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# FDA Grants Priority Review and EMA Accepts Regulatory Submission for Pfizer's Abrocitinib, an Oral Once-Daily JAK1 Inhibitor, for Patients 12 and Up with Moderate to Severe Atopic Dermatitis

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**-Filings based on robust abrocitinib clinical trial data demonstrating significant symptom improvement versus placebo as well as a consistent safety profile-**

NEW YORK--(BUSINESS WIRE)-- Pfizer Inc. (NYSE: PFE) announced today that the U.S. Food and Drug Administration (FDA) accepted for filing and granted Priority Review designation to the company's New Drug Application (NDA) for abrocitinib (100mg and 200mg), an investigational oral once-daily Janus kinase 1 (JAK1) inhibitor, for the treatment of moderate to severe atopic dermatitis (AD) in patients 12 and older. The FDA is expected to make a decision in April 2021. The European Medicines Agency (EMA) has also accepted the Marketing Authorization Application (MAA) for abrocitinib in the same patient population with a decision anticipated in the second half of 2021.

"Atopic dermatitis is a serious, unpredictable, and often debilitating condition that can have a significant impact on the daily lives of patients and their families," said Michael Corbo, PhD, Chief Development Officer, Inflammation & Immunology, Pfizer Global Product Development. "We are grateful to those who participated in our clinical studies supporting these regulatory filings and proud that the FDA has granted abrocitinib both Breakthrough Therapy and Priority Review designations. We are working diligently with the regulatory authorities to bring abrocitinib to patients in the U.S. and the EU, where, if approved, it may provide an effective and convenient new option."

The filings were based on the results of a robust Phase 3 clinical trial program, across which abrocitinib demonstrated statistically superior improvements in skin clearance, disease extent, and severity, as well as rapid improvements (measured as early as Week 2) in itch versus placebo. Abrocitinib also demonstrated a consistent safety profile across trials and was generally well-tolerated. Findings from the following studies in the abrocitinib JAK1 Atopic Dermatitis Efficacy and Safety (JADE) global development program were included in the submissions:

- JADE MONO-1 and JADE MONO-2: A pair of studies designed to evaluate the efficacy and safety of two doses (100mg and 200mg once daily) of abrocitinib monotherapy compared to placebo.
- JADE COMPARE: Designed to evaluate the efficacy and safety of two doses (100mg and 200mg once daily) of abrocitinib compared to placebo in patients on background topical therapy. The study also included an active control arm, dupilumab, a biologic treatment administered by subcutaneous injection,

compared with placebo.

“Many patients with moderate to severe atopic dermatitis have poorly controlled disease. They need additional treatment options that alleviate the symptoms most important to them,” said Jonathan Silverberg, MD, PhD, MPH, Department of Dermatology, The George Washington University School of Medicine and Health Sciences. “Abrocitinib has demonstrated strong efficacy at relieving the signs and symptoms of atopic dermatitis, including rapid reduction of itch, across multiple clinical trials. If abrocitinib is approved, it could make a meaningful difference in real-world clinical practice.”

Priority Review designation is granted to medicines that the FDA considers to have the potential to provide significant improvements in the safety and effectiveness of the treatment, prevention or diagnosis of a serious condition. Abrocitinib received Breakthrough Therapy designation from the FDA for the treatment of patients with moderate to severe AD in February 2018. Abrocitinib also received a Promising Innovative Medicine (PIM) designation from the UK’s Medicines and Healthcare Products Regulatory Agency (MHRA) earlier this year, which indicates that a product may be eligible for the early access to medicines scheme (EAMS) based on early clinical data. EAMS aims to give patients with life threatening or seriously debilitating conditions access to medicines that do not yet have a marketing authorization when there is a clear unmet medical need.

Pfizer recently announced results from the fourth trial in the JADE global development program, JADE TEEN. Additional data from other studies in the JADE program will be presented and published in the coming months.

**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.[1,2] 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.[2,3]

AD is one of the most common, chronic, relapsing childhood dermatoses, affecting up to 10% of adults and up to 20% of children worldwide.[3,4]

**About Pfizer’s Immunokinase 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.[5] JAK inhibition may offer patients with these conditions a potential new advanced treatment option.[6]

Pfizer’s leading JAK biology and chemistry expertise, combined with our research experience, has uniquely enabled the company to take a different R&D approach to that of other companies involved in JAK research, resulting in one of the broadest immunokinase inhibitor pipelines. Instead of studying a single molecule for all its potential uses, where it may not be optimal for some, Pfizer’s candidates with unique selectivity profiles are purposefully matched to the conditions where we believe they have the greatest potential to, if approved, address unmet need. Pfizer has five unique immunokinase inhibitors in late-stage clinical trials for the potential treatment of ten immune-mediated diseases:

- Abrocitinib: A JAK1 inhibitor currently under regulatory review by the FDA and EMA for the potential treatment of moderate-to-severe AD among adolescents and adults
- Ritlecitinib (PF-06651600): An oral, JAK3/TEC family kinase inhibitor in a phase 3 clinical trial for the potential treatment of alopecia areata (AA) and in phase 2 for vitiligo, Crohn's disease (CD), and ulcerative colitis (UC)
- Brepocitinib (PF-06700841): A tyrosine kinase 2(TYK2)/JAK1 inhibitor in phase 2 clinical trials for the potential treatment of psoriasis and AD in topical formulation, and, in oral formulation for psoriatic arthritis, CD, UC, vitiligo, systemic lupus erythematosus (SLE), AA and hidradenitis suppurativa (HS)
- PF-06826647: A TYK2 inhibitor under investigation in phase 2 clinical trials for the potential treatment of psoriasis and HS
- PF-06650833: An IL-1 receptor associated kinase 4 (IRAK4) inhibitor under investigation for the potential treatment of rheumatoid arthritis and HS in phase 2 clinical trials

**Pfizer Inc.: 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 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 October 27, 2020. 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, regulatory filings with the FDA and EMA for abrocitinib, 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 other jurisdictions for any potential indication for abrocitinib or in any jurisdictions for any other investigational kinase inhibitor therapies; whether and when the applications for abrocitinib pending with the FDA and EMA may be approved and whether and when any such other 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;*

*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, 2019 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] Hanifin JM, Reed ML. A population-based survey of eczema in the United States. Dermatitis. 2007;18(2):82-91.
[2] Bieber T. Atopic dermatitis. Dermatology. 2012;1(3):203-217.
[3] 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.
[4] Nutten S. Atopic dermatitis: global epidemiology and risk factors. Ann Nutr Metab. 2015;66(suppl 1):8-16.
[5] Banerjee, S., Biehl, A., Gadina, M. et al. JAK–STAT Signaling as a Target for Inflammatory and Autoimmune Diseases: Current and Future Prospects. *Drugs.* 2017;77: 521. https://doi.org/10.1007/s40265-017-0701-9.
[6] Telliez JB, Dowty ME, Wang L, Jussif J, Lin T, Li L, et al. Discovery of a JAK3-selective inhibitor: functional differentiation of JAK3-selective inhibition over pan-JAK or JAK1-selective inhibition. ACS Chem Biol. 2016;11(12):3442–51. doi:10.1021/acschembio.6b00677.

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