



# Pfizer Initiates Phase 3 Program for PF-04965842, a JAK1 Inhibitor in Development for Moderate-to-Severe Atopic Dermatitis

Thursday, December 14, 2017 - 02:30am

Global program to commence with pivotal study B7451012 in North America, Australia and Europe; broader regional rollout in 2018

Pfizer Inc. (NYSE:PFE) today announced the initiation of a Phase 3 program for its once-daily Janus kinase 1 (JAK1) inhibitor PF-04965842, to evaluate the efficacy and safety of PF-04965842 for the treatment of moderate-to-severe atopic dermatitis (AD). This is the first trial in the JAK1 Atopic Dermatitis Efficacy and safety (JADE) global development program.

“By initiating this Phase 3 program in atopic dermatitis, we hope to provide a new potential treatment option for people suffering with this condition,” said Michael Corbo, Chief Development Officer, Inflammation & Immunology, Pfizer Global Product Development. “Pfizer continues to build a leadership position in inflammation and immunology research with the advancement of this important, Pfizer-discovered investigational oral JAK1 inhibitor.”

## **About the Phase 3 Trial B7451012**

This Phase 3 trial is a randomized, double-blind, placebo-controlled, parallel-group study designed to evaluate the efficacy and safety of PF-04965842 in 375 patients 12 years and older with moderate-to-severe AD. Trial participants will be randomly assigned to receive 200 mg or 100 mg once daily or placebo.

The primary endpoints are the proportion of patients achieving an Investigator Global Assessment (IGA) score of 0/1 and  $\geq 2$  point improvement, and the proportion of patients with at least a 75% or greater change from baseline in their Eczema Area and Severity Index (EASI) score. Key secondary endpoints include the pruritus numerical rating scale, the Pruritus and Symptoms Assessment for Atopic Dermatitis (PSAAD) electronic diary and safety measures such as the incidence of treatment emergent adverse events and laboratory abnormalities. The treatment duration will be 12 weeks, the same duration as the Phase 2b study B7451006, with a 4 week safety follow-up period or the option to enter a long-term extension study (B7451015) at Week 12. More on the study can be found on [www.clinicaltrials.gov](http://www.clinicaltrials.gov) under the identifier NCT03349060.

The design of the Phase 3 trial is based on the Phase 2 results that were presented at the 26th Congress of the European Academy of Dermatology and Venereology in September 2017.

### **About Atopic Dermatitis**

Atopic dermatitis, also commonly called atopic eczema, is inflammation of the skin and characterized by erythema (redness), itching (pruritus), induration (hardening)/papulation (formation of papules), and oozing/crusting.

### **About Pfizer's Kinase Inhibitor Leadership**

PF-04965842 is an oral small molecule that selectively inhibits Janus kinase 1 (JAK1). Inhibition of JAK1 modulates multiple cytokines involved in pathophysiology of AD including interleukin (IL)-4, IL-13, IL-31 and interferon gamma (IFN $\gamma$ ).

“We look forward to advancing other kinase inhibitors currently in mid-stage research for other diseases such as alopecia, psoriasis, inflammatory bowel disease, and rheumatoid arthritis,” said Michael Vincent, M.D, Ph.D., Senior Vice President and Chief Scientific Officer of Inflammation and Immunology Research at Pfizer.

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, which, if successful, could potentially deliver transformative therapies for patients. Pfizer has three additional kinase inhibitors in Phase 2 development across multiple indications:

PF-06651600: A JAK3 inhibitor under investigation for the treatment of rheumatoid arthritis, ulcerative colitis and alopecia areata  
PF-06700841: A tyrosine kinase 2 (TYK2)/JAK1 inhibitor under investigation for the treatment of psoriasis, ulcerative colitis

and alopecia areata PF-06650833: An interleukin-1 receptor-associated kinase 4 (IRAK4) inhibitor under investigation for the treatment of rheumatoid arthritis

## **Working together for a healthier world®**

At Pfizer, we apply science and our global resources to bring therapies to people that extend and significantly improve their lives. We strive to set the standard for quality, safety and value in the discovery, development and manufacture of health care products. Our global portfolio includes medicines and vaccines as well as many of the world's best-known consumer health care products. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments and cures that challenge the most feared diseases of our time. Consistent with our responsibility as one of the world's premier innovative biopharmaceutical companies, we collaborate with health care providers, governments and local communities to support and expand access to reliable, affordable health care around the world. For more than 150 years, we have worked to make a difference for all who rely on us. We routinely post information that may be important to investors on our website at [www.pfizer.com](http://www.pfizer.com). In addition, to learn more, please visit us on [www.pfizer.com](http://www.pfizer.com) and follow us on Twitter at @Pfizer and @Pfizer\_News, LinkedIn, YouTube and like us on Facebook at [Facebook.com/Pfizer](https://www.facebook.com/Pfizer).

**DISCLOSURE NOTICE:** The information contained in this release is as of December 12, 2017. Pfizer assumes no obligation to update forward-looking statements contained in this release as the result of new information or future events or developments.

This release contains forward-looking information about PF-04965842 and Pfizer's ongoing investigational programs in kinase inhibitor therapies, including their potential benefits, that involves substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Risks and uncertainties include, among other things, the uncertainties inherent in research and development, including the ability to meet anticipated clinical trial commencement and completion dates and regulatory submission dates, as well as the possibility of unfavorable clinical trial results, including unfavorable new clinical data and additional analyses of existing data; risks associated with preliminary data; the risk that clinical trial data are subject to differing interpretations, and, even when we view data as sufficient to support the safety and/or effectiveness of a product candidate, regulatory authorities may not share our views and may require additional data or may deny approval altogether; whether regulatory authorities will be satisfied with the design of and results from our clinical studies; whether and when drug applications may be filed in any jurisdictions for any potential indication for PF-04965842 or any other investigational

kinase inhibitor therapies; whether and when any such applications may be approved by regulatory authorities, which will depend on the assessment by such regulatory authorities of the benefit-risk profile suggested by the totality of the efficacy and safety information submitted, and, if approved, whether PF-04965842 or any such other investigational kinase inhibitor therapies will be commercially successful; decisions by regulatory authorities regarding labeling, safety and other matters that could affect the availability or commercial potential of PF-04965842 or any other investigational kinase inhibitor therapies; and competitive developments.

A further description of risks and uncertainties can be found in Pfizer's Annual Report on Form 10-K for the fiscal year ended December 31, 2016 and in its subsequent reports on Form 10-Q, including in the sections thereof captioned "Risk Factors" and "Forward-Looking Information and Factors That May Affect Future Results", as well as in its subsequent reports on Form 8-K, all of which are filed with the U.S. Securities and Exchange Commission and available at [www.sec.gov](http://www.sec.gov) and [www.pfizer.com](http://www.pfizer.com).

Media: Neha Wadhwa, 212-733-2835 [Neha.Wadhwa@pfizer.com](mailto:Neha.Wadhwa@pfizer.com) or Investors: Ryan Crowe, 212-733-8160 [Ryan.crowe@pfizer.com](mailto:Ryan.crowe@pfizer.com)