Pfizer Logo

Pfizer Presents Positive Phase 3 Data at the 28th Congress of the European Academy of Dermatology and Venereology for Abrocitinib in Moderate to Severe Atopic Dermatitis

Saturday, October 12, 2019 - 12:45am

–Abrocitinib met all co-primary and secondary endpoints in JADE MONO-1 study– –Findings follow recent positive top-line results for second abrocitinib Phase 3 pivotal study, JADE MONO-2–

Pfizer Inc. (NYSE: PFE) announced today complete results from a Phase 3, 12-week, pivotal study (JADE MONO-1) in patients aged 12 and older with moderate to severe atopic dermatitis (AD). Abrocitinib, an investigational oral Janus kinase 1 (JAK1) inhibitor, met all the co-primary and key secondary endpoints, which were related to skin clearance and itch relief compared to placebo. Safety data showed that both evaluated doses of abrocitinib (200mg and 100mg) were well tolerated and were consistent with a companion study (JADE MONO-2) from the JAK1 Atopic Dermatitis Efficacy and Safety (JADE) global development program. The results were shared as a Late-Breaking presentation at the 28th Congress of the European Academy of Dermatology and Venereology (EADV) taking place October 9-13, 2019 in Madrid, Spain.

The co-primary study endpoints in JADE MONO-1 were the proportion of patients who achieved an Investigator Global Assessment (IGA) score of clear (0) or almost clear (1) skin and two-point or greater improvement relative to baseline; 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 four-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), a patient-reported measurement scale developed by Pfizer. Other secondary endpoints included the proportion of patients who achieved a 90% or greater change in EASI score, and the percentage change from baseline in their SCORing Atopic Dermatitis (SCORAD) response at all scheduled time points.

“There is a critical need for additional treatment options for patients living with moderate to severe atopic dermatitis,” said Michael Corbo, PhD, Chief Development Officer, Inflammation & Immunology, Pfizer Global Product Development. “We are pleased by these findings, which together with the recently reported positive top-line results from our second Phase 3 trial, encourage us that, if approved, abrocitinib may provide the first oral, once-daily treatment option for these patients.”

JADE MONO-1 Study Efficacy Results[1]

Both doses of abrocitinib significantly improved the IGA and EASI-75 dose response outcomes compared to placebo. By week 12, the following co-primary efficacy and secondary endpoint results were seen:

	Abrocitinib 200mg (N=154)	Abrocitinib 100mg (N=156)	Placebo (N=77)
IGA Response Rate	43.8%	23.7%	7.9%
EASI-75 Response Rate	62.7%	39.7%	11.8%
NRS ?4-Point Improvement Response Rate	57.2%	37.7%	15.3%
EASI-90 Response Rate	38.6%	18.6%	5.3%

The percentage changes in SCORAD were significantly greater at all time points in the 200mg and 100mg treatment arms compared to placebo.

JADE MONO-1 Safety Results[1]

The most frequently reported treatment-emergent adverse events in abrocitinib-treated patients (200mg, 100mg) were short-lasting nausea (20.1%, 9.0%), headache (9.7%, 7.7%), and nasopharyngitis (11.7%, 14.7%), while for placebo, it was dermatitis (16.9%). Observed serious adverse events (SAEs) for abrocitinib 200mg were inflammatory bowel disease, peritonsillitis, dehydration, and asthma (2 cases). SAEs seen for the 100mg dose included retinal detachment, acute pancreatitis, appendicitis, dizziness, and seizures. In the placebo arm, SAEs were condition aggravated, appendicitis, meniscal degeneration, and atopic dermatitis. Other safety findings included:

	Abrocitinib 200mg (N=154)	Abrocitinib 100mg (N=156)	Placebo (N=77)
Rate of Serious Adverse Events	3.2%	3.2%	1.9%
Rate of Discontinuation due to an Adverse Event	5.8%	5.8%	9.1%

Additional Details About the JADE MONO-1 Study

The double-blind, parallel group study randomized a total of 387 subjects to abrocitinib 200mg, abrocitinib 100mg, or placebo. 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.

For additional information about the JADE MONO-1 study, please visit https://www.clinicaltrials.gov.

Pfizer recently announced positive top-line results from the companion Phase 3 study from the JADE program (JADE MONO-2), suggesting similar positive safety and efficacy results. Additional data for abrocitinib and new findings from the JADE program will be shared in early 2020.

Phase 2b data for abrocitinib were recently published in *JAMA Dermatology*.

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 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.[2]

About Atopic Dermatitis

AD is a chronic skin disease characterized by inflammation of the skin and skin barrier defects.[3,4] Lesions of AD are characterized by erythema (redness), itching, induration (hardening)/papulation (formulation of papules), and oozing/crusting.[3,4]

AD is one of the most common, chronic, relapsing childhood dermatoses, affecting up to 10% of adults and up to 20% of children worldwide.[5,6]

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.[7] JAK inhibition may offer patients with these conditions a potential new advanced treatment option.[8]

Pfizer's leading JAK biology and chemistry expertise from years of JAK research experience, has enabled the company to take a different R&D approach, resulting in the broadest immunokinase inhibitor pipeline. Instead of studying a single molecule for all its potential uses, where it may not be optimal for some, Pfizer's candidates 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 nine immune-mediated diseases:

- Abrocitinib: A JAK inhibitor in Phase 3 clinical trials for the treatment of moderate-to-severe AD among adolescents and adults
- PF-06651600: An oral, JAK3/TEC family kinase inhibitor in Phase 3 clinical trial for the treatment of alopecia areata (AA) and in Phase 2 for vitiligo, Crohn's disease (CD), and ulcerative colitis (UC)
- PF-06700841: A tyrosine kinase 2(TYK2)/JAK1 inhibitor in Phase 2 clinical trials for the treatment of psoriasis and AD in topical formulation, and, in oral formulation for psoriatic arthritis, CD, UC, vitiligo, systemic lupus erythematosus (SLE), and AA

- PF-06826647: A TYK2 inhibitor under investigation in Phase 2 clinical trials for the treatment of psoriasis
- PF-06650833: An IL-1 receptor associated kinase 4 (IRAK4) inhibitor under investigation for the treatment of rheumatoid arthritis in Phase 2 clinical trial

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 12, 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, 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.

---

[1] Simpson E, Sinclair R, Forman S *et al*. Efficacy and Safety of Abrocitinib in Patients With Moderate-to-Severe Atopic Dermatitis: Results From the Phase 3, JADE MONO-1 Study. Oral presentation at the 28th Congress of

the European Academy of Dermatology and Venereology (EADV), October 9-13, 2019, Madrid, Spain
[2] U.S. Food and Drug Administration. Fact Sheet: Breakthrough Therapies at https://www.fda.gov/RegulatoryInformation/LawsEnforcedbyFDA/SignificantA... (link is external) accessed on August 16, 2019.
[3] Hanifin JM, Reed ML. A population-based survey of eczema in the United States. Dermatitis. 2007;18(2):82-91.
[4] Bieber T. Atopic dermatitis. Dermatology. 2012;1(3):203-217.
[5] 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.
[6] Nutten S. Atopic dermatitis: global epidemiology and risk factors. Ann Nutr Metab. 2015;66(suppl 1):8-16.
[7] 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.
[8] 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.

Media Contact: Steve Danehy 212-733-1538 Steven.Danehy@pfizer.com Investor Contact: Bryan Dunn 212-733-8917 Bryan.Dunn@pfizer.com