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Sanofi and Regeneron announce results for Dupixent (dupilumab)

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The results of the study was presented at the 26th European Academy of Dermatology and Venereology (EADV) Congress

Sanofi and Regeneron Pharmaceuticals, Inc. has announced positive results from the Phase 3 CAFÉ study of Dupixent (dupilumab) in adults with moderate-to-severe atopic dermatitis (AD) who are inadequately controlled with or intolerant to the broad immunosuppressant drug cyclosporine A (CSA), or when this treatment is medically inadvisable.

According to the study, Dupixent with topical corticosteroids (TCS) significantly improved measures of overall disease severity, skin clearing, itching, and patient reported quality of life measures.

Dupixent is a human monoclonal antibody that is designed to simultaneously inhibit overactive signalling of IL-4 and IL-13 cytokines.

Atopic dermatitis is a form of eczema, is a chronic inflammatory disease with symptoms often appearing as a rash on the skin.

The primary endpoint of the study was the proportion of patients that achieved a 75 percent or greater improvement in the Eczema Area and Severity Index (EASI-75) score at 16 weeks from baseline. EASI is a tool used to measure the extent and severity of the disease. Fifty-nine percent of patients who received Dupixent weekly with TCS, and 63 percent of patients who received Dupixent every two weeks with TCS achieved EASI-75, compared to 30 percent of those patients who received placebo with TCS (p less than 0.0001).

The mean percent change improvement in EASI from baseline at 16 weeks (a secondary endpoint) was 78 percent and 80 percent for patients who received Dupixent weekly or every two weeks with TCS, respectively, compared to 47 percent for those who received placebo plus TCS (p less than 0.0001).

Dr. Marjolein De Bruin-Weller, Dermatologist, National Expertise Center for Atopic Dermatitis, University Medical Center Utrecht said, “In moderate-to-severe atopic dermatitis, some patients stop cyclosporine therapy due to intolerance or lack of efficacy, or are not candidates because of other medical conditions or contraindicated medications. In the CAFÉ study, Dupixent with topical corticosteroids significantly improved overall measures of disease severity including lesions, itch, quality of life measures and symptoms of anxiety and depression in these patients. The safety profile in this study was consistent with three previous positive Dupixent Phase 3 studies in moderate-to-severe atopic dermatitis.”

No new adverse events were reported in the study. Conjunctivitis was more frequent in patients who received Dupixent with TCS, with 16 percent and 28 percent reported in patients who received Dupixent weekly or every two weeks with TCS, respectively, compared to 11 percent for patients who received placebo with TCS. Injection site reactions were reported in 11 percent and 4 percent among patients who received DUPIXENT with TCS weekly or every two weeks, respectively, compared to 5 percent for patients who received placebo with TCS. Skin infections were reported in 4 percent and 2 percent among patients who received Dupixent weekly or every two weeks with TCS, respectively, compared to 8 percent for patients who received placebo with TCS.

A total of 325 patients in Europe were randomized into three treatment groups in the 16-week study to receive either Dupixent 300 mg weekly with TCS, Dupixent 300 mg every two weeks with TCS or placebo with TCS.