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Pfizer gets Breakthrough Therapy designation from FDA to treat atopic dermatitis

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Pfizer receives Breakthrough Therapy designation from FDA for PF-04965842, an oral JAK1 Inhibitor to treat atopic dermatitis

Pfizer Inc. announced its once-daily oral Janus kinase 1 (JAK1) inhibitor PF-04965842 received Breakthrough Therapy designation from the U.S. Food and Drug Administration (FDA) for the treatment of patients with moderate-to-severe atopic dermatitis (AD).

The Phase 3 program for PF-04965842 initiated in December and is the first trial in the JAK1 Atopic Dermatitis Efficacy and Safety (JADE) global development program.

Breakthrough Therapy Designation was initiated as part of the Food and Drug Administration Safety and Innovation Act (FDASIA) signed in 2012.

PF-04965842 is an oral small molecule that selectively inhibits Janus kinase1.

Inhibition of JAK1 is thought to modulate multiple cytokines involved in pathophysiology of AD including interleukin (IL)-4, IL-13, IL-31 and interferon gamma.

Pfizer has established a leading kinase research capability with multiple unique kinase inhibitor therapies in development.

As a pioneer in JAK science, the Company is advancing several investigational programs with novel selectivity profiles.

Achieving Breakthrough Therapy Designation from FDA is an important milestone for Pfizer and patients living with the often devastating impact of moderate-to-severe atopic dermatitis, their providers and caregivers.