Pfizer Logo

Pfizer Receives Breakthrough Therapy Designation from FDA for PF-04965842, an oral JAK1 Inhibitor, for the Treatment of Patients with Moderate-to-Severe Atopic Dermatitis

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Pfizer Inc. (NYSE:PFE) today 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.

“Achieving Breakthrough Therapy Designation is an important milestone not only for Pfizer but also for patients living with the often devastating impact of moderate-to-severe atopic dermatitis, their providers and caregivers,” said Michael Corbo, Chief Development Officer, Inflammation & Immunology, Pfizer Global Product Development. “We look forward to working closely with the FDA throughout our ongoing Phase 3 development program with the hope of ultimately bringing this important new treatment option to these patients.”

Breakthrough Therapy Designation was initiated as part of the Food and Drug Administration Safety and Innovation Act (FDASIA) signed in 2012. As defined by the FDA, a breakthrough therapy is a drug intended to be used alone or in combination with one or more other drugs to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. If a drug is designated as a breakthrough therapy, the FDA will expedite the development and review of such drug.[1]

About PF-04965842 and Pfizer’s Kinase Inhibitor Leadership

PF-04965842 is an oral small molecule that selectively inhibits Janus kinase (JAK) 1. 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, 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. In addition, to learn more, please visit us on www.pfizer.com and follow us on Twitter at @Pfizer and @Pfizer_News, LinkedIn, YouTube and like us on Facebook at Facebook.com/Pfizer.

DISCLOSURE NOTICE: The information contained in this release is as of February 14, 2018. 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 and www.pfizer.com.

1 Food and Drug Administration Fact Sheet Breakthrough Therapies at https://www.fda.gov/RegulatoryInformation/LawsEnforcedbyFDA/SignificantA... accessed on January 25, 2018

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