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European Commission Approves Pfizer’s Cibinqo® (abrocitinib) for the Treatment of Adults with Moderate-to-Severe Atopic Dermatitis

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Cibinqo is a once-daily oral treatment with proven efficacy demonstrated in a large-scale clinical trial program

NEW YORK--(BUSINESS WIRE)-- Pfizer Inc. (NYSE: PFE) today announced that the European Commission (EC) has approved the 100 mg and 200 mg doses of Cibinqo® (abrocitinib), an oral, once-daily, Janus kinase 1 (JAK1) inhibitor, for the treatment of moderate-to-severe atopic dermatitis (AD) in adults who are candidates for systemic therapy. Additionally, a 50 mg dose was approved to treat moderate-to-severe AD specifically in patients with moderate and severe renal impairment (kidney failure) or certain patients receiving treatment with inhibitors of cytochrome P450 (CYP) 2C19.

“For adults living with moderate-to-severe atopic dermatitis, Cibinqo could help provide relief from the hallmark symptom of intense itch and has demonstrated rapid improvements in skin clearance, extent, and severity of disease, versus placebo,” said Dr. Stephan Weidinger, Professor of Dermatology at Christian-Albrechts University Kiel and Vice Head of the Department of Dermatology at the University Hospital Schleswig-Holstein, Kiel, Germany. “The approval of Cibinqo in the European Union makes me hopeful for many patients who will have this additional option to help manage the often painful and disruptive symptoms of moderate-to-severe atopic dermatitis.”

The approval of Cibinqo was based on the results of five clinical studies of more than 2,800 patients including four Phase 3 studies and an ongoing long-term open label extension study. Cibinqo demonstrated meaningful improvements across measures of symptom relief and disease control versus placebo. In one trial including an active control arm with dupilumab, which evaluated patients on background topical medicated therapy, Cibinqo 200 mg was associated with a greater improvement in itch relief after two weeks than dupilumab. Cibinqo also demonstrated a consistent safety profile across trials, including in a long-term extension study, showing a favorable benefit-risk profile.

“There have been few treatment innovations over the last decade for those in the European Union suffering with the daily discomfort, distress, and pain caused by moderate-to-severe atopic dermatitis,” said Mike Gladstone, Global President of Pfizer Inflammation & Immunology. “The safety and efficacy established through a rigorous clinical trial program, designed to evaluate measures of symptom relief most important to patients, gives us great confidence in the positive impact Cibinqo could have on those living with this debilitating immuno-inflammatory condition.”

The most common adverse events reported with Cibinqo in ?5% of patients were nausea (15.1%) and headache (7.9%). The most frequent serious adverse reactions were infections (0.3%).

Additional Details on the Cibinqo Clinical Trial Program

Findings from the following five studies in the Cibinqo JAK1 Atopic Dermatitis Efficacy and Safety (JADE) global development program were included in the submission to support this approval. The trials evaluated measures of improvements for AD including the Investigator Global Assessment (IGA), Eczema Area and Severity Index (EASI), and Peak Pruritus Numerical Rating Scale (PP-NRS):

- JADE MONO-1 and JADE MONO-2: A pair of randomized, double-blind, placebo-controlled studies designed to evaluate the efficacy and safety of two doses (100 mg and 200 mg once daily) of Cibinqo monotherapy in 778 patients 12 years of age and older with moderate-to-severe AD. The studies assessed the co-primary endpoints of IGA and EASI-75 responses at Week 12. Key secondary endpoints in MONO-1 and MONO-2 included improvement of ?4 points in the severity of PP-NRS at Weeks 2, 4, and 12.
- JADE COMPARE: A randomized, double-blind, placebo-controlled study designed to evaluate the efficacy and safety of two doses (100 mg and 200 mg once daily) of Cibinqo in 837 adult patients with moderate-to-severe AD on background topical medicated therapy. The study also included an active control arm with dupilumab, a biologic treatment administered by subcutaneous injection, compared with placebo. The study assessed the co-primary endpoints of IGA (0 or 1) and EASI-75 responses at Week 12. Key secondary endpoints in COMPARE were PP-NRS4 at Week 2, compared to patients in both the dupilumab and placebo groups, in addition to IGA (0 or 1) response and EASI-75 at Week 16, compared to patients in the placebo group only.
- JADE REGIMEN: An induction, randomized withdrawal, double-blind, placebo-controlled study designed to evaluate the efficacy and safety of two doses (100 mg and 200 mg once daily) of Cibinqo in patients 12 years of age and older with moderate-to-severe AD. Following response to 12-week, open label, induction treatment with abrocitinib 200 mg, 798 patients (64.7% of those enrolled in the study) were randomized into one of three arms: 100 mg, 200 mg, or placebo. The primary endpoint following response in the 12-week induction phase was the loss of response requiring rescue treatment, a protocol-defined “flare,” among groups during the blinded treatment period up to 40 weeks. During the blinded treatment period, subjects meeting the protocol definition of flare entered an open-label rescue period during which they receive a 12-week course of abrocitinib 200 mg once daily with topical therapy per local standard of care. The key secondary endpoint was the loss of IGA response.
- JADE EXTEND: An ongoing, large, open-label, study designed to assess the long-term safety and efficacy of Cibinqo in a 92-week initial treatment period, followed by a variable length secondary treatment period during which subjects will receive treatment with open-label abrocitinib.

Select findings for Cibinqo 100 mg, 200 mg, and placebo follow. P-value differences versus placebo across endpoints in JADE MONO-1, JADE MONO-2, and JADE COMPARE were *p<0.01 or **p<0.001. Treatment effects in subgroups, such as age or weight, were consistent with the results in the overall study populations.

- JADE MONO-1:
  - IGA Response Rate (Week 12): 23.7%*, 43.8%**, and 7.9%, respectively
  - EASI-75 Response Rate (Week 12): 39.7%**, 62.7%**, and 11.8%, respectively
  - NRS ?4-Point Improvement Response Rate (Week 12): 37.7%**, 57.2%**, and 15.3%, respectively

- JADE MONO-2
  - IGA Response Rate (Week 12): 28.4%**, 38.1%**, and 9.1%, respectively
  - EASI-75 Response Rate (Week 12): 44.5%**, 61%**, and 10.4%, respectively
  - NRS ?4-Point Improvement Response Rate (Week 12): 45.2%**, 55.3%**, and 11.5%, respectively

- JADE COMPARE

- IGA Response Rate (Week 12): 36.6%**, 48.4%**, and 14%, respectively
- EASI-75 Response Rate (Week 12): 58.7%**, 70.3%**, and 27.1%, respectively
- NRS ?4-Point Improvement Response Rate (Week 2): 31.8%**, 49.1%**, and 13.8%, respectively
- IGA Response Rate (Week 16): 34.8%**, 47.5%**, and 12.9%, respectively
- EASI-75 Response Rate (Week 16): 60.3%**, 71%**, and 30.6%, respectively

- JADE REGIMEN
  - Flare Prevention Rate: 57.4%, 81.1%, and 19.1%, respectively
  - Rate of Patients Receiving Rescue Treatment: 39.2%, 16.2%, and 76.4%, respectively

- JADE EXTEND
  - Among patients who completed treatment in one of the above studies and entered EXTEND, most patients maintained their response at Week 48 with Cibinqo 100 mg and 200 mg:
    - IGA Response Rate (Week 48): 60% and 70%, respectively
    - EASI-75 Response Rate (Week 48): 79% and 87%, respectively
    - NRS ?4-Point Improvement Response Rate (Week 48): 62% and 83%, respectively

About Cibinqo® (abrocitinib)

Cibinqo 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).

Cibinqo received marketing authorization from the UK Medicines and Healthcare products Regulatory Agency (MHRA), the Japanese Ministry of Health, Labour and Welfare (MHLW) and Korea's Ministry of Food and Drug Safety (MFDS) earlier this year.

About Atopic Dermatitis

AD is a chronic inflammatory skin disease characterized by dry skin, intense itching and recurrent relapsing eczematous lesions with a heterogeneous clinical presentation. AD lesions are characterized by erythema (skin turning red or purple depending on normal skin color), induration (hardening)/papulation (formulation of papules), lichenification, oozing/crusting.[i,ii,iii]

AD affects up to 10% of adults worldwide.[iv] The prevalence of AD in adults in Europe is approximately 5-10%.[v,vi] Approximately 1 in 3 adults with AD have moderate-to-severe disease·[vii,viii]

About Pfizer Inflammation & Immunology

At Pfizer Inflammation & Immunology, we strive to deliver breakthroughs that enable freedom from day-to-day suffering for people living with autoimmune and chronic inflammatory diseases, which can be debilitating, disfiguring and distressing, dramatically affecting what they can do. With a focus on immuno-inflammatory conditions in Rheumatology, Gastroenterology and Medical Dermatology, our current portfolio of approved medicines and investigational molecules spans multiple action and delivery mechanisms, from topicals to small molecules, biologics and biosimilars. The root cause of many immunological diseases is immuno-inflammation, which requires specifically designed agents. Our differentiated R&D approach resulted in one of the broadest pipelines in the industry, where we purposefully match molecules to diseases where we believe they can make the biggest difference. Building on our decades-long commitment and pioneering science, we continue to advance the standard of care for patients living with immuno-inflammatory diseases and are working hand-in-hand with patients, caregivers and the broader healthcare community on healthcare solutions for the many

challenges of managing chronic inflammatory diseases, allowing patients to live their best lives.

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 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 December 10, 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 Cibinqo (abrocitinib), including its potential benefits and an approval by the European Commission, 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 Cibinqo; whether and when the application for Cibinqo pending with the U.S. Food and Drug Administration may be approved and whether and when any such other 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, 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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