Pfizer Logo

Japan’s MHLW Approves Pfizer’s CIBINQO® (abrocitinib) for Adults and Adolescents with Moderate to Severe Atopic Dermatitis

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NEW YORK--(BUSINESS WIRE)-- Pfizer Inc. (NYSE: PFE) today announced that the Japanese Ministry of Health, Labour and Welfare (MHLW) has approved CIBINQO® (abrocitinib), an oral, once-daily, Janus kinase 1 (JAK1) inhibitor, for the treatment of moderate to severe atopic dermatitis (AD) in adults and adolescents aged 12 years and older with inadequate response to existing therapies. CIBINQO will be available in Japan in doses of 100mg and 200mg.

“There have been limited treatment options available for moderate to severe atopic dermatitis and we’re hopeful for the positive impact CIBINQO may have on the lives of people in Japan living with this chronic and potentially debilitating disease,” said Angela Hwang, Group President, Pfizer Biopharmaceuticals Group. “We want to thank the Japanese Ministry of Health, Labour and Welfare, as well as all those who participated in our extensive clinical trial program and their families, for making this important treatment option a reality. Our priority will now be to ensure CIBINQO is routinely accessible to as many patients as possible.”

The approval of CIBINQO in Japan was based on the results from 1,513 patients across four Phase 3 studies, ranging from 12 to 16 weeks of treatment, and a long-term extension study from a robust clinical trial program.

Regulatory applications for abrocitinib have been submitted to countries around the world for review, including the United States, Australia, and the European Union. The UK Medicines and Healthcare products Regulatory Agency (MHRA) granted Great Britain marketing authorization for CIBINQO earlier this month.

About CIBINQO® (abrocitinib)

CIBINQO (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.[i,ii]

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] In Japan, AD affects approximately 3% of adults and 13% of children.[v,vi]

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 September 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 an approval by the Japanese Ministry of Health, Labour and Welfare and 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; whether and when the applications for abrocitinib pending with the U.S. Food and Drug Administration, European Medicines Agency and Australian Therapeutic Goods Administration 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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