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Regeneron, Sanofi's Dupixent gets FDA nod to treat teenâ??s atopic dermatitis

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In a Phase 3 trial, Dupixent significantly reduced the extent and severity of disease and itching, and helped adolescents achieve clearer skin



Regeneron Pharmaceuticals and Sanofi announced that the U.S. Food and Drug Administration (FDA) has approved Dupixent® (dupilumab) for adolescent patients 12 to 17 years of age with moderate-to-severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. Dupixent can be used with or without topical corticosteroids.

"For the first time, adolescents with uncontrolled moderate-to-severe atopic dermatitis have an approved biologic treatment option to help control persistent, often debilitating symptoms such as chronic itch and widespread rash. Today's approval expands the use of Dupixent in the U.S. to include both adults and adolescents with atopic dermatitis or moderate-to-severe asthma," said George D. Yancopoulos, M.D., Ph.D., President and Chief Scientific Officer at Regeneron.

"Given that Dupixent targets a key pathway in type 2 inflammation, we are also investigating it in a broad development program in patients with other type 2 inflammatory diseases including eosinophilic esophagitis, chronic rhinosinusitis with nasal polyps, where we recently announced positive Phase 3 results and Priority Review of a U.S. regulatory submission, and food and environmental allergies."

Dupixent is a targeted biologic therapy that inhibits signaling of interleukin-4 (IL-4) and interleukin-13 (IL-13), two key proteins that may play a central role in type 2 inflammation that underlies atopic dermatitis and several other allergic diseases.

The FDA evaluated the Dupixent application under Priority Review, which is reserved for medicines that represent potentially significant improvements in safety or efficacy in treating serious conditions. Dupixent was also granted Breakthrough Therapy designation by the FDA for inadequately controlled moderate-to-severe atopic dermatitis in adolescents. The Breakthrough Therapy designation was created to expedite the development and review of drugs developed for serious or life-threatening conditions.

Dupixent has been studied in more than 7,000 patients 12 years and older in over 30 clinical trials. The safety profile of Dupixent in the adolescent trial was similar to the safety profile from trials in adults with atopic dermatitis, and consistent through 52 weeks.