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Sanofi and Regeneron Pharmaceuticals, Inc has recently announced that the U.S. Food and Drug Administration (FDA) approved Dupixent (dupilumab) Injection, the first and only biologic medicine approved for the treatment of adults with moderate-to-severe atopic dermatitis (AD) whose disease is not adequately controlled with topical prescription therapies, or when those therapies are not advisable.

Julie Block, President and Chief Executive Officer, National Eczema Association said, "People with moderate-to-severe atopic dermatitis cope with intense, sometimes unbearable symptoms that can impact them for most of their lives. To date, there have been few options available to treat people with moderate-to-severe atopic dermatitis who have uncontrolled disease. That's why today's approval of Dupixent is so important for our community. Now we have a treatment that is expected to help address patients suffering from this devastating disease."

Dupixent is a human monoclonal antibody that is designed to specifically inhibit overactive signaling of two key proteins, IL-4 and IL-13, which are believed to be major drivers of the persistent underlying inflammation in AD. Dupixent comes in a pre-filled syringe and can be self-administered as a subcutaneous injection every other week after an initial loading dose.

Dupixent can also be used with or without topical corticosteroids. It should not be used in patients who are allergic to

dupilumab or any of the ingredients in Dupixent.

George D. Yancopoulos, M.D., Ph.D., Founding Scientist, President, and Chief Scientific Officer, Regeneron said, "Dupixent is the result of years of tireless research by our scientists into the underlying causes of allergic and atopic diseases. In atopic dermatitis, Dupixent was shown to help clear the skin and manage the intense itch caused by the disease."

Dupixent was evaluated by the FDA with Priority Review, which is reserved for medicines that represent potentially significant improvements in safety or efficacy in treating serious conditions. This followed the FDA's 2014 Breakthrough Therapy designation for Dupixent for inadequately controlled moderate-to-severe AD. Breakthrough Therapy designation was created by the FDA to expedite the development and review of drugs developed for serious or life-threatening conditions/ Dupixent represents the first time this designation was granted for a dermatological disease, other than in dermatologic cancers.

Olivier Brandicourt, M.D., Chief Executive Officer, Sanofi said, "We strive to transform scientific innovation into therapeutic solutions that make a meaningful difference to people's lives. The approval of Dupixent offers new hope for adults with moderate-to-severe AD in the United States, and we look forward to working with regulatory authorities around the world to bring this important new medicine to patients globally."

Sanofi Genzyme, the specialty care global business unit of Sanofi, and Regeneron will market Dupixent in the United States. Dupixent is expected to be available to patients and providers in the U.S. later this week.