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FDA Approves Pfizer's Supplemental New Drug Application for CIBINQO® (abrocitinib)

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Label expansion for CIBINQO provides new systemic oral option for adolescents (12 to <18 years) with moderate-to-severe atopic dermatitis

NEW YORK--(BUSINESS WIRE)-- Pfizer Inc. (NYSE: PFE) announced today that the United States (U.S.) Food and Drug Administration (FDA) approved its supplemental New Drug Application (sNDA) for CIBINQO ® (abrocitinib), expanding its indication to include adolescents (12 to <18 years) with refractory, moderate-to-severe atopic dermatitis (AD) whose disease is not adequately controlled with other systemic drug products, including biologics, or when use of those therapies is inadvisable. CIBINQO was previously approved only for the treatment of adults 18 years and older.

“This is a meaningful advancement for the many adolescents across the U.S. who are affected by the persistent itching and discomfort that accompanies uncontrolled moderate-to-severe atopic dermatitis,” said Lawrence Eichenfield, MD, Chief of Pediatric and Adolescent Dermatology at Rady Children’s Hospital in San Diego. “The extended indication of CIBINQO offers potential relief for young atopic dermatitis patients in need and their families.”

The CIBINQO prescribing information was updated to include data from JADE TEEN, a Phase 3, randomized, placebo-controlled clinical trial. JADE TEEN, which supported the expanded indication, evaluated both the 100 mg and 200 mg doses of CIBINQO versus placebo in adolescents 12 to <18 years of age with moderate-to-severe AD while also on background therapy with topical medications. The trial evaluated measures of improvements in skin clearance, itch, disease extent, and severity, including the Investigator Global Assessment (IGA), Peak Pruritus Numerical Rating Scale (PP-NRS), and Eczema Area and Severity Index (EASI).

“Moderate-to-severe atopic dermatitis can have debilitating physical and emotional impacts on adolescents,” said Angela Hwang, Chief Commercial Officer, President, Global Biopharmaceuticals Business, Pfizer. “As an efficacious once-daily pill, we believe that CIBINQO offers an important new treatment option for adolescents burdened by uncontrolled symptoms of atopic dermatitis. Encouraged by an increasing uptake in the adult population, we look forward to bringing this important new oral medicine to adolescents who have yet to find relief from this inflammatory skin condition with current options.”

Data from the robust clinical trial program included in the prescribing information now stems from five randomized, placebo-controlled clinical trials and a long-term extension study with more than 1,600 patients treated with CIBINQO. Across the trials to date, CIBINQO demonstrated a consistent safety profile and profound improvements in skin clearance, extent of disease, and severity as well as rapid improvement in itch after two weeks, for some people living with AD versus placebo, including adolescents.

Across trials, the most common adverse events reported in ?1% of patients treated with CIBINQO for up to 16 weeks included nasopharyngitis (12.4% with CIBINQO 100 mg, 8.7% with CIBINQO 200 mg, and 7.9% with placebo), nausea (6%, 14.5%, and 2.1%, respectively), and headache (6%, 7.8%, and 3.5%, respectively).

Additional Details on the JADE TEEN Clinical Trial

- JADE TEEN: A randomized, double-blind, placebo-controlled, parallel group study. A total of 285 individuals 12 to <18 years of age with moderate-to-severe atopic dermatitis were randomized to receive once-daily abrocitinib 200 mg, abrocitinib 100 mg, or placebo for 12 weeks while also on background topical therapy. Eligible subjects completing the 12-week treatment period of the study had the option to enter a long-term extension (LTE) study, B7451015. The trial assessed the co-primary endpoints of IGA 0 or 1 and EASI-75 responses at Week 12.
  Select findings from JADE TEEN are as follows:
  - IGA 0 or 1 Response Rate (Week 12): 39% with CIBINQO 100 mg, 46% with CIBINQO 200 mg, and 24% with placebo
  - EASI-75 Response Rate (Week 12): 64%, 71%, and 41%, respectively
  - Proportion of participants achieving PP-NRS at least a 4-point decrease from baseline (Week 2): 13%, 25%, and 8%, respectively
  - Safety profile seen in JADE TEEN was consistent with the pivotal trials and findings for the adult population

About CIBINQO ® (abrocitinib)
CIBINQO is an oral inhibitor of 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, IL-22, and thymic stromal lymphopoietin (TSLP).

To date, CIBINQO has received marketing authorization in the U.S., the European Union, Great Britain, and other countries, and has launched in Germany, Japan, China, and ?20 other markets worldwide.

About Atopic Dermatitis
AD is a chronic skin disease characterized by inflammation of the skin and skin barrier defects.[1,2] Most people know AD is a skin condition, but many don't realize it can be caused in part by an abnormal immune response beneath the skin. This dysregulated immune response is thought to contribute to inflammation within the skin and the signs of AD on the surface. Lesions of AD are characterized by erythema (red/pink or discolored skin patches, depending on normal skin color), itching, lichenification (thick/leathery skin), induration (hardening)/papulation (formulation of papules), and oozing/crusting.[1,2]

AD is one of the most common inflammatory skin diseases, affecting approximately 5-10% of adults in the U.S. and approximately 11% of children in the U.S.[1,2,3,4,5] Approximately 1 in 3 adults and 1 in 3 children and adolescents, 17 and under, with AD have moderate-to-severe disease.[6,7]

U.S. IMPORTANT SAFETY INFORMATION

WARNING: SERIOUS INFECTIONS, MORTALITY, MALIGNANCY, MAJOR ADVERSE CARDIOVASCULAR EVENTS, AND THROMBOSIS

Serious Infections
Patients treated with CIBINQO may be at increased risk for developing serious infections that may lead to hospitalization or death. The most frequent serious infections reported with CIBINQO were herpes simplex, herpes zoster, and pneumonia.

If a serious or opportunistic infection develops, discontinue CIBINQO and control the infection.

Reported infections from Janus kinase (JAK) inhibitors used to treat inflammatory conditions:

- **Active tuberculosis, which may present with pulmonary or extrapulmonary disease. Test for latent TB before and during therapy; treat latent TB prior to use. Monitor all patients for active TB during treatment, even patients with initial negative, latent TB test.**
- **Invasive fungal infections, including cryptococcosis and pneumocystosis. Patients with invasive fungal infections may present with disseminated, rather than localized, disease.**
- **Bacterial, viral (including herpes zoster), and other infections due to opportunistic pathogens.**

Avoid use of CIBINQO in patients with an active, serious infection, including localized infections. The risks and benefits of treatment with CIBINQO should be carefully considered prior to initiating therapy in patients with chronic or recurrent infections or those who have resided or traveled in areas of endemic tuberculosis or endemic mycoses.

Patients should be closely monitored for the development of signs and symptoms of infection during and after treatment with CIBINQO, including the possible development of tuberculosis in patients who tested negative for latent tuberculosis infection prior to initiating therapy.

Consider yearly screening for patients in highly endemic areas for TB. CIBINQO is not recommended for use in patients with active TB. For patients with a new diagnosis of latent TB or prior untreated latent TB, or for patients with a negative test for latent TB but who are at high risk for TB infection, start preventive therapy for latent TB prior to initiation of CIBINQO.

Viral reactivation, including herpes virus reactivation (eg, herpes zoster, herpes simplex), was reported in clinical studies with CIBINQO. If a patient develops herpes zoster, consider interrupting CIBINQO until the episode resolves. Hepatitis B virus reactivation has been reported in patients receiving JAK inhibitors. Perform viral hepatitis screening and monitoring for reactivation in accordance with clinical guidelines before starting therapy and during therapy with CIBINQO. CIBINQO is not recommended for use in patients with active hepatitis B or hepatitis C.

MORTALITY
In a large, randomized postmarketing safety study in rheumatoid arthritis (RA) patients 50 years of age and older with at least one cardiovascular risk factor comparing another JAK inhibitor to TNF blocker treatment, a higher rate of all-cause mortality (including sudden cardiovascular death) was observed with the JAK inhibitor. CIBINQO is not approved for use in RA patients.

MALIGNANCIES
Malignancies, including non-melanoma skin cancer (NMSC), were reported in patients treated with CIBINQO. Lymphoma and other malignancies have been observed in patients receiving JAK inhibitors used to treat inflammatory conditions. Perform periodic skin examination for patients who are at increased risk for skin cancer. Exposure to sunlight and UV light should be limited by wearing protective clothing and using broad-spectrum sunscreen.

In a large, randomized postmarketing safety study of another JAK inhibitor in RA patients, a higher rate of malignancies (excluding non-melanoma skin cancer [NMSC]) was observed in patients treated with the JAK inhibitor compared to those treated with TNF blockers. CIBINQO is not approved for use in RA patients. A higher rate of lymphomas was observed in patients treated with the JAK inhibitor compared to those treated with TNF blockers. A higher rate of lung cancers was observed in current or past smokers treated with

the JAK inhibitor compared to those treated with TNF blockers. **Patients who are current or past smokers are at additional increased risk.**

Consider the benefits and risks for the individual patient prior to initiating or continuing therapy with CIBINQO, particularly in patients with a known malignancy (other than a successfully treated NMSC), patients who develop a malignancy when on treatment, and patients who are current or past smokers.

MAJOR ADVERSE CARDIOVASCULAR EVENTS (MACE)

Major adverse cardiovascular events were reported in patients treated with CIBINQO. In RA patients 50 years of age and older with at least one cardiovascular risk factor treated with another JAK inhibitor, a higher rate of major adverse cardiovascular events (MACE) (defined as cardiovascular death, myocardial infarction, and stroke), was observed when compared with TNF blockers. CIBINQO is not approved for use in RA patients. **Patients who are current or past smokers are at additional increased risk. Discontinue CIBINQO in patients that have experienced a myocardial infarction or stroke.**

Consider the benefits and risks for the individual patient prior to initiating or continuing therapy with CIBINQO, particularly in patients who are current or past smokers and patients with other cardiovascular risk factors. Patients should be informed about the symptoms of serious cardiovascular events and the steps to take if they occur.

THROMBOSIS

Deep vein thrombosis (DVT) and pulmonary embolism (PE) have been reported in patients treated with CIBINQO. Thrombosis, including PE, DVT, and arterial thrombosis have been reported in patients receiving JAK inhibitors used to treat inflammatory conditions. Many of these adverse reactions were serious and some resulted in death. In RA patients 50 years of age and older with at least one cardiovascular risk factor treated with another JAK inhibitor, a higher rate of overall thrombosis, DVT, and PE were observed when compared with TNF blockers. CIBINQO is not approved for use in RA patients.

Avoid CIBINQO in patients that may be at increased risk of thrombosis. If symptoms of thrombosis occur, discontinue CIBINQO and treat patients appropriately.

CONTRAINDICATION

CIBINQO is contraindicated in patients taking antiplatelet therapies, except for low-dose aspirin (?81 mg daily), during the first 3 months of treatment.

LABORATORY ABNORMALITIES

Hematologic Abnormalities: Treatment with CIBINQO was associated with an increased incidence of thrombocytopenia and lymphopenia. Prior to CIBINQO initiation, perform a complete blood count (CBC). CBC evaluations are recommended at 4 weeks after initiation and 4 weeks after dose increase of CIBINQO. Discontinuation of CIBINQO therapy is required for certain laboratory abnormalities.

Lipid Elevations: Dose-dependent increase in blood lipid parameters were reported in patients treated with CIBINQO. Lipid parameters should be assessed approximately 4 weeks following initiation of CIBINQO therapy, and thereafter patients should be managed according to clinical guidelines for hyperlipidemia. The effect of these lipid parameter elevations on cardiovascular morbidity and mortality has not been determined.

IMMUNIZATIONS

Prior to initiating CIBINQO, complete all age-appropriate vaccinations as recommended by current immunization guidelines, including prophylactic herpes zoster vaccinations. Avoid vaccination with live vaccines immediately prior to, during, and immediately after CIBINQO therapy.

RENAL IMPAIRMENT
Avoid use in patients with severe renal impairment or end stage renal disease, including those on renal replacement therapy.

HEPATIC IMPAIRMENT
Avoid use in patients with severe hepatic impairment.

ADVERSE REACTIONS
Most common adverse reactions (?1%) in subjects receiving 100 mg and 200 mg include: nasopharyngitis, nausea, headache, herpes simplex, increased blood creatine phosphokinase, dizziness, urinary tract infection, fatigue, acne, vomiting, oropharyngeal pain, influenza, gastroenteritis.

Most common adverse reactions (?1%) in subjects receiving either 100 mg or 200 mg also include: impetigo, hypertension, contact dermatitis, upper abdominal pain, abdominal discomfort, herpes zoster, and thrombocytopenia.

Inform patients that retinal detachment has been reported in CIBINQO clinical trials. Advise patients to immediately inform their healthcare provider if they develop any sudden changes in vision.

DRUG INTERACTIONS
Monitor appropriately or dose titrate P-gp substrate where small concentration changes may lead to serious or life-threatening toxicities when coadministered with CIBINQO. See Prescribing Information for clinically relevant drug interactions.

USE IN PREGNANCY
Available data from pregnancies reported in clinical trials with CIBINQO are not sufficient to establish a drug-associated risk for major birth defects, miscarriage, or other adverse maternal or fetal outcomes. Advise females of reproductive potential that CIBINQO may impair fertility.

There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to CIBINQO during pregnancy. Pregnant women exposed to CIBINQO and health care providers are encouraged to call 1-877-311-3770 or visit CIBINQOPregnancyRegistry.com.

LACTATION
Advise women not to breastfeed during treatment with CIBINQO and for one day after the last dose.

INDICATION
CIBINQO is indicated for the treatment of adults and pediatric patients 12 years of age and older with refractory, moderate-to-severe atopic dermatitis whose disease is not adequately controlled with other systemic drug products, including biologics, or when use of those therapies is inadvisable.

Limitations of Use: CIBINQO is not recommended for use in combination with other JAK inhibitors, biologic immunomodulators, or with other immunosuppressants.

Please see full Prescribing Information, including BOXED WARNING, at CIBINQOPI.com or click here

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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 February 10 , 2023. 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 CIBINQO (abrocitinib), including its potential benefits , and an expanded indication in the U.S. to include adolescents (12 to <18 years) with refractory, moderate-to-severe atopic dermatitis whose disease is not adequately controlled with other systemic drug products, including biologics, or when use of those therapies is inadvisable, 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, uncertainties regarding the commercial success of CIBINQO; 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 particular jurisdictions for any potential indication for CIBINQO; whether and when any applications that may be pending or filed for CIBINQO 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 CIBINQO 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 CIBINQO ; 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, 2021 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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[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] Shaw TE, Currie GP, Koudelka CW, Simpson EL. Eczema prevalence in the United States: data from the 2003 National Survey of Children's Health.
[4] 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.
[5] Kim BE, Leung DYM. Significance of Skin Barrier Dysfunction in Atopic Dermatitis. Allergy Asthma Immunol Res. 2018;10(3):207-215. doi:10.4168/aair.2018.10.3.207.
[6] Silverberg JI. Public health burden and epidemiology of atopic dermatitis. Dermatol Clin. 2017;35:283-289.
[7] Chiesa Fuxench ZC, Block JK, Boguniewicz M, et al. Atopic dermatitis in America study: a cross-sectional study examining the prevalence and disease burden of atopic dermatitis in the US adult population. J Invest Dermatol. 2019;139(3):583-590.

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