PRURITUS

A RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED STUDY OF MONOCLONAL ANTI-IGE ANTIBODY OMALIZUMAB IN THE MANAGEMENT OF PRURITUS IN CHRONIC SPONTANEOUS URTICARIA IN THE PEDIATRIC POPULATION

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Background:Chronic spontaneous urticaria (CSU) is defined as the spontaneous appearance of itchy wheals, with or without angioedema, persisting for more than 6 weeks. In recent years, monoclonal Anti-IgE antibody 'omalizumab' has been tried in other allergic disorders like atopic dermatitis and bronchial asthma in the pediatric age group, however there are no studies till date of this novel therapeutic regimen in the pediatric age group to control the itching in chronic spontaneous urticaria in the pediatric age group.

Objective: This study sought to evaluate the efficacy and safety of monoclonal Anti-IgE antibody omalizumab in patients between the group of 6 to 15 years with moderate-to-severe chronic idiopathic urticaria who remained symptomatic despite H1-antihistamine therapy (licensed doses)

Methods: This was a double-blind, placebo-controlled trial with children between the age group of 6 to 15 years randomized to omalizumab or placebo. Randomly assigned 50 children with comparable baseline age and serum IgE levels received eight subcutaneous injections, spaced 4 weeks apart, of omalizumab at a dose of 150 mg or placebo, followed by a 48-week observation period. Mean Urticaria activity score (UAS) at baseline was 5.9 points (range, 4–6 points).

Results: As compared to a placebo there was a statistically significant reduction in FcεRI expression on basophils and pDC2 in omalizumab treated children. Serum IgE levels and Urticaria activity scores were significantly reduced in the Omalizumab group as compared to the placebo group both at 24 and 48 weeks.

Conclusions: The clinical signs and symptoms of chronic idiopathic urticaria in the pediatric population who had remained symptomatic despite the use of approved doses of H1-antihistamines, improved significantly. Thus, omalizumab is an effective and well-

tolerated add-on therapy for children with CSU who are symptomatic despite background therapy with antihistamines.