13 November 2025
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Human Medicines Division

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

Taltz

Ixekizumab

Procedure no: EMA/PAM/0000293431

Note

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

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1. Introduction

On 22 August 2025, the MAH submitted a completed paediatric study for Taltz, 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

Study I1F-MC-RHCD (RHCD), referred to in the SmPC as "IXORA-Peds" was a Phase 3, multicentre, double-blind, randomised, placebo-controlled study examining the effects of ixekizumab versus placebo in participants from 6 to less than 18 years of age with moderate-to-severe plaque psoriasis.

The MAH stated that Study I1F-MC-RHCD (RHCD) is part of a clinical development program for paediatric psoriasis.

Clinical Study Reports (CSR) from 12 and 48 week database locks have been submitted earlier to the Agency, while the abbreviated CSR (aCSR) provides final study results including data from the safety follow-up period. A copy of the 48 week CSR and the aCSR are submitted in this application.

Three separate CSRs have been prepared for Study RHCD.

- First, the 12-week primary endpoint data provided the foundation of an extension of indication variation seeking the addition of paediatric psoriasis on 15 October 2019. The primary, 12-week CSR with a database lock date of 28 June 2019 was provided with variation, EMEA/H/C/003943/II/0031.
- Subsequently, a 48-week CSR with a database lock date of 25 November 2019 was submitted on 19 May 2020 as the basis for a partial PIP compliance check (C3-001050-PIP01-10-M05, Opinion 31 July 2020).
- Finally, an abbreviated CSR was prepared following the Safety Follow-up Period with a database lock date of 12 May 2021.

Taltz™ (LY2439821, ixekizumab) is a humanised immunoglobulin G subclass 4 monoclonal antibody that binds with high affinity and specificity to interleukin-17A, a proinflammatory cytokine.

Ixekizumab was approved in the EU for the treatment of

- adult patients with moderate-to-severe plaque psoriasis on 25 April 2016 (EMEA/H/C/3943)
- adult patients with active psoriatic arthritis on 18 January 2018 (EMEA/H/C/003943/II/0009)
- adult patients with active radiographic axial spondyloarthritis or non-radiographic axial spondyloarthritis on 02 June 2020 (EMEA/H/C/003943/II/0030).
- paediatric patients (aged 6 years and older with a body weight of at least 25 kg) and adolescents who are candidates for systemic therapy with moderate-to-severe plaque psoriasis on 26 June 2020 (EMEA/H/C/003943/II/0031).

2.2. Information on the pharmaceutical formulation used in the study

Ixekizumab injection (solution for injection) is now available in 2 strengths, 40 and 80 mg injections. Single-dose PFS and single-dose pens for subcutaneous injection, both are available, delivering 80 mg in 1 mL. In addition, ixekizumab as a 40-mg (in 0.5 mL) PFS was approved on 28 March 2025. In countries where the 40-mg PFS is not available, ixekizumab doses of 40 mg must be prepared and administered by a qualified healthcare professional using the commercial ixekizumab 80 mg per mL PFS (Taltz Summary of Product Characteristics).

Formulation used in study I1F-MC-RHCD (RHCD):
Participants received ixekizumab at doses of 20, 40, or 80 mg based on body weight, with starting doses of 40, 80, and 160 mg, respectively. If a participant changed the weight category during the study, the dose was adjusted accordingly.
Ixekizumab was supplied as an injectable solution in 1-mL, single-dose, pre-filled, disposable manual syringes to deliver ixekizumab 80 mg. A lower dose of ixekizumab or placebo was prepared by injecting the contents of the 80-mg syringe into an empty sterile vial, then withdrawing and administering the required volume with a disposable syringe (0.5 mL for 40 mg and 0.25 mL for 20 mg).

2.3. Clinical aspects

2.3.1. Introduction

The MAH submitted final reports (48 week CSR and abbreviated CSR) for:

- Study I1F-MC-RHCD (RHCD): A multicenter, double-blind, randomized, placebo-controlled study to evaluate safety, tolerability, and efficacy of ixekizumab in patients from 6 to less than 18 years of age with moderate-to-severe plaque psoriasis.

2.3.2. Clinical study

Study I1F-MC-RHCD (RHCD): A multicenter, double-blind, randomized, placebo-controlled study to evaluate safety, tolerability, and efficacy of ixekizumab in patients from 6 to less than 18 years of age with moderate-to-severe plaque psoriasis.

Description

Study RHCD was a Phase 3, multicentre, double-blind, randomised, placebo-controlled study examining the effects of ixekizumab versus placebo in participants from 6 to less than 18 years of age with moderate-to-severe plaque psoriasis (PASI score ≥12, sPGA ≥3, and body surface area ≥10% at screening and baseline) and including etanercept as a reference group.

Figure 1 presents the study design (main study). The study consists of 5 periods:

- Period 1: Screening Period (Visit 1), where patient eligibility was assessed and occurred approximately 7 to 30 days before Period 2, Induction (baseline; Week 0; Visit 2).
- Period 2: Double-Blind Treatment Period (Induction Period), from Week 0 (baseline; Visit 2) to Week 12 (Visit 7), inclusive, evaluated the efficacy and safety of ixekizumab compared with placebo.
- Period 3: 48-Week Open-Label Maintenance Period, occurring after Week 12 (Visit 7) to Week 60 (Visit 19), inclusive, assessed the long-term efficacy and safety of ixekizumab. Patients randomized to the ixekizumab group during Period 2, Induction, continued on the dose

received during the previous period. Patients randomized to placebo during Period 2, Induction, received ixekizumab at doses of 20, 40, or 80 mg based on weight.

- Period 4: Extension Period, occurring after Week 60 (Visit 19) to Week 108 (Visit 31), inclusive, assessed long-term efficacy and safety of ixekizumab. Patients continued open-label treatment with ixekizumab at the dose received during the previous period (Period 3). (See the RHCD EU CSR Addendum for details regarding the EU-specific randomized withdrawal phase during Period 4.)
- Period 5: Post-Treatment Follow-Up Period, occurring from the last treatment period visit or Early Termination Visit for up to 24 weeks following that visit. This period is for safety monitoring after treatment discontinuation for any patient receiving at least 1 dose of study drug.

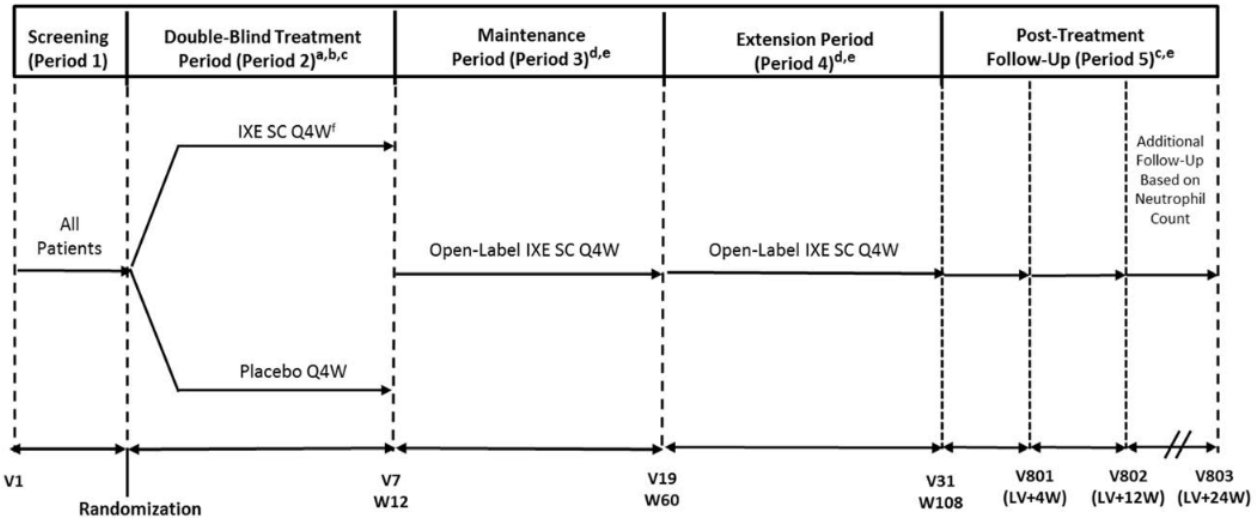

Figure 1. Study design for study I1F-MC-RHCD

Methods

Study participants

In summary, a total of 171 participants were randomly assigned to the 2 treatment groups as the intent-to-treat population:

- 115 participants to ixekizumab Q4W, and
- 56 participants to placebo.

A total of 127 participants (74.3%) completed the study and 44 participants (25.7%) discontinued the study.

Treatments

This study involved a comparison of ixekizumab administered by subcutaneous (SC) injection and placebo (Double-Blind Treatment Period; Period 2), followed by Open-Label Maintenance Period; Period 3) and Extension (or Randomized Withdrawal; see Protocol Addendum I1F-MC-RHCD[2]) Period (Period 4). Table 1 shows the treatment regimens.

Treatment Regimens

	Period 2[a]			Period 3[a]	Period 4[a]
	Week 0	Week 4 and Week 8	Week 12	Week 16 through Week 56	Week 60 through Week 104
Ixekizumab >50 kg	160 mg (two 80-mg SC injections)	80-mg Q4W SC injection	80-mg SC injection + a placebo injection at Week 12	Ixekizumab 80-mg Q4W SC injection	Ixekizumab 80-mg Q4W SC injection OR matching placebo[d]
Ixekizumab 25-50 kg	80-mg SC injection	40-mg Q4W SC injection	40-mg SC injection + a placebo injection at Week 12	Ixekizumab 40-mg Q4W SC injection	Ixekizumab 40-mg Q4W SC injection OR matching placebo[d]
Ixekizumab <25 kg	40-mg SC injection	20-mg Q4W SC injection	20-mg SC injection + a placebo injection at Week 12	Ixekizumab 20-mg Q4W SC injection	Ixekizumab 20-mg Q4W SC injection OR matching placebo[d]
Etanercept[b] All weight groups	0.8 mg/kg, not exceeding 50 mg per dose		No injections because of the washout period	Ixekizumab Q4W SC per weight group above[c]	Ixekizumab Q4W SC per weight group above OR matching placebo[d]
Placebo >50 kg	Placebo for ixekizumab 160 mg (2 placebo SC injections)	Placebo for ixekizumab 80-mg Q4W SC injection	Starting ixekizumab dose: 160-mg (administered as two 80-mg SC injections)	Ixekizumab 80-mg Q4W SC injection	Ixekizumab 80-mg Q4W SC injection OR matching placebo[d]
Placebo 25-50 kg	Placebo for ixekizumab 80-mg SC injection	Placebo for ixekizumab 40-mg Q4W SC injection	Starting ixekizumab dose: 80-mg (administered as two 40-mg SC injections)	Ixekizumab 40-mg Q4W SC injection	Ixekizumab 40-mg Q4W SC injection OR matching placebo[d]
Placebo <25 kg	Placebo for ixekizumab 40-mg SC injection	Placebo for ixekizumab 20-mg Q4W SC injection	Starting ixekizumab dose: 40-mg (administered as two 20-mg SC injections)	Ixekizumab 20-mg Q4W SC injection	Ixekizumab 20-mg Q4W SC injection OR matching placebo[d]

Abbreviations: CSR = clinical study report; EU = European Union; Q4W = every 4 weeks; SC = subcutaneous; sPGA = static Physicians Global Assessment.

[a] See Section 9.1 for a description of the study periods.

[b] Etanercept treatment group only for patients participating in Protocol Addendum I1F-MC-RHCD(2). In this CSR, data for these patients are summarized as part of the All Ixekizumab Safety Population.

[c] From Week 20.

[d] From Week 60, for patients from the EU who meet response criteria (sPGA 0,1) and are randomised to ixekizumab or placebo (per Protocol Addendum I1F-MC-RHCD[2]).

Objective(s)

Primary

The primary objective was to assess whether ixekizumab Q4W was superior to placebo at Week 12 (Visit 7) in the treatment of paediatric participants (children and adolescents) with moderate-to-severe plaque psoriasis as measured by PASI 75 and by sPGA (0,1).

Other secondary objectives

- To assess whether ixekizumab Q4W is superior to placebo as measured by the
  *proportion of participants achieving PASI 50, PASI 75, PASI 90, and PASI 100
  *proportion of participants achieving sPGA (0,1) and sPGA (0)
  *change from baseline in itching severity (Itch Numeric Rating Scale) score
  *proportion of participants achieving Children's Dermatology Life Quality Index or Dermatology Life Quality Index (0,1), and
  *change from baseline in Nail Psoriasis Severity Index, Psoriasis Severity Index, and/or Palmoplantar Psoriasis Severity Index score in case of nail, scalp, or hand/feet involvement.
- To summarise the efficacy of ixekizumab Q4W at Week 24 (Visit 10) and Week 48 (Visit 16) as measured by
  *PASI 75
  *sPGA (0,1)
  *PASI 90
  *sPGA (0), and
  *PASI 100.
- To evaluate the potential development of anti-ixekizumab antibodies and its impact on participant efficacy of ixekizumab.

- To measure ixekizumab exposure and characterise the pharmacokinetics of ixekizumab in paediatric participants.
- To assess the relationship between exposure and efficacy and exposure and immunogenicity.
- To assess the safety of ixekizumab.

Results

Efficacy results

Primary efficacy analysis

The study achieved its co-primary objective of PASI 75 and sPGA (0,1) at Week 12.

The efficacy results at week 12 are presented in Table 2 (table from SmPC section 5.1).

Table 1. Efficacy results in pediatric patients with plaque psoriasis, NRI

Endpoints	Ixekizumab[a] (N=115) n (%)	Placebo (N=56) n (%)	Difference vs placebo (95% CI)	Etanercept[b] (N=30) n (%)	Difference vs etanercept (95% CI)[b]
sPGA "0" (clear) or "1" (almost clear)[c]					
week 4	55 (48)	4 (7)	40.7 (29.3, 52.0)[f]	0(0)	36.8 (21.5, 52.2)
week 12[c]	93 (81)	6 (11)	70.2 (59.3, 81.0)[f]	16 (53)	23.0 (0.6, 45.4)
sPGA "0" (clear)[d]	60 (52)	1 (2)	50.4 (40.6, 60.2)[f]	5 (17)	46.5 (26.2, 66.8)
PASI 75					
week 4	62 (54)	5 (9)	45.0 (33.2, 56.8)[f]	3 (10)	34.7 (15.6, 53.8)
week 12[c]	102 (89)	14 (25)	63.7 (51.0, 76.4)[f]	19 (63)	20.9 (0.1, 41.7)
PASI 90[d]	90 (78)	3 (5)	72.9 (63.3, 82.5)[f]	12 (40)	36.3 (14.2, 58.5)
PASI 100[d]	57 (50)	1 (2)	47.8 (38.0, 57.6)[f]	5 (17)	43.9 (23.4, 64.3)
Itch NRS (≥4 point improvement)[d, e]	59 (71)	8 (20)	51.1 (35.3, 66.9)[f]	Not evaluated	---

The ixekizumab treatment group had statistically significant and clinically meaningful higher PASI 75 responses versus the placebo group at Week 12 (non-responder imputation):

- 88.7%, ixekizumab Q4W ($p<0.001$ vs placebo), and
- 25.0%, placebo.

The ixekizumab treatment group had statistically significant and clinically meaningful higher sPGA (0,1) responses versus the placebo group at Week 12 (non-responder imputation):

- 80.9%, ixekizumab Q4W ($p<0.001$ vs placebo), and
- 10.7%, placebo.

Secondary efficacy analysis

Statistically significant and clinically meaningful improvements in efficacy were observed for the ixekizumab Q4W treatment group compared with the placebo group across the co-primary and all gated secondary objectives, measured by PASI and sPGA. The results from other secondary efficacy and health outcome measures were consistent with, and supportive of, the co-primary and gated secondary endpoint results.

The results from most of the tertiary/exploratory efficacy and health outcome measures were consistent and supportive of the other efficacy endpoint results. Significant improvements were observed at Weeks 60 and 108 for PASI and sPGA.

The results of PASI75 and sPGA (0,1) at weeks 60 and 108 were as follows:

The proportion of patients achieving PASI 75 at Weeks 60 and 108 (NRI) were

- 83.0% (Week 60), and
- 76.6% (Week 108).

The proportion of patients achieving sPGA (0,1) at Weeks 60 and 108 (NRI) were

- 74.5% (Week 60), and
- 68.1% (Week 108).

For participants initially randomly assigned to ixekizumab at Week 0, who received ixekizumab throughout the study (intent-to-treat population), clinically meaningful improvements in efficacy and health outcome endpoints were sustained through Week 108.

In addition, for the double-blind, randomised withdrawal period, the proportion of participants relapsing to sPGA ≥2 was significantly greater in the placebo group compared with the ixekizumab Q4W treatment group.

In conclusion, the ixekizumab Q4W group demonstrated efficacy across multiple endpoints, with clinically meaningful improvements, in the treatment of paediatric participants from 6 to less than 18 years of age with moderate-to-severe plaque psoriasis. Additional details were provided in the primary 12-week CSR RHCD, 48-week CSR RHCD, and final abbreviated CSR RHCD.

Safety results

Complete safety results were provided in the primary 12-week CSR RHCD, 48-week CSR RHCD, and final abbreviated CSR RHCD.

Exposure

During the Combined Treatment Periods (Periods 2, 3, and 4), a total of 196 patients were treated with at least 1 dose of ixekizumab Q4W, representing a total of 342.8 years of patient-years of exposure, which includes 181patients who were treated with ixekizumab for at least 1 year. The mean patient-days of exposure was 638.8 days.

Adverse events

During the Combined Treatment Periods (Periods 2, 3, and 4), TEAEs were reported in 87.8% of all participants and most TEAEs were either mild (41.3%) or moderate (40.3%) in severity. Severe TEAEs were reported by 6.1% of all ixekizumab-treated participants. The percentage of participants with TEAEs judged by the investigator to be related to study treatment was 41.3%.

The most frequent TEAEs reported in at least 10% of ixekizumab-treated participants by preferred term were

- Nasopharyngitis (21.9%)
- Upper respiratory tract infection (20.9%)
- Injection site reaction (16.8%)
- Headache (15.3%), and
- Pharyngitis (11.2%).

During the 48-Week, Double-Blind Randomized Withdrawal Period (Period 4), TEAEs were reported in 73.5% of participants in the ixekizumab Q4W group and 60.6% of participants in the placebo group. The percentage of participants with TEAEs judged by the investigator to be related to study treatment was 17.6% in the ixekizumab Q4W group and 18.2% in the placebo group. Most TEAEs were mild (52.9% in the ixekizumab Q4W group and 39.4% in the placebo group) or moderate (17.6% in the ixekizumab Q4W group and 18.2% in the placebo group) in severity. Severe TEAEs were reported by 2.9% of participants in the ixekizumab Q4W group and 3.0% of participants in the placebo group. The most frequent TEAE, reported in at least 10% of ixekizumab-treated participants, by preferred term was Nasopharyngitis (32.4% in the ixekizumab Q4W group and 12.1% in the placebo group).

During the Post-Treatment Follow-Up Period (Period 5), at least 1 follow-up-emergent adverse event (FEAE) was reported in 14.8% of participants in the ixekizumab Q4W group. In the ixekizumab group, psoriasis (2.4%) was the only follow-up-emergent adverse event reported in more than 1 participant, all other follow-up-emergent adverse events were reported in 1 participant each.

Deaths

No deaths were reported during the study.

Serious adverse events

During the Combined Treatment Periods (Periods 2, 3, and 4), SAEs occurred in 7.7% of the patients. The most frequently reported SAEs were

- Splenic rupture (2 participants)
- Crohn's disease (2 participants), and
- Dehydration (2 participants).

During the 48-Week, Double-Blind, Randomized Withdrawal Period (Period 4), SAEs were reported in 8.8% of the patients in the ixekizumab Q4W group. No SAEs were reported in the placebo group.

Discontinuations

During the Combined Treatment Periods (Periods 2, 3, and 4), discontinuations of ixekizumab due to an adverse event occurred in 2.6% of the participants, which included

- Crohn's disease n = 2 (1.0%)
- Pityriasis rubra pilaris n = 1 (0.5%)
- Psoriasis n = 1 (0.5%), and
- Astrocytoma n = 1 (0.5%).

Adverse events of special interest

During the Combined Treatment Periods (Periods 2, 3, and 4), the most frequently reported categories of AESIs were as follows:

- Infections: n = 145 (74.0% [Incidence rate =42.3]). One ixekizumab- treated patient (0.5%) reported a TEAE of Varicella zoster virus infection and 1 ixekizumab-treated patient (0.5%) reported a TEAE of Herpes simplex. None of these were categorized as opportunistic infections.
- Injection-site reactions: n = 40 (20.4% [Incidence rate =11.7])
- Allergic reactions/hypersensitivities: n = 20 (10.2% [Incidence rate =5.8])
- Depression: n = 8 (4.1% [Incidence rate =2.3])
- Inflammatory Bowel Disease (adjudicated as probable Crohn's disease): n = 4 (2.0% [Incidence rate =1.2])
- Hepatic events (enzyme abnormalities and hepatic steatosis): n = 4 (2.0% [Incidence rate =1.2])
- Cytopenias: n = 3 (1.5% [Incidence rate =0.9]). Three patients (1.5%) reported Neutropenia (PT) and 1 of these patients also reported Leukopenia.
- Malignancies: n = 1 (0.5% [Incidence rate =0.3]). One patient was hospitalized and discontinued due to astrocytoma.

During the 48-Week, Double-Blind, Randomized Withdrawal Period (Period 4), the most frequently reported category of AESIs was Infections, which was reported more frequently in the ixekizumab Q4W group (58.8%) than in the placebo group (30.3%).

Pharmacokinetics

Mean ixekizumab trough concentrations at predicted steady state were consistent over time and across weight dosing groups, with geometric mean concentrations in the range of 2.49 to 3.44 µg/mL for the 25- to 50-kg and >50-kg groups, see Figure 2. There were insufficient PK data for the <25-kg group to be able to summarize the data.

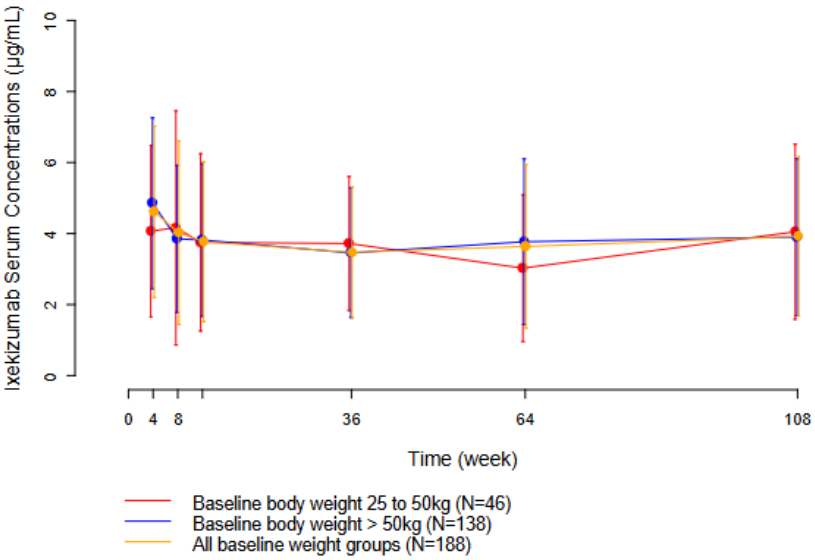

Figure 2. Mean (SD) ixekizumab serum trough concentrations versus protocol time from Weeks 0 to 108 by baseline weight category for pediatric patients randomized to ixekizumab Q4W

Immunogenicity

Immunogenicity findings were consistent with the known profile of ixekizumab. Antidrug antibodies had no clinically meaningful impact on efficacy or safety.

The MAH's conclusions

The ixekizumab group demonstrated consistently greater efficacy across multiple endpoints, with statistically significant and clinically meaningful improvements in the treatment of paediatric participants (aged 6 to less than 18 years) with moderate-to-severe plaque psoriasis compared with placebo, as well as sustained improvements through Week 108 for participants who received ixekizumab throughout the study.

The observed safety profile for paediatric participants from 6 to less than 18 years of age with moderate-to-severe plaque psoriasis in this global, multicentre study was consistent with that reported for ixekizumab in adult participants with moderate-to-severe plaque psoriasis, psoriatic arthritis, and radiographic axial spondyloarthritis, except for Crohn's disease (2.0%), conjunctivitis (8.2%), influenza (6.6%), and urticaria (2.6%), which were reported at a higher frequency in paediatric participants with psoriasis.

Ixekizumab has demonstrated clinically meaningful and statistically significant improvements in skin clearance, itch, and quality of life. These improvements were seen rapidly and were sustained in participants for up to Week 108. While there is a risk for infection and Inflammatory Bowel Disease, the risk profile for paediatric participants is consistent with the known safety profile for ixekizumab described in the currently approved EU labelling, and the risks do not outweigh the substantial clinical benefits observed with ixekizumab.

Summary of Product Characteristics Proposal/Justification

As discussed, registration of the paediatric psoriasis indication was based on the Study RHCD 12-week primary endpoint data. Following internal review of the Study RHCD 48-week and end-of-study data, the MAH concluded that additional revisions to the ixekizumab SmPC were neither warranted nor desired. Furthermore, with this Article 46 submission, no SmPC changes are requested.

2.3.3. Discussion on clinical aspects

The 12-week primary endpoint data from study I1F-MC-RHCD was provided with variation EMEA/H/C/003943/II/0031 (extension of indication with addition of paediatric psoriasis) and assessment of data resulted in approval of the indication "Paediatric plaque psoriasis (age 6 years and above)".

The efficacy and safety results from the 12-week part of the study (period 2) are presented in the SmPC of Taltz, section 5.1 and 4.8, respectively.

Now the final study results from study I1F-MC-RHCD have been provided including results from period 3 (48-week open-label maintenance period), period 4 (extension period including withdrawal phase) and period 5 (safety follow-up period).

The secondary efficacy analysis at week 60 (period 3) and week 108 (period 4) demonstrated sustained improvements at weeks 60 and 108 in the parameters PASI 75 and sPGA (0,1).

The safety results including the combined treatment periods (periods 2, 3, and 4), were consistent with the previously reported safety data from period 2 only.

In conclusion, the final study results following 108 weeks do not indicate reduced efficacy or additional safety issues following long-term treatment compared to previously reported results following 12-weeks treatment.

SmPC:

The MAH did not propose any revisions to the SmPC, which is not fully agreed. The fact that the study has continued for 108 weeks is important information and should be reflected in section 5.1 of the SmPC. It would be useful to add a brief description of the study design for the additional treatment periods, along with information on the sustained efficacy in the parameters PASI 75 and sPGA (0,1) observed over 108 weeks.

Also, the information in section 4.8 of the SmPC regarding patient years of exposure should be updated from the present number of 207 to 343 patient years of exposure.

3. CHMP overall conclusion and recommendation

The benefit-risk of ixekizumab is unchanged.

The final study results of study I1F-MC-RHCD including dosing over 108 weeks were consistent with the previously reported results of period 1 (12 weeks of dosing) which is described in section 5.1 of the SmPC. No new safety risks were observed and the results of the efficacy parameters PASI 75 and sPGA (0,1) were sustained following long-term treatment.

No update to the Summary of Product Characteristics has been proposed by the applicant based on these data. This is not agreed since it is considered valuable to include information that the study has continued for 108 weeks.

The MAH is requested to submit a variation to update SmPC sections 4.8 and 5.1 with the following information:

- The fact that the study has continued for 108 weeks is important information and should be reflected in section 5.1 of the SmPC. It would be useful to add a brief description of the study design for the additional treatment periods, along with information on the sustained efficacy in the parameters PASI 75 and sPGA (0,1) observed over 108 weeks.
- The information in section 4.8 of the SmPC regarding patient years of exposure should be updated from the present number of 207 to 343 patient years of exposure.

In line with the above, the MAH has confirmed its intent to submit a Type II C.I.3.b variation no later than 60 days after the receipt of these conclusions.

☒ **Fulfilled:**

In view of the available data regarding the paediatric population in study I1F-MC-RHCD with Taltz, the MAH should either submit a variation in accordance with Articles 16 and 17 of Regulation (EC) No 726/2004 or provide a justification for not doing so. This should be provided without any delay and ***no later than 60 days after the receipt*** of these conclusions.