24 July 2025
EMADOC-1700519818-2349591
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/0000268411

Note

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

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

Status of this report and steps taken for the assessment			
Current step[1]	**Description**	**Planned date**	**Actual Date**
☐	Start of Procedure	26 May 2025	26 May 2025
☐	CHMP Rapporteur AR	30 June 2025	30 June 2025
☐	CHMP comments	14 July 2025	14 July 2025
☐	Updated CHMP Rapporteur AR	17 July 2025	n/a
☒	CHMP outcome	24 July 2025	24 July 2025

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1. Introduction

On 24 April 2025, the MAH submitted a completed paediatric study 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 the submitted study is a real-world study designed as a retrospective longitudinal chart review study aimed to describe the patient characteristics, treatment patterns, drug utilization, healthcare resource utilization (HCRU), and clinical outcomes of atopic dermatitis (AD) patients treated with upadacitinib in Chinese real-world settings using the existing data.

2.2. Information on the pharmaceutical formulation used in the study

Not applicable.

2.3. Clinical aspects

2.3.1. Introduction

The MAH submitted a final report for:

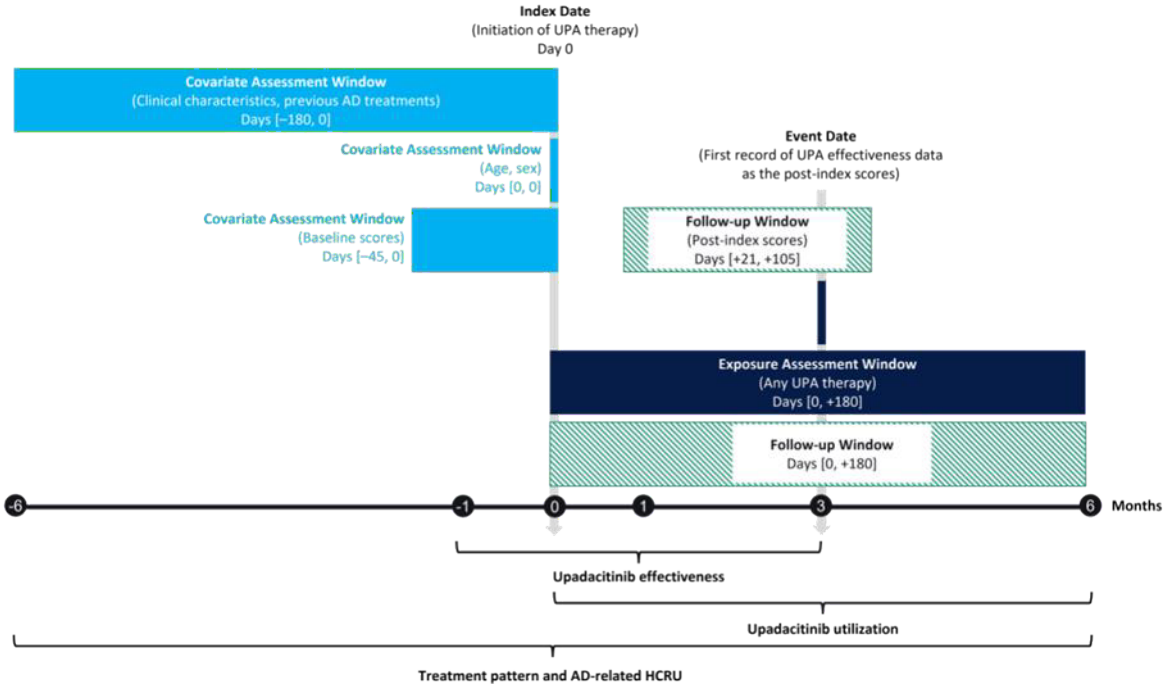
- Study H24-962 A retrospective chart review study in China: REAL-world patient characterISTICs, treatment pattern, clinical outcomes, and healthcare resource utilization in Chinese patients receiving upadacitinib for atopic dermatitis.

2.3.2. Clinical study

Study H24-962

Description

Study design



Methods

Data from 19 August 2021 to 29 June 2024 was used for the study.

Results

Baseline demographics

A total of 150 patients entered the full analysis set (FAS). The mean age of AD patients receiving initiating upadacitinib was 29.5 years, with the majority of patients aged between 12 and 39 years. Specifically, 38.0% of patients were aged 12-17 years, 39.3% were aged 18-39 years. The mean (SD) disease duration time (i.e., the time from the first onset of AD to the time of enrollment) was 3.6 (3.86) years, with a median (interquartile range [IQR]) of 1.7 (0.9- 6.2) years. Based on physician assessment with integration of baseline eczema area and severity index (EASI) or investigator global assessment (IGA) scores for severity stratification, the refined classification identified moderate AD in 36 patients (24.0%), moderate to severe AD in 54 patients (36.0%), and severe AD in 60 patients (40.0%). Among the basic characteristics of AD, pruritus was the most common symptom (129 patients [86.0%]), followed by typical morphology and distribution (95 patients [63.3%]). The concomitant atopic comorbidity with the highest proportion was allergic rhinitis (21 patients [14.0%]).

This study did not target a paediatric population.

Efficacy results

For the primary outcome, 76% (95% confidence interval [CI]: 68.35-82.59) of patients achieved EASI ≤7 or IGA×BSA ≤30 within 3 months of the index date. Clinical outcomes were evaluated based on the post-index scores (EASI, IGA× BSA, IGA, BSA, pruritus numerical rating scale [NRS] or pruritus visual analog scale [VAS]) in a follow-up period of up to 3 months, about 70% of patients achieved mild to clear. Fifty-seven patients (38.0%) achieved EASI ≤3. Seventy-five patients (51.7%), 46 patients (31.7%), and

23 patients (15.9%) achieved BSA <10%, BSA <5% and BSA <2%, respectively. Fifty-nine patients (39.3%) achieved IGA 0/1, including 21 patients (14.5%) with both

IGA 0/1 and BSA ≤2%. Fifty-five patients (37.7%) achieved NRS ≤ 1 or VAS ≤ 1.0. For EASI, IGA×BSA, pruritus NRS, and pruritus VAS score, the median percentage decline from baseline to up to 3 months of follow-up was above 60%, with a 48.40% decrease in IGA score.

Treatment patterns: A total of 80 patients (53.3%) had previous AD treatment, with 78 receiving topical therapy and 64 receiving systemic treatment. A total of 142 patients (94.7%) had concomitant AD treatment, with 139 receiving topical therapy and 97 receiving systemic treatment. Few patients reported other medications or phototherapy. Furthermore, among patients who had concomitant with topical corticosteroids (TCS) and topical calcineurin inhibitor (TCI), the mean TCS/TCI-free, TCS-fee, and TCI-free days were 49.9 (42.08) days, 56.0 (42.61) days, and 50.4 (47.07) days, respectively. The median (95% CI) time to first discontinuation was 2.0 (2.0-2.9) months for TCS and TCI combined, 2.2 (2.0-2.9) months for TCS alone, and 3.7 (2.7-NA) months for TCI alone.

Drug utilization: Most patients (144 [96.0%]) received an initial dose of upadacitinib 15 mg. Thirty-one patients (20.7%) experienced dosage adjustment of upadacitinib, primarily due to disease improvement or stability. The majority of dose adjustments made due to improvement or stability were related to reducing the frequency of administration 108 patients (72.0%) interrupted upadacitinib treatment, but no specific cause was identified. 34.7% of patients discontinued upadacitinib treatment, and the main reasons were disease improvement or stability. A total of 6 patients (4.0%) switched from upadacitinib to another advanced AD therapy, primarily due to inadequate disease control [4 patients [66.7%]). Additionally, 22 patients (14.7%) had a proportion of Proportion of Days Covered values ≥ 80%.

AD-related HCRU 6 months *before and after the initiation of upadacitinib:* The mean (standard deviation [SD]) number of outpatient visits was 3.1 (2.78) before upadacitinib initiation, compared to 4.5 (2.67) after upadacitinib initiation. No patients visited the emergency room or were hospitalized for AD within 6 months before and after upadacitinib initiation. The proportion of patients with any AD-related laboratory tests and examinations before and after upadacitinib initiation was 68.7% and 23.3%, respectively. There was no statistically significant difference in the total number of AD-related laboratory tests and examinations within 6 months before and after upadacitinib initiation, P = 0.7891. However, the total types of AD-related laboratory tests and examinations before upadacitinib treatment were significantly higher than after treatment, P = 0.0048. Of the 105 patients who recorded upadacitinib-related laboratory tests and examinations within 6 months post-initiation, the mean (SD) number was 1.8 (0.95), with a mean (SD) number of types of 11.2 (6.25). The proportion of patients with any upadacitinib-related laboratory test and examination within 6 months after upadacitinib initiation was 70.0%.

Safety results

No safety data were collected in this study.

2.3.3. Discussion on clinical aspects

The assessment of the benefit-risk profile of upadacitinib is not affected by this study. No updates to the Summary of Medicinal Product Characteristics were proposed by the MAH, this was agreed by the CHMP.

3. CHMP overall conclusion and recommendation

☒ **Fulfilled:**

No regulatory action required.