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Pfizer Announces Positive Top-Line Results from Phase 3 Study of Investigational Oral JAK1 Candidate, Abrocitinib (PF-04965842), in Patients Aged 12 and Older with Moderate to Severe Atopic Dermatitis

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Study achieves all co-primary and secondary endpoints

Pfizer Inc. (NYSE: PFE) announced today positive top-line results from a Phase 3 pivotal study (B7451012) evaluating the efficacy and safety of its investigational oral Janus kinase 1 (JAK1) inhibitor, abrocitinib (PF-04965842), in patients aged 12 and older with moderate to severe atopic dermatitis (AD).

B7451012 was a randomized, double-blind, placebo-controlled, parallel-group study designed to evaluate the efficacy and safety of two doses (100mg and 200mg once daily) of abrocitinib monotherapy over 12 weeks. Top-line results showed that by week 12 the percentage of patients achieving each co-primary efficacy endpoint and each key secondary endpoint with either dose of abrocitinib was statistically significantly higher than placebo. In addition, the results demonstrate response to treatment for a statistically significant number of patients during the first two to four weeks following first dose.

“Moderate to severe atopic dermatitis is a chronic, inflammatory skin disease that can take both a physical and emotional toll on the millions of patients living with the condition worldwide,” said Michael Corbo, PhD, Chief Development Officer, Inflammation & Immunology, Pfizer Global Product Development. “These top-line findings are encouraging and provide evidence that abrocitinib, if approved, could be an effective new oral once-daily treatment option for patients.”

The co-primary study endpoints were the proportion of patients who achieved an Investigator Global Assessment (IGA) score of clear (0) or almost clear (1) skin and ?2 point improvement; and the proportion of patients who achieved at least a 75% or greater change from baseline in their Eczema Area and Severity Index (EASI) score. The key secondary endpoints were the proportion of patients achieving a 4 point or larger reduction in itch severity measured with the pruritus numerical rating scale (NRS) and the magnitude of decrease in the Pruritus and Symptoms Assessment for Atopic Dermatitis (PSAAD).

Safety results show that both doses of abrocitinib were well-tolerated, and there were no unexpected safety events. The discontinuation rates due to an adverse event were low in each treatment arm (5.8% and 5.8% in 100mg and 200mg) compared to placebo (9.1%).

Additional Details About the Study

A total of 387 subjects were randomized to abrocitinib 200mg, abrocitinib 100mg, and placebo in the trial. Randomization was stratified by baseline disease severity (moderate [IGA=3] and severe [IGA=4] AD) and age (age <18 and ?18 years). Eligible subjects completing the 12-week treatment period of the study had the option to enter a long-term extension (LTE), study B7451015. Subjects discontinuing early from treatment, or who were otherwise ineligible for the LTE study, entered a 4-week follow up period in this study.

Detailed analyses of B7451012, including additional efficacy and safety data, will be submitted for presentation at a future scientific meeting and published in a prominent medical journal. B7451012 is the first trial in the JAK1 Atopic Dermatitis Efficacy and Safety (JADE) global development program. Additional data from another study in the JADE program will be available later this year.

For additional information about B7451012, please visit https://www.clinicaltrials.gov.

About Abrocitinib (PF-04965842)

Abrocitinib (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.

Abrocitinib received Breakthrough Therapy designation from the U.S. Food and Drug Administration (FDA) for the treatment of patients with moderate to severe AD in February 2018. 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 Atopic Dermatitis

AD is a chronic skin disease characterized by inflammation of the skin and skin barrier defects.[2,3] Lesions of AD are characterized by erythema (redness), itching, induration (hardening)/papulation (formulation of papules), and oozing/crusting.[2,3]

AD is one of the most common, chronic, relapsing childhood dermatoses, affecting 1% to 3% of adults and 15% to 20% of children worldwide.[4] Approximately 50% of pediatric AD patients globally have recurrent symptoms into adolescence and adulthood.[5,6]

About Pfizer's Kinase Inhibitor Leadership

The JAK pathways are believed to play an important role in inflammatory processes as they are involved in signaling for over 50 cytokines and growth factors, many of which drive immune-mediated conditions.[7] JAK inhibition may offer patients with these conditions a potential new advanced treatment option.[8]

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 continuing to advance several investigational programs for molecules with novel selectivity profiles, which, if approved, could potentially deliver transformative therapies for patients. In addition to abrocitinib, Pfizer has several kinase inhibitors in clinical trials across multiple indications, including:

- PF-06700841: A tyrosine kinase 2(TYK2)/JAK1 inhibitor under investigation for the treatment of psoriasis, Crohn's disease, ulcerative colitis, vitiligo, and alopecia areata
- PF-06650833: An IL-1 receptor associated kinase 4 (IRAK4) inhibitor under investigation for the treatment of rheumatoid arthritis
- PF-06826647: A TYK2 inhibitor under investigation for the treatment of inflammatory bowel disease (IBD)
- PF-06651600: An oral, JAK3 inhibitor under investigation for the treatment of alopecia areata, vitiligo, rheumatoid arthritis, Crohn's disease, and ulcerative colitis

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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 May 15, 2019. 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 a product candidate, abrocitinib (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 endpoints, commencement and/or completion dates for our clinical trials, regulatory submission dates, regulatory approval dates and/or launch dates, as well as the possibility of unfavorable new clinical data and further analyses of existing clinical data; the risk that clinical trial data are subject to differing interpretations and assessments by regulatory authorities; 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 abrocitinib or any other investigational kinase inhibitor therapies; whether and when any such applications may be approved by regulatory authorities, which will depend on myriad factors, including making a determination as to whether the product's benefits outweigh its known risks and determination of the product's efficacy and, if approved, whether abrocitinib or any such other investigational kinase inhibitor therapies will be commercially successful; decisions by regulatory authorities impacting labeling, manufacturing processes, safety and/or other matters that could affect the availability or commercial potential of abrocitinib 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, 2018 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.

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