Dupilumab Approved for Atopic Dermatitis in Teenagers

On March 11, 2019, the U.S. Food and Drug Administration (FDA) expanded the labeled use of Dupixent® (dupilumab), to include those patients between the ages of 12 and 17. Dupilumab is a subcutaneous injection used to treat moderate to severe atopic dermatitis that is not adequately controlled with topical therapies or when those therapies are inadvisable. Originally approved in 2017 for adults with atopic dermatitis, dupilumab is also indicated as an adjunct therapy for patients with moderate to severe asthma, presenting with an eosinophilic phenotype or are oral corticosteroid-dependent. Regeneron Pharmaceuticals Inc. and Sanofi S.A. are the co-manufactures of dupilumab.

Dupilumab is a human monoclonal IgG4 antibody that inhibits interleukin-4 (IL-4), and interleukin-13 (IL-13) cytokine induced responses, which includes preventing release of pro-inflammatory cytokines, chemokines, and IgE. In a post from Regeneron Pharmaceuticals, they noted that dupilumab is the "only therapy that targets the IL-4/IL-13 pathway, a key driver of the allergic or type 2 inflammation that underlies atopic dermatitis. In a Phase 3 trial, Dupixent® significantly reduced the extent and severity of disease and itching, and helped adolescents achieve clearer skin" (Regeneron Staff, 2019). Of note from the Phase 3 trial, the average improvement in the Eczema Area and Severity Index (EASI) from baseline was approximately 66% in the dupilumab group, compared with the placebo group which saw a 24% improvement at 16 weeks.

Dupilumab is available as a 200mg or 300mg pre-filled syringe. In the setting of asthma it is given initially as a loading dose of 400mg subcutaneously, followed by 200mg every other week; or 600mg as a loading dose, followed by 300mg every other week for those asthma patients who are oral corticosteroid dependent. For those with atopic dermatitis, the initial loading dose is 600mg subcutaneously, divided in 2 different injections sites (300mg each), which is followed by 300mg subcutaneously every other week. Dupilumab can be administered in an outpatient clinic or, with adequate training by a healthcare provider, administration by the patient or caregiver at home for convenience can take place. Future results of clinical trials in patients with chronic rhinosinusitis, pediatric patients (6 months to 5 years of age, and 6 to 11 years of age) with atopic dermatitis, pediatric patients (6 to 11 years of age) with asthma, eosinophilic esophagitis patients, patients with food and environmental allergies, and those with chronic obstructive pulmonary disease (COPD) are all forthcoming.

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