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EMA/427091/2024
Human Medicines Division

Assessment report for paediatric studies submitted according to Article 46 of the Regulation (EC) No 1901/2006

Cibinqo

Abrocitinib

Procedure no: EMEA/H/C/005452/P46/005.1

Note

Assessment report as adopted by the CHMP with all information of a commercially confidential nature deleted.

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Status of this report and steps taken for the assessment				
Current step[1]	**Description**	**Planned date**	**Actual Date**	**Need for discussion[2]**
☐	Start of procedure	19 Aug 2024	19 Aug 2024	☐
☐	CHMP Rapporteur Assessment Report	23 Sept 2024	10 Sept 2024	☐
☐	CHMP members comments	07 Oct 2024	n/a	☐
☐	Updated CHMP Rapporteur Assessment Report	10 Oct 2024	n/a	☐
☒	CHMP adoption of conclusions:	17 Oct 2024	17 Oct 2024	☐

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1. Introduction

On 5 August 2024, the MAH submitted a completed paediatric study for abrocitinib (Cibinqo), in accordance with Article 46 of Regulation (EC) No1901/2006, as amended.

A short critical expert overview has also been provided.

2. Scientific discussion

2.1. Information on the development program

The MAH stated that study B7451094 is a stand-alone study.

The MAH has submitted the final study report for study B7451094, addressing the follow-up paediatric safety and post-baseline knee MRI data from study B7451094 titled 'a randomized, open-label, parallel-group study to evaluate the safety and efficacy of abrocitinib 100 mg and 200 mg tablets in participants aged 12 years and older with moderate to severe atopic dermatitis in India', supplementary to the main study B7451094 submitted in November 2023 (procedure EMEA/H/C/005452/P46/005).

The rationale to perform study B7451094 is that as per the Indian consensus statement for management of atopic dermatitis (AD), patients with AD suffer from dry skin and defective skin barrier function, that manifests mainly as pruritus. Systemic therapy is used to treat patients with moderate to severe AD on failure of topical treatments. Currently approved systemic agents in India have modest efficacy in patients with moderate to severe AD but are associated with adverse events (AEs) that often limit long-term use.

Data from phase 3 studies (B7451012, B7451013, B7451014, B7451029, B7451036, B7451050) that evaluated abrocitinib 100 mg and 200 mg in patients with moderate to severe AD reported statistically significant improvement in efficacy endpoints in both treatment groups compared to the placebo group with an acceptable safety profile. A substudy assessing potential effects of abrocitinib on bone development in adolescent participants via knee MRI was incorporated to the main long-term extension B7451015 study, to support an indication expansion in adolescents in the EU. The purpose of the B7451094 substudy was to provide follow-up safety and knee MRI data for abrocitinib in Indian adolescents to support local registration in India.

2.2. Information on the pharmaceutical formulation used in the study

Study intervention used in study B7451094 was abrocitinib 100 mg tablet, provided centrally by the sponsor. It was the same formulation approved and marketed in the EU and the US.

2.3. Clinical aspects

2.3.1. Introduction

Abrocitinib is a Janus kinase (JAK)1 inhibitor. In the EU, Cibinqo is indicated for the treatment of moderate-to-severe atopic dermatitis in adults and adolescents 12 years and older who are candidates for systemic therapy.

The MAH has submitted the final study report for study B7451094, addressing the follow-up paediatric safety and post-baseline knee MRI data from study B7451094, supplementary to the main study report B7451094 submitted in November 2023 (procedure EMEA/H/C/005452/P46/005).

2.3.2. Clinical study B7451094

Description

Study B7451094 was a randomised, open-label, parallel-group study to evaluate the safety and efficacy of abrocitinib 100 mg and 200 mg tablets in participants aged 12 years and older with moderate to severe AD in India.

Study design

A total of 200 participants were enrolled from 15 sites in India, and randomly assigned to study intervention. Safety endpoints were assessed throughout the entire study. Secondary efficacy assessments were conducted from screening to EOT visit.

Eligible participants must have met the eligibility criteria at baseline. Participants who met eligibility criteria at baseline underwent Day 1 assessments and were randomised in a 1:1 ratio to receive abrocitinib 200 mg QD or abrocitinib 100 mg QD in an open-label manner.

Main study

In the main study, the total treatment period was 12 weeks. All participants underwent a 4-week off-treatment safety follow-up period thereafter.

Substudy

Study B7451094 included a substudy evaluating whether abrocitinib had any potential effects on adolescent bone utilising knee MRI. All adolescent participants (12 to <18 years) continued to receive study intervention until 1 year after randomisation in the main study.

Methods

Study participants

Enrolled in this substudy were participants with moderate to severe AD aged ≥12 years and <18 years at the time of informed consent.

Treatments

Orally administered study intervention, abrocitinib 100 mg tablet(s), was administered QD from Day 1 to Week 12. Participants were dispensed bottles of study intervention at Day 1, Week 2, Week 4 and Week 8 visits in the main study. Adolescents were planned to be dispensed bottles of study intervention during the main study and at Week 12, Week 24 and Week 36 visits in the substudy. Participants were given clear dosing instructions to take either 1 tablet or 2 tablets of study intervention QD by mouth with meals. Participants swallowed the oral study intervention whole and did not manipulate or chew the medication prior to swallowing.

Objective(s) and Outcomes/endpoints

Table 1. Study objectives and endpoints

Type	Objective	Endpoints	Reference
Primary			
Safety Section 5.2.1	To evaluate the safety of abrocitinib in participants aged 12 years and older with moderate to severe AD.	• Incidence of AEs and SAEs.	Final data were reported in PCD CSR[4]. Supplemental data for substudy populations are reported in this CSR.
Secondary			
Efficacy Section 5.1	To assess the efficacy of abrocitinib in participants aged 12 years and older with moderate to severe AD.	• Response based on IGA score of clear (0) or almost clear (1) and greater than or equal to 2 points improvement from baseline at Week 12. • Response based on achieving ≥75% improvement from baseline in the EASI total score (EASI-75) at Week 12. • Response based on ≥75% improvement from baseline in SCORAD (SCORAD75) at Week 12. • Change from baseline in POEM at Week 12 and at all scheduled time points. • Change from baseline in ADCT at Week 12 and at all scheduled timepoints.	Final data were reported in PCD CSR[4].
Primary Substudy			
Safety	To evaluate the potential effects of abrocitinib on bone development in adolescent participants 12 to <18 years of age, as assessed by knee MRI.	• The proportion of bone safety findings in knee MRI 1 year after randomization in adolescent participants exposed to abrocitinib 100 mg and 200 mg QD.	Baseline data were reported in PCD CSR[4]. Final data are reported in this CSR.

Sample size

Adolescent participants 12 to <18 years of age in the main study will be eligible for enrollment into the substudy.

Randomisation and blinding (masking)

All participants were centrally assigned to randomised study intervention using interactive response technology.

This was an open-label study.

Statistical methods

The planned analyses and analysis populations are described in the final version of the SAP.

Changes in planned analyses prior to database lock

All changes in the planned analyses for the study were implemented by SAP amendments (amendment 1 dated 12 May 2022 and amendment 2 dated 13 July 2023).

Changes following study database lock

The unit of heart rate in the ECG CRF page was fixed to "msec" instead of "bpm". "bpm" was the appropriate unit as per the protocol and the data was collected in "bpm". Therefore, a footnote "The unit of ECG Mean Heart Rate is bpm, all other ECG parameters are in msec" was implemented in the Summary of ECG Table and the ECG listing instead of modifying any values.

Results

Participant flow

All 35 screened substudy participants were randomised and treated. Out of 35 treated participants, 19 participants received abrocitinib 200 mg QD and 16 participants received abrocitinib 100 mg QD. A total of 27 participants (77.1%) completed the study treatment phase in the substudy. The main reason for study intervention discontinuation was physician's decision (11.4%). All 32 substudy participants (91.4%) (17 [89.5%] received abrocitinib 200 mg QD and 15 [93.8%] received abrocitinib 100 mg QD) who entered the post-dose follow-up phase completed this phase.

Table 2. Disposition Events Summary - Substudy Analysis Set (SAS) (Protocol B7451094_sCSR)

Number (%) of Participants	Abrocitinib 200 mg QD (N=19) n (%)	Abrocitinib 100 mg QD (N=16) n (%)	Total (N=35) n (%)
Disposition phase: treatment			
Participants Entered:	19 (100.0)	16 (100.0)	35 (100.0)
Discontinued	7 (36.8)	1 (6.3)	8 (22.9)
Reason for discontinuation			
Adverse event	2 (10.5)	0	2 (5.7)
Lost to follow-Up	1 (5.3)	0	1 (2.9)
Physician's decision	4 (21.1)	0	4 (11.4)
Withdrawal by parent/guardian	0	1 (6.3)	1 (2.9)
Completed	12 (63.2)	15 (93.8)	27 (77.1)
Ongoing	0	0	0
Disposition phase: follow-up			
Participants Entered:	17 (89.5)	15 (93.8)	32 (91.4)
Discontinued	0	0	0
Reason for discontinuation			
Adverse event	0	0	0
Lost to follow-Up	0	0	0
Physician's decision	0	0	0
Withdrawal by parent/guardian	0	0	0
Completed	14 (73.7)	15 (93.8)	29 (82.9)
Ongoing	3 (15.8)	0	3 (8.6)

Participants 10031010,10091010 discontinued treatment and Participant 10181004 completed study treatment; all 3 participants completed both EOT and follow-up visits.
However, they are counted in this table as Ongoing because DISPOSITION - FOLLOW-UP CRFs were not available for completion due to technical error.
Therefore, there should be no Ongoing participants and Completed study follow-up should read as 17 (89.5) and 32 (91.4) for Abrocitinib 200 mg QD and Total groups, respectively.

Recruitment

Study initiation date: 16 July 2022 (first participant first visit)

Study completion date: 14 March 2024 (last participant last visit)

Baseline data

Demography and baseline characteristics

More than half of the substudy participants were female (19 participants, 54.3%). The median age of all participants was 14.0 years (range: 12.0-18.0 years). Median weight was 45.9 kg (range: 30.0-72.7 kg) and median BMI was 20.5 kg/m^2 (range: 14.2-30.3 kg/m^2).

Table 3. Demographic Characteristics - Substudy Analysis Set (SAS) (Protocol B7451094_sCSR)

	Abrocitinib 200 mg QD (N=19)	Abrocitinib 100 mg QD (N=16)	Total (N=35)
Age (years), n (%)			
<18	17 (89.5)	16 (100.0)	33 (94.3)
18-44	2 (10.5)	0	2 (5.7)
Median (range)	14.0 (12.0, 18.0)	14.0 (12.0, 17.0)	14.0 (12.0, 18.0)
Mean (SD)	14.79 (2.25)	14.44 (1.36)	14.63 (1.88)
Gender, n (%)			
Male	7 (36.8)	9 (56.3)	16 (45.7)
Female	12 (63.2)	7 (43.8)	19 (54.3)
Race, n (%)			
Asian	19 (100.0)	16 (100.0)	35 (100.0)
Ethnicity, n (%)			
Not Hispanic or Latino	19 (100.0)	16 (100.0)	35 (100.0)

Two participants (10021017, 10091010) were 17 years old at the time of screening. However, since only year of birth was collected, the derived age was 18 years after applying month and day imputation to date of birth.

Table 4. Physical Measurements at Baseline - Substudy Analysis Set (SAS) (Protocol B7451094_sCSR)

Parameter		Abrocitinib 200 mg QD (N=19)	Abrocitinib 100 mg QD (N=16)	Total (N=35)
HEIGHT (CM)	n	19	16	35
	Mean (SD)	151.6 (14.49)	153.4 (8.85)	152.4 (12.11)
	Median (range)	152.2 (125.2, 174.5)	151.0 (140.0, 173.0)	152.0 (125.2, 174.5)
WEIGHT (KG)	n	19	16	35
	Mean (SD)	48.5 (13.47)	48.3 (10.93)	48.4 (12.20)
	Median (range)	45.5 (30.0, 72.7)	46.2 (31.0, 71.8)	45.9 (30.0, 72.7)
BODY MASS INDEX (KG/M^2)	n	19	16	35
	Mean (SD)	20.9 (3.65)	20.4 (3.95)	20.7 (3.74)
	Median (range)	20.8 (15.1, 28.1)	19.9 (14.2, 30.3)	20.5 (14.2, 30.3)

Body Mass Index (kg/m^2) = weight (kg) / [height (cm) x 0.01]^2.

Number analysed

For safety analyses, participants were analyzed according to the treatment they actually received (19 participants received abrocitinib 200 mg QD; 16 participants received abrocitinib 100 mg QD).

Efficacy results

There were no efficacy analyses in this substudy.

Safety results

Extent of exposure

Range and median exposure were comparable between treatment groups (median duration was 49.57 weeks and 50.14 weeks for participants received abrocitinib 200 mg QD and 100 mg QD, respectively). Most participants had 36 weeks or more of exposure. One participant (5.3%) in abrocitinib 200 mg QD group had actual dosing duration of <8 weeks.

Compliance

Most (34) participants followed the prespecified study intervention compliance (80%-120% compliance) per protocol. Only 1 participant in the abrocitinib 200 mg QD group had an overall compliance of <80% during the substudy. No participant had an overall compliance of >120%.

Adverse events

Table 5. Treatment-Emergent Adverse Events (All Causalities) - Substudy Analysis Set (SAS) (Protocol B7451094_sCSR)

Number (%) of Participants	Abrocitinib 200mg QD n (%)	Abrocitinib 100mg QD n (%)
Participants evaluable for adverse events	19	16
Number of adverse events	14	13
Participants with adverse events	8 (42.1)	5 (31.3)
Participants with medication error events	0	0
Participants with serious adverse events	0	0
Participants with severe adverse events	0	0
Participants discontinued from study due to adverse events[a]	2 (10.5)	0
Participants discontinued study drug due to AE and continue Study[b]	0	0
Participants with temporary discontinuation due to adverse events	4 (21.1)	2 (12.5)

Included data up to 28 days after last dose of study.
Except for the Number of Adverse Events participants are counted only once per treatment in each row.
Serious Adverse Events - according to the investigator's assessment.
a. Participants who have an AE record that indicates that the AE caused the participant to be discontinued from the study
b. Participants who have an AE record that indicates that Action
Taken with Study Treatment was Drug Withdrawn but AE did not
Cause the Participant to be discontinued from Study MedDRA v27.0
coding dictionary applied.
The table presents data collected from the Main Study until Substudy Follow-up.

Table 6. Treatment-Emergent Adverse Events (Treatment Related) - Substudy Analysis Set (SAS) (Protocol B7451094_sCSR)

Number (%) of Participants	Abrocitinib 200 mg QD n (%)	Abrocitinib 100 mg QD n (%)
Participants evaluable for adverse events	19	16
Number of adverse events	5	1
Participants with adverse events	3 (15.8)	1 (6.3)
Participants with medication error events	0	0
Participants with serious adverse events	0	0
Participants with severe adverse events	0	0
Participants discontinued from study due to adverse events[a]	1 (5.3)	0
Participants discontinued study drug due to AE and continue Study[b]	0	0
Participants with temporary discontinuation due to adverse events	0	0

Included data up to 28 days after last dose of study.
Except for the Number of Adverse Events participants are counted only once per treatment in each row.
Serious Adverse Events - according to the investigator's assessment.
a. Participants who have an AE record that indicates that the AE caused the participant to be discontinued from the study
b. Participants who have an AE record that indicates that Action Taken with Study Treatment was Drug Withdrawn but AE did not Cause the Participant to be discontinued from Study
MedDRA v27.0 coding dictionary applied.
The table presents data collected from the Main Study until Substudy Follow-up.

All-causality TEAEs

Table 7. Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (All Causalities) - Substudy Analysis Set (SAS) (Protocol B7451094_sCSR)

Number of Participants Evaluable for AEs	Abrocitinib 200 mg QD (N=19)	Abrocitinib 100 mg QD (N=16)
Number (%) of Participants: by SYSTEM ORGAN CLASS and Preferred Term	**n (%)**	**n (%)**
With Any adverse event	8 (42.1)	5 (31.3)
GASTROINTESTINAL DISORDERS	2 (10.5)	1 (6.3)
Gastritis	0	1 (6.3)
Nausea	2 (10.5)	0
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	1 (5.3)	2 (12.5)
Pyrexia	1 (5.3)	2 (12.5)
INFECTIONS AND INFESTATIONS	6 (31.6)	3 (18.8)
Eczema herpeticum	1 (5.3)	0
Herpes zoster	1 (5.3)	0
Joint tuberculosis	1 (5.3)	0
Nasopharyngitis	2 (10.5)	1 (6.3)
Pharyngitis	0	1 (6.3)
Pyoderma	0	1 (6.3)
Varicella	1 (5.3)	0
Varicella zoster virus infection	1 (5.3)	0
Viral infection	0	1 (6.3)
NERVOUS SYSTEM DISORDERS	1 (5.3)	1 (6.3)
Dizziness	0	1 (6.3)
Headache	1 (5.3)	0
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	1 (5.3)	2 (12.5)
Asthma	0	1 (6.3)
Cough	1 (5.3)	1 (6.3)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	2 (10.5)	2 (12.5)
Dermatitis atopic	1 (5.3)	2 (12.5)
Rosacea	1 (5.3)	0
VASCULAR DISORDERS	0	1 (6.3)
Hypotension	0	1 (6.3)

Participants are only counted once per treatment per event.
Totals for the No. of Participants at a higher level are not necessarily the sum of those at the lower levels since a participant may report two or more different adverse events within the higher level category.
Included data up to 28 days after last dose of study.
MedDRA v27.0 coding dictionary applied.
The table presents data collected from the Main Study until Substudy Follow-up.

Treatment-related TEAEs

Table 8. Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (Treatment Related) - Substudy Analysis Set (SAS) (Protocol B7451094_sCSR)

Number of Participants Evaluable for AEs Number (%) of Participants: by SYSTEM ORGAN CLASS Higher Level Group Term and Preferred Term	Abrocitinib 200 mg QD (N=19) n (%)	Abrocitinib 100 mg QD (N=16) n (%)
With Any adverse event	3 (15.8)	1 (6.3)
GASTROINTESTINAL DISORDERS	2 (10.5)	0
Gastrointestinal signs and symptoms	2 (10.5)	0
Nausea	2 (10.5)	0
INFECTIONS AND INFESTATIONS	1 (5.3)	0
Mycobacterial infectious disorders	1 (5.3)	0
Joint tuberculosis	1 (5.3)	0
NERVOUS SYSTEM DISORDERS	1 (5.3)	1 (6.3)
Headaches	1 (5.3)	0
Headache	1 (5.3)	0
Neurological disorders NEC	0	1 (6.3)
Dizziness	0	1 (6.3)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	1 (5.3)	0
Skin appendage conditions	1 (5.3)	0
Rosacea	1 (5.3)	0

Participants are only counted once per treatment per event.
Totals for the No. of Participants at a higher level are not necessarily the sum of those at the lower levels since a participant may report two or more different adverse events within the higher level category.
Included data up to 28 days after last dose of study.
MedDRA v27.0 coding dictionary applied.
The table presents data collected from the Main Study until Substudy Follow-up.

Deaths

No events of death were reported in the substudy.

Serious adverse events

No SAEs were reported in the substudy.

Discontinuations from study intervention or study due to adverse events

Temporary discontinuation from study intervention due to AEs

Four (21.1%) participants from abrocitinib 200 mg QD group experienced 4 AEs of herpes zoster, nasopharyngitis, varicella and pyrexia, which were all considered as unrelated to the study intervention and resulted in temporary discontinuation of the study intervention.

Two (12.5%) participants from abrocitinib 100 mg QD group experienced 4 AEs of pharyngitis, viral infection, pyrexia and hypotension, which were all considered as unrelated to the study intervention and resulted in temporary discontinuation of the study intervention.

Permanently discontinuation of study due to AEs

Two participants in the abrocitinib 200 mg QD group experienced 2 moderate AEs of eczema herpeticum and joint tuberculosis (treatment-related) that resulted in permanently discontinuation from the study.

Adjudicated safety events

There were 4 participants with AEs meeting the adjudication criteria, 2 with opportunistic infections (varicella zoster virus infection and joint tuberculosis) and 2 with special interest infections (herpes zoster and eczema herpeticum). For 1 of the 2 participants meeting the adjudication criterion of special interest infections, an event of eczema herpeticum was adjudicated twice with the same results.

Clinical laboratory evaluation

The proportion of participants who had laboratory abnormalities (without regard to baseline abnormalities) was higher in the abrocitinib 200 mg QD group (84.2%) compared to that in the abrocitinib 100 mg QD group (62.5%). No laboratory abnormalities were reported as AEs in this substudy.

Vital signs and electrocardiograms

No clinically meaningful findings in the vital signs measurements, ECGs, physical examination assessments, or other observations related to safety were observed in this substudy.

Knee MRI results

A total of 35 adolescents were enrolled in the substudy (2 of the 35 participants were 17 years old at the time of screening based on year of birth only, however, the derived age was 18 years after applying month and day imputation to date of birth. Thus, there were 33 participants <18 years old.

All 35 participants underwent MRI scans of the knee at baseline. Five participants (14.3%) had an MRI finding on central read, which underwent subsequent review by an independent adjudication committee. The adjudication outcomes for the baseline MRI scans were: no participant (0%) had bone safety findings; 4 participants (11.4%) had one or more 'other finding' (2 had bone marrow edema signal, 2 had altered soft tissue fat signal), the remaining participant had no adjudicated abnormalities.

Out of 35 participants, 29 participants underwent knee MRI at EOT visit. Out of 29 participants evaluated, 1 (2.9%) had an MRI finding on central read, which underwent subsequent adjudication review. Adjudication showed no abnormalities for the MRI scan. Therefore, adjudication outcomes for the EOT MRI scans showed no bone safety findings or 'other finding' in any participants.

2.3.3. Discussion on clinical aspects

In accordance with Article 46 of Regulation (EC) No1901/2006, the MAH has submitted the final study report for study B7451094, addressing the follow-up paediatric safety and post-baseline knee MRI data from study B7451094, supplementary to the main study report submitted in November 2023 (procedure EMEA/H/C/005452/P46/005).

Study B7451094, a randomised, open-label, parallel-group study to evaluate the safety and efficacy of abrocitinib 100 mg and 200 mg tablets in participants aged 12 years and older with moderate to severe atopic dermatitis in India, was conducted in support of the local registration of abrocitinib in India. The aim of the substudy was to evaluate potential effects of abrocitinib on bone development in adolescent patients.

The substudy enrolled 35 adolescents with a median age of 14 years (range: 12.0-18.0 years), with 19 patients receiving abrocitinib 200 mg QD and 16 patients receiving abrocitinib 100 mg QD. Median duration of exposure was 50 weeks.

AEs were reported by 42.1% and 31.3% of patients in the 200 mg and 100 mg treatment arms, respectively. AEs were most frequently reported in the SOC 'Infections and infestation' (31.6% and 18.8% with 200 mg and 100 mg, respectively). The most frequently reported AEs (reported in at least 2 patients in either treatment arm) were nausea, pyrexia, nasopharyngitis and dermatitis atopic. No deaths or SAEs were reported during the study. Two patients in the 200 mg arm discontinued due to AEs (eczema herpeticum and joint tuberculosis).

Adjudicated safety events were reported in 4 patients: 2 patients with opportunistic infections (varicella zoster virus infection and joint tuberculosis), and 2 patients with infections of special interest (herpes zoster and eczema herpeticum).

The event of joint tuberculosis in a 16-year-old male patient was reported with a time to onset of 172 days; the event was of moderate severity and led to treatment discontinuation and discontinuation from the study. This patient was reported with a medical history of atopic dermatitis of approximately 1-year duration. No concomitant medications were reported other than those taken for the treatment of tuberculosis. In section 4.4 of the SmPC, a statement is included that tuberculosis has been observed in clinical studies. Although a causal association in the present case is possible based on the immunosuppressive effect of abrocitinib, an update of section 4.8 of the SmPC is not warranted based on this single case report. Opportunistic infections, including tuberculosis, are adequately addressed in sections 4.2, 4.3 and 4.4 of the SmPC.

The potential effect of abrocitinib on bone development in adolescents was evaluated through knee MRI at baseline and following approximately 1 year of treatment with abrocitinib. No bone safety findings or other findings were reported.

3. CHMP overall conclusion and recommendation

The safety data reported in adolescent patients was generally consistent with the known safety profile of abrocitinib; no new safety concern is raised. No bone safety findings based on MRI data were observed in study B7451094; however, the results should be interpreted with caution given the small number of subjects. The MAH does not propose an update of the product information which is agreed by the CHMP.

The benefit-risk balance of abrocitinib in the authorised indication remains positive.

☒ Fulfilled:

No regulatory action required.