21 May 2026
EMADOC-1700519818-3226293
Human Medicines Division

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

RINVOQ

upadacitinib

Procedure no: EMA/PAM/0000336291

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**
☐	Start of Procedure	23 March 2026	23 March 2026
☐	CHMP Rapporteur AR	28 April 2026	28 April 2026
☐	CHMP comments	11 May 2026	n/a
☐	Updated CHMP Rapporteur AR	13 May 2026	n/a
☒	CHMP outcome	21 May 2026	21 May 2026

Administrative information

Procedure resources	
Rapporteur	**Kristina Dunder**

Table of contents

1. Introduction

On 9 March 2026, the MAH submitted a completed paediatric study (Study P20-442) for RINVOQ, 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 P-20-442 "A post-marketing observational study to evaluate safety and effectiveness of upadacitinib in adolescent patients ages 12 to <18 years old diagnosed with Atopic Dermatitis (AD) in Japan" is a standalone study.

2.2. Information on the pharmaceutical formulation used in the study

Updacitinib is a selective and reversible Janus kinase (JAK) inhibitor. The product is formulated as a depot tablet for adult and adolescent patients with atopic dermatitis according to the Rinvoq label. Upadacitinib was not provided by the MAH and thus the investigators used the commercially available drug. The dosage was 15 or 30 mg, determined by the attending physician.

2.3. Clinical aspects

2.3.1. Introduction

The MAH submitted a final report for:

- Study number P20-442 "A post-marketing observational study to evaluate safety and effectiveness of upadacitinib in adolescent patients ages 12 to <18 years old diagnosed with Atopic Dermatitis (AD) in Japan"

2.3.2. Clinical study

Clinical study P-20-442

Description

This study was an observational, multicenter, prospective, centrally registered, non-interventional, non-comparative post-marketing surveillance conducted in accordance with ministerial ordinance on good post-marketing study practice (GPSP), ordinance of the Ministry of Health and Welfare in Japan. Patients who were treated with upadacitinib as per investigator's medical judgment in accordance with the approved label in Japan during the study period were registered in this study. Patients were followed for safety and efficacy up to 2 years (104 weeks) following the first dose of upadacitinib. Data was collected via registration form and case report form (CRF) completed by participating physicians based on routine medical records.

Methods

Study participants

A total of 181 patients were included in the safety analysis set and 169 in the effectiveness analysis set. The mean age was 13.8 years, with 71% of patients aged 12 to < 15 years and 29% aged 15 to <18 years. Most patients were male (61.3 % in the safety analysis set and 62.7% in the effectiveness analysis set), there were 38 patients and 32 patients in the safety analysis set and effectiveness analysis set, respectively, weighing between 30 and <40 kg. The majority of patients in the effectiveness analysis set (50.3%) had atopic dermatitis lasting 5 years or more, and nearly all presented with moderate-to-severe disease at baseline (EASI ≥16). Prurigo nodularis was present in 31.5%, and the average baseline pruritus score was 6.5/10, indicating marked itching. The mean POEM score reflected moderate-to-severe symptoms before treatment.

Treatments

Dosage and administration were determined by the attending physician with reference to the package insert.

Objectives

The objectives of this study were to obtain real-world safety and effectiveness data from AD patients aged 12 to <18 years old treated with upadacitinib in Japan.

Sample size

The target sample size was 170 patients.

Results

Efficacy results

At the last evaluation point, the vIGA-AD 0/1 score achievement rate was 40.5% (66/163 patients). The mean (SD) and median of percent change in WP-NRS from baseline to last evaluation point were -58.5% (38.4) and -66.7% respectively. The improvement rate proportion of achieving a meaningful improvement (reduction) a score of WP-NRS $\geq$ 4 at the last evaluation point was 70.4% (81/115 patients), and the 0/1 achievement rate of achieving no/minimal itch (WP-NRS 0/1) was 41.2% (63/153 patients). Mean (SD) and median of percent changes in POEM (total score) from baseline to last evaluation point were -53.5% (64.2) and -71.6%. The proportion of achieving a meaningful improvement (reduction) in WP-NRS $\geq$ 4 at the last evaluation point was 70.4% (81/115 patients), and the proportion of achieving no/minimal itch (WP-NRS 0/1) was 41.2% (63/153 patients).

Safety results

In this Post Marketing Observational Study, causality of reported AEs assessed as "reasonable possibility" are reported in this report as adverse drug reactions (ADRs).

The incidence proportion of AEs was 28.2% (51/181 patients), and that of serious adverse events (SAEs) was 1.1% (2/181 patients). The most common AEs ($\geq$ 5%) by system organ class (SOC) were skin and subcutaneous tissue disorders (12.2%), and infections and infestations (9.4%). The most common AEs ($\geq$ 2%) by preferred term (PT) were acne (8.8%), headache (2.8%), herpes zoster, and dermatitis atopic (2.2% each). Reported SAEs were eczema herpeticum and appendicitis, each occurring in 0.6% of patients. The incidence proportion of AEs leading to discontinuation of upadacitinib was 5.5% (10/181 patients) and the incidence proportion of ADRs was 5.0% (9/181 patients). There were no SAEs leading to discontinuation of upadacitinib.

The incidence proportion of ADRs was 22.1% (40/181 patients), and that of serious adverse drug reactions (SADRs) was 0.6% (1/181 patients). Common ADRs (≥ 5%) by SOC were skin and subcutaneous tissue disorders (8.8%) and infections and infestations (7.7%). Common ADRs (≥ 2%) by PT were acne (8.3%), headache (2.8%), and herpes zoster (2.2%). One SADR of appendicitis was reported in a 14-year-old patient weighing 30-40 kg with a medical history of varicella and no concomitant disease. Appendicitis developed on Day 79 from the start of upadacitinib and recovered on Day 7 after onset.

The initial dose of upadacitinib was 15 mg. Upadacitinib was interrupted on the day of the onset of the appendicitis and resumed after the recovery of this ADR. The event was assessed by the investigator as unrelated to treatment with upadacitinib.

2.3.3. Discussion on clinical aspects

The results of the performed study support the clinical safety and efficacy of upadacatinib used in the treatment of adolescent patients with atopic dermatitis.

The safety results were consistent with those reported in clinical studies. The benefit-risk of upadacitinib remains unchanged and warrants no update to the Summary of Product Characteristics.

3. CHMP overall conclusion and recommendation

There are no new findings of clinical and safety in the performed Post-Marketing study. The MAH has not suggested any update of the Summary of Product Characteristics, which is endorsed by the CHMP.

☒ **Fulfilled:**

No regulatory action required.