

## IMPORTANT SAFETY INFORMATION

### Cibinqo (Abrocitinib) Prescriber Brochure

This document is approved by the Executive Directorate of Pharmacovigilance at SFDA

This Prescriber Brochure contains important safety information that you need to consider when prescribing and maintaining patients on Cibinqo therapy, namely:

- Thrombotic events including pulmonary embolism (PE).<sup>1</sup>
- Potential risk of serious infections (including herpes simplex, herpes zoster and pneumonia).<sup>1</sup>
- Potential risk of malignancy (including non-melanoma skin cancers (NMSC)).<sup>1</sup>
- Potential risk of increases in blood lipid parameters and cardiovascular diseases.<sup>1</sup>
- Embryo-foetal lethality in pregnancy.<sup>1</sup>

**Please read this brochure in full along with the prescribing information.**

#### About Cibinqo

Cibinqo is a Janus kinase (JAK) 1 inhibitor.<sup>1</sup>

Cibinqo is indicated for the treatment of moderate-to-severe atopic dermatitis in adults who are candidates for systemic therapy.<sup>1</sup>

#### Safety Information

##### Thrombotic events including pulmonary embolism (PE):<sup>1</sup>

Events of deep venous thrombosis (DVT) and PE have been reported in patients receiving Cibinqo.

Cibinqo should be used with caution in patients at high risk for DVT/PE.<sup>1</sup>

##### Before starting Cibinqo:<sup>1</sup>

- Risk factors that should be considered in determining the patient's risk for DVT/PE include older age, obesity, a medical history of DVT/PE, prothrombotic disorder, use of combined hormonal contraceptives or hormone replacement therapy, patients undergoing major surgery, or prolonged immobilization.<sup>1</sup>

##### If clinical features of a DVT/PE occur:<sup>1</sup>

- Cibinqo treatment should be discontinued, and patients should be evaluated promptly, followed by appropriate treatment.<sup>1</sup>

## Cibinqo (Abrocitinib) Prescriber Brochure

### Serious Infections (including herpes simplex, herpes zoster and pneumonia):<sup>1</sup>

Cibinqo must not be initiated in patients with active serious systemic infections, including tuberculosis (TB).<sup>1</sup> The most frequent serious infections in clinical studies were herpes simplex, herpes zoster, and pneumonia.<sup>1</sup>

Patients should be closely monitored for the development of signs and symptoms of infection, during and after treatment with Cibinqo.<sup>1</sup>

A patient who develops a new infection during treatment should undergo prompt and complete diagnostic testing and appropriate antimicrobial therapy should be initiated.<sup>1</sup>

The patient should be closely monitored and therapy should be temporarily interrupted if the patient is not responding to standard therapy.<sup>1</sup>

### Before starting Cibinqo:

- The risks and benefits of treatment should be carefully considered prior to initiating in patients:<sup>1</sup>
  - o with chronic or recurrent infection.<sup>1</sup>
  - o who have been exposed to TB.<sup>1</sup>
  - o with a history of a serious or an opportunistic infection.<sup>1</sup>
  - o who have resided or travelled in areas of endemic TB or endemic mycoses.<sup>1</sup>
  - o with underlying conditions that may predispose them to infection.<sup>1</sup>

### Tuberculosis (TB)

- Patients should be screened for TB before starting treatment and yearly screening for patients in highly endemic areas for TB should be considered.<sup>1</sup>
- Cibinqo must not be given to patients with active TB.<sup>1</sup> For patients with a new diagnosis of latent TB or prior untreated latent TB, preventive therapy for latent TB should be started prior to initiation of Cibinqo.<sup>1</sup>

### Viral reactivation

- Patients should be screened for viral hepatitis before and during therapy with Cibinqo in accordance with clinical guidelines. If hepatitis B virus DNA is detected while receiving Cibinqo, a liver specialist should be consulted.<sup>1</sup>

## Cibinqo (Abrocitinib) Prescriber Brochure

---

### If a new infection develops during treatment with Cibinqo:<sup>1</sup>

- Immediately carry out complete diagnostic testing and initiate appropriate antimicrobial therapy.<sup>1</sup>
- Closely monitor the patient and Cibinqo therapy should be temporarily interrupted if the patient is not responding to standard therapy.<sup>1</sup>

### If a patient develops a serious infection, sepsis or opportunistic infection:<sup>1</sup>

- Consider dose interruption of Cibinqo until the infection is controlled.<sup>1</sup>

### Vaccines:<sup>1</sup>

No data are available on the response to vaccination in patients receiving Cibinqo.<sup>1</sup> Before initiating treatment, it is recommended that patients be brought up to date with all immunizations, including prophylactic herpes zoster vaccinations, in agreement with current immunization guidelines.<sup>1</sup>

Use of live, attenuated vaccines should be avoided during or immediately prior to treatment.<sup>1</sup>

### Laboratory monitoring:

Complete blood count should be monitored before treatment initiation, 4 weeks after initiation of therapy and thereafter according to routine patient management (Including Platelet Count, Absolute Lymphocyte Count, Absolute Neutrophil Count and Haemoglobin.)<sup>1</sup>

---

## **Malignancy:**

Malignancies, including NMSC, have been observed in clinical studies with Cibinqo.<sup>1</sup> Clinical data are insufficient to assess the potential relationship of exposure to Cibinqo and the development of malignancies.<sup>1</sup> Long-term safety evaluations are ongoing.<sup>1</sup>

### Before starting Cibinqo:

- The risks and benefits of treatment should be considered prior to initiating in patients with a known malignancy other than a successfully treated NMSC or cervical cancer in situ or when considering continuing Cibinqo therapy in patients who develop a malignancy.<sup>1</sup>
- Periodic skin examination is recommended for patients who are at increased risk for skin cancer.<sup>1</sup>

## Cibinqo (Abrocitinib) Prescriber Brochure

### Potential risk of increases in blood lipid parameters and cardiovascular diseases<sup>1</sup>

Dose dependent increases in blood lipid parameters were reported in patients treated with Cibinqo.<sup>1</sup>

Lipid parameters should be assessed approximately 4 weeks following initiation of therapy and thereafter according to the patient's risk for cardiovascular disease.<sup>1</sup>

The effect of lipid parameter elevations on cardiovascular morbidity and mortality has not been determined.<sup>1</sup> Patients with abnormal lipid parameters should be further monitored and managed according to clinical guidelines, due to the known cardiovascular risks associated with hyperlipidaemia.<sup>1</sup>

In patients with a high burden of cardiovascular risk factors, the risks and benefits of abrocitinib compared to that of other available therapies for atopic dermatitis should be considered.<sup>1</sup> If abrocitinib is chosen, interventions to manage lipid concentrations should be implemented according to local guidelines.<sup>1</sup>

### Embryo-foetal lethality in pregnancy<sup>1</sup>

There are no or limited amount of data on the use of Cibinqo in pregnant women.<sup>1</sup> Studies in animals have shown reproductive toxicity.<sup>1</sup>

- Cibinqo is contraindicated during pregnancy.<sup>1</sup>
- Women of reproductive potential should be advised to use effective contraception during treatment and for 1 month following the final dose of Cibinqo.<sup>1</sup> Pregnancy planning and prevention for females of reproductive potential should be encouraged.<sup>1</sup>
- Advise patients to inform their healthcare provider immediately if they think they could be pregnant or if pregnancy is confirmed.

### Important points to remember - Patient Card

Prior to starting treatment with Cibinqo:

- Patient Cards should be given to the patients to explain the important safety information that patients need to be aware of.<sup>2</sup>
- Patients are encouraged to talk to their doctor or pharmacist in case of any side effects.<sup>2</sup>
- If patients have any further questions, they should ask their doctor or pharmacist.<sup>2</sup>
- Advise patients about the importance of keeping the Patient Card with them.<sup>2</sup>
- Advise patients that they should read the Patient Card along with the Patient Information Leaflet.<sup>2</sup>

## Cibinqo (Abrocitinib) Prescriber Brochure

### Further information:

- As a healthcare professional, it is important that you report any suspected adverse reactions to:
  - The National Pharmacovigilance & Drug safety Centre (NPC) at Saudi Food and Drug Authority (SFDA)  
SFDA Call Center: 19999  
Toll Free Phone: 8002490000  
Fax: +966-11-2057662  
E-mail: [npc.drug@sfda.gov.sa](mailto:npc.drug@sfda.gov.sa)  
Website: <http://ade.sfda.gov.sa/>
  - Pharmacovigilance Department in the company  
E-mail: [SAU.AEReporting@pfizer.com](mailto:SAU.AEReporting@pfizer.com)

- For extra copies, please send an email with your contact details and the required Quantities to [SAU.AEReporting@pfizer.com](mailto:SAU.AEReporting@pfizer.com)

**PE:** Pulmonary Embolism; **JAK:** Janus kinase; **DVT:** Deep Venous Thrombosis; **TB:** Tuberculosis; **NMSC:** Non-Melanoma Skin Cancer

#### References:

1. CIBINQO<sup>®</sup> Summary of Product Characteristics, Saudi Arabia, March, 2024.
2. CIBINQO<sup>®</sup> Patient Information Leaflet, Saudi Arabia, March 2024