regimen in CIU/CSU patients who relapse or are not well controlled after initial treatment.

1313 | Etiological reasons and prognosis of acute urticaria in children under 5 years of age

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Introduction: Urticaria is a skin lesion that is characterized by erythematous, raised, itchy plaques. It is termed as acute, chronic or recurrent. In most cases of acute urticaria etiological reasons are unknown. Aim of this study was to determine etiology of acute urticaria in children under 5 years of age and to reveal clinical and laboratory characteristics of patients.

Objectives: Children less than 5 years old who were referred to our clinic between July 2015 and July 2016 for acute urticaria were enrolled into the study. Informed consent was taken from the parents of the patients. Their clinical and laboratory data were recorded.

Results: A total of 83 patients [male (n = 49)] with a median age of 2.12 (1.27-3.39) years were included into the study. Angioedema was more common in the patients under 2 years of age (P = .001). Trigger factor could be detected in 62.6% of patients of whom 78.8% had active infections. Other etiologic factors were foods in four patients; vaccines in two patients, drug in one patient, grass pollen in 2 patients, animal fur in 1 patient, dermographism in 1 patient. There was no relationship between steroid intake and urticaria activity score (UAS) or duration of urticaria. Urticaria recurred in 33.2% of the patients and resolved with antihistamine treatment in 86.7%. Median score of UAS was 15 (8-21). 55.4% of the patients had mild urticaria (UAS < 16). There was no relation between eosinophilia and urticaria type (acute-chronic-recurrent), steroid intake or having atopy. All patients who had atopy for foods were under 2 years old. Serological positivity was detected in twenty patients (24%) [herpes simplex type (HSV) 1 (n = 10), EBV (n = 5), *Streptococcus* (n = 4), *Mycoplasma pneumoniae* (n = 1)]. The most common infectious cause was upper respiratory tract infection (URTI). Urticaria recurred in 33.2% of the patients and 7.2% out of 83 occurred as chronically. Urticaria did not recur in patients with positive viral serology (P = .02).

Conclusions: The most common etiological reason of acute urticaria in the preschool period was URTI. HSV type 1 was the most frequently reported among the agents that could be determined by serologic methods. The other causative agents were foods, followed by vaccines, drugs and aeroallergens.