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Positive Top-Line Results From Pfizer's Phase 3 JADE DARE Trial Comparing the Efficacy of Abrocitinib and Dupilumab for Moderate to Severe Atopic Dermatitis

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-JADE DARE trial met co-primary and key secondary endpoints and demonstrated a safety profile consistent with previous studies-

NEW YORK--(BUSINESS WIRE)-- Pfizer Inc. (NYSE: PFE) today announced that JADE DARE (B7451050), a 26-week, randomized, double-blind, double-dummy, active-controlled, multi-center Phase 3 study, met its co-primary and key secondary efficacy endpoints. The study showed that abrocitinib was statistically superior compared to dupilumab in each evaluated efficacy measure and had a safety profile consistent with previous studies. The head-to-head study was designed to directly compare the efficacy of abrocitinib 200mg versus dupilumab 300mg, in adult participants on background topical therapy with moderate to severe atopic dermatitis (AD). Abrocitinib 200mg was administered by once-daily oral tablet and dupilumab was administered by subcutaneous injection every other week following a 600mg induction dose.

"The results from our first formal head-to-head trial for abrocitinib illustrate its potential for meaningful symptom relief for patients and further build upon the substantial body of data from the JADE development program," said Michael Corbo, PhD, Chief Development Officer, Inflammation & Immunology, Pfizer Global Product Development. "We're pleased that the study findings show the potential impact abrocitinib could have to help people living with moderate to severe atopic dermatitis in reducing their itch significantly and in achieving near complete skin clearance."

The co-primary efficacy endpoints in JADE DARE were the proportion of patients achieving at least a 4-point improvement in the severity of Peak Pruritus Numerical Rating Scale (PP-NRS4) from baseline at Week 2 and the proportion of patients achieving Eczema Area and Severity Index (EASI)-90 (?90% improvement from baseline) at Week 4. The key secondary endpoint was the proportion of patients achieving EASI-90 at Week 16. The study will allow assessment of any difference in efficacy that may persist at month 6 of treatment.

A larger percentage of patients treated with abrocitinib 200mg experienced adverse events compared to dupilumab 300mg. The proportion of patients experiencing serious adverse events, severe adverse events, and adverse events leading to study discontinuation were similar in both treatment arms. Two deaths occurred in patients treated with abrocitinib 200mg, which were characterized by the investigator as unrelated to the study drug. One death was attributed to COVID-19 and the second was attributed to intracranial hemorrhage and cardiorespiratory arrest, and classified as a major adverse cardiovascular event (MACE). There were no cases of malignancies or venous thromboembolism (VTE) events confirmed through adjudication. The safety profile seen with abrocitinib was consistent with previous studies in the JADE program.

The study is part of the JAK1 Atopic Dermatitis Efficacy and Safety (JADE) global development program for abrocitinib. Full results from JADE DARE will be submitted for presentation at a future scientific meeting and publication in a medical journal. Additionally, at the appropriate time, Pfizer intends to share these data with the U.S. Food and Drug Administration (FDA) and other regulatory agencies around the world reviewing submissions for abrocitinib.

About Abrocitinib

Abrocitinib 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 atopic dermatitis, including interleukin IL-4, IL-13, IL-31, IL-22, and thymic stromal lymphopoietin (TSLP).

About Atopic Dermatitis

AD is a chronic skin disease characterized by inflammation of the skin and skin barrier defects.[i,ii] Lesions of AD are characterized by erythema (skin turning red or purple depending on normal skin color), itching, induration (hardening)/papulation (formulation of papules), and oozing/crusting.[ii,iii]

AD is one of the most common, chronic, relapsing childhood dermatoses, affecting up to 10% of adults and up to 20% of children worldwide.[iii,iv]

About Pfizer: Breakthroughs That Change Patients' Lives

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, including innovative medicines and vaccines. 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 170 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 August 30, 2021. 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, including its 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 other jurisdictions for any potential

indication for abrocitinib; whether and when the applications for abrocitinib pending with the U.S. Food and Drug Administration and European Medicines Agency may be approved and whether and when any such other applications that may be pending or filed 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 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; uncertainties regarding the commercial or other impact of the results of Janus kinase (JAK) inhibitor studies and data and actions by regulatory authorities based on analysis of such studies and data, which will depend, in part, on benefit-risk assessments and labeling determinations; uncertainties regarding the impact of COVID-19 on our business, operations, and financial results; 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, 2020 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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[iii] Oszukowska M, Michalak I, Gutfreund K, et al. Role of primary and secondary prevention in atopic dermatitis. *Postep Derm Alergol*. 2015:32(6):409-420.
[iv] Nutten S. Atopic dermatitis: global epidemiology and risk factors. *Ann Nutr Metab*. 2015;66(suppl 1):8-16.

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