25 June 2026
EMADOC-1700519818-3325357
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/0000337807

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**
☐	CHMP Rapporteur AR	1 June 2026	1 June 2026
☐	CHMP comments	15 June 2026	n/a
☐	Updated CHMP Rapporteur AR	18 June 2026	n/a
☒	CHMP outcome	25 June 2026	25 June 2026

[1] Tick the box corresponding to the applicable step – do not delete any of the steps. If not applicable, add n/a instead of the date.

[2] Criteria for CHMP plenary discussion: substantial disagreement between the Rapporteur and other CHMP members and/or at the request of the Rapporteur or the Chair

Table of contents

1. Introduction

On 12 March 2026, 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 P19-565 (Special Drug use-results survey of evaluating safety and effectiveness of Upadacitinib (Rinvoq) in patients with Rheumatoid Arthritis (RA)) is a stand alone study.

2.2. Information on the pharmaceutical formulation used in the study

The study drug (Rinvoq: RVQ, Upadacitinib: UPA) was not provided by AbbVie; instead, investigators used the commercially available drug as registered in Japan for this Post-marketing Observational Study (PMOS).

2.3. Clinical aspects

2.3.1. Introduction

In accordance with the re-examination system in Japan, under which newly approved drugs are monitored for 8 years, a PMOS was conducted in order to evaluate the safety and efficacy of upadacitinib in patients with RA. This PMOS was conducted based on the GPSP Ordinance (Good Post-marketing Study Practice).

The MAH submitted a final report for:

- P19-565 – Special Drug use-results survey of evaluating safety and effectiveness of Upadacitinib (Rinvoq) in patients with Rheumatoid Arthritis (RA)). All-Patients PMOS with 3-Year Observation for approval condition in Japan.

2.3.2. Clinical study

Description

Study P19-565 was designed as an unblinded, multicenter, prospective, centrally registered, non-interventional, non-comparative, All-Patients PMOS conducted in accordance with GPSP.

The primary objective was to assess/evaluate the safety and effectiveness of upadacitinib in patients with RA in clinical practice.

Secondary objectives were to assess the frequency of serious infection in clinical practice at 24 weeks, to assess the frequency of serious infection, malignancies, major adverse cardiac event (MACE) and venous thromboembolism (VTE) in clinical practice at 3 years, and to evaluate the effectiveness in clinical practice at 24 weeks for patients receiving upadacitinib.

Study size was approximately 1,000 patients who were administered upadacitinib for the treatment of rheumatoid arthritis.

Methods

Study participants

A total of 2739 patients were included in the safety analysis set and 1911 in the effectiveness analysis set. In the safety analysis set, the mean age was 65.76 years, with 5 patients < 18 years, including 1 patient < 15 years. Most patients were female (80.61%) and > 65 years (59.69%).

Paediatric Data

Five paediatric patients (< 18 years) were evaluated in this PMOS Study P19-565: 2 patients in the upadacitinib 7.5 mg/day group and 3 patients in the upadacitinib 15 mg/day group. One patient was < 15 years.

One patient had upadacitinib use > 6 months and < 12 months, 1 patient had upadacitinib use > 30 months and < 36 months, and 3 patients had upadacitinib use for over 36 months. Mean duration of upadacitinib use was 896 days among paediatric patients with a range of 288 to 1,092 days. The mean total exposure to upadacitinib in paediatric patients was 9,804 mg with a range of 2,520 to 16,380 mg.

No AEs were observed in paediatric patients. Of the 5 paediatric patients, 4 patients were included in the effectiveness analysis, and all 4 achieved remission according to DAS28-CRP (Disease Activity Score 28-joint count using C-reactive protein), including the 1 patient < 15 years.

Conclusions by the Applicant

The results of this PMOS support the well-established safety and effectiveness profile of upadacitinib for adult patients with RA. Although adolescent exposure was minimal in this study, upadacitinib was found to be effective and well tolerated in this population. No new or unexpected safety concerns emerged over three years. No additional safety measures are considered necessary at this time. The benefit-risk of upadacitinib is unchanged, and no update to the Summary of Product Characteristics is warranted by the MAH as a result of this Japanese post observational study.

3. CHMP overall conclusion and recommendation

Five patients less than 18 years of age were evaluated in this 3 years Post-marketing Observational Study (PMOS) conducted in Japan to evaluate the safety and efficacy of upadacitinib in patients with RA. No new relevant findings of clinical efficacy or safety were observed, as no AEs were observed in paediatric patients, and the 4 paediatric patients included in the effectiveness analysis achieved remission according to DAS28-CRP, including the 1 patient < 15 years.

The submission of this data under Article 46 of Regulation (EC) No1901/2006 is acknowledged. The MAH has not suggested any update of the Summary of Product Characteristics, which is endorsed by the CHMP. The benefit-risk balance for Rinvoq remains unchanged.

☒ Fulfilled.

No regulatory action required.