21 May 2026
EMADOC-1700519818-3257335
Human Medicines Division

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

Anzupgo

Delgocitinib

Procedure no: EMA/PAM/0000335934

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	28 April 2026	23 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

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1. Introduction

On 6 March 2026, the MAH submitted results for one adolescent patient enrolled in a completed clinical study for Anzupgo, 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 study LP0133-2283: "A phase 3 trial to evaluate efficacy, safety, and pharmacokinetics of twice-daily applications of delgocitinib cream 20 mg/g in chinese adults and adolescents (12-17 years of age) with moderate to severe chronic hand eczema" was not part of the delgocitinib CHE PIP, but part of the clinical development program of delgocitinib for CHE, and was conducted to support a MAA of Anzupgo in China. 1 adolescent was randomised in the trial.

A separate Type II variation is ongoing to evaluate the CHE indication extension to include the adolescent patient group 12-17 years of age based on the Adolescent Study LP0133-1426 DELTA TEEN (EMA/VR/0000315280).

2.2. Information on the pharmaceutical formulation used in the study

According to the MAH, since the excipients used in the topical cream formulation of delgocitinib are considered safe for pediatric participants, a pediatric-specific formulation has not been considered necessary. The 20 mg/g cream formulation has been used in all phase 3 clinical trials sponsored by the MAH.

2.3. Clinical aspects

2.3.1. Introduction

The MAH submitted results for one adolescent patient that was enrolled in the Phase 3 study conducted in China to evaluate efficacy, safety, and PK (PK in adults only) of delgocitinib cream 20 mg/g in Chinese adults and adolescents with moderate to severe CHE:

- LP0133-2283: "A Phase 3 Trial to Evaluate Efficacy, Safety, and Pharmacokinetics of Twice-Daily Applications of Delgocitinib Cream 20 mg/g in Chinese Adults and Adolescents (12-17 Years of Age) with Moderate to Severe Chronic Hand Eczema"

In addition, the protocol of the study has been submitted.

According to the MAH, the clinical trial was conducted in compliance with the clinical trial protocol, ICH GCP, and the applicable regulatory requirement(s).

2.3.2. Clinical study

Clinical study number and title

LP0133-2283: "A Phase 3 Trial to Evaluate Efficacy, Safety, and Pharmacokinetics of Twice-Daily Applications of Delgocitinib Cream 20 mg/g in Chinese Adults and Adolescents (12-17 Years of Age) with Moderate to Severe Chronic Hand Eczema"

Description

Methods

Trial 2283 was a confirmatory clinical trial conducted in China. The trial had a randomised (2:1), double-blind, vehicle-controlled treatment period of 16 weeks, followed by an open-label as-needed treatment period of 36 weeks. The trial was designed to include Chinese adults and adolescents with moderate to severe CHE.

The design of the 16-week treatment period was similar to that of the phase 3 trials in adults (Trials 1401 and 1402) and adolescents (Trial 1426), and the design of the 36-week treatment period was similar to that of the long-term extension trial in adults (Trial 1403). In addition, the key eligibility criteria in Trial 2283 were similar to those in Trials 1401, 1402, and 1426, with few exceptions:

- Trial 2283 included both adults (aged ≥18 years) and adolescents (aged 12-17 years), whereas Trials 1401 and 1402 included only adults (aged ≥18 years) and Trial 1426 included only adolescents (aged 12-17 years).
- Trial 2283 included an inclusion criterion of a HESD itch score (weekly average) of ≥4 points. This criterion was also included in Trials 1401 and 1402, but not in Trial 1426.
- Trial 2283 prohibited treatment with traditional Chinese medicines (including herbals) (systemic: within 28 days prior to baseline; cutaneously applied on the hands: within 14 days prior to baseline).

Results

One adolescent with severe CHE at baseline was randomised in Trial 2283. The adolescent was randomised to delgocitinib cream 20 mg/g in the 16-week treatment period and continued on-treatment in the open-label treatment period until end of trial (Week 52).

Efficacy results

The efficacy results for the adolescent participant are presented in Table 1. The efficacy measures rated severity and extent of CHE (IGA-CHE and HECSI), and severity of CHE signs and symptoms (HESD). The results are observed data.

Table 1. Overview of efficacy results for the adolescent randomised in Trial 2283

Efficacy measures	Baseline	Week 16	Week 52
IGA-CHE			
IGA-CHE score	4	2	1
IGA-CHE TS	-	No[a]	Yes
HECSI			
HECSI score	64	12	3
HECSI-90	-	No[b]	Yes
HECSI-75	-	Yes[b]	Yes
Percent change in HECSI score from baseline	-	-81.25%[b]	-95.31%
HESD			
HESD itch score (weekly average)	5.286	2.000	1.400
Reduction of HESD itch score (weekly average) of ≥4-points from baseline	-	No[b]	No
HESD pain score (weekly average)	5.000	2.000	1.400
Reduction of HESD pain score (weekly average) of ≥4-points from baseline	-	No[b]	No
HESD score (weekly average)	4.976	2.000	1.433

Reduction of HESD score (weekly average) of ≥4-points from baseline	-	No[b]	No

Notes: 'Yes/no' denotes whether the endpoint was achieved or not. **a** = primary endpoint result; **b** = key secondary endpoint result.

Abbreviations: HECSI = Hand Eczema Severity Index; HECSI-75/90 = at least 75%/90% improvement in HECSI score from baseline; HESD = Hand Eczema Symptom Diary; IGA-CHE = Investigator's Global Assessment for chronic hand eczema; IGA-CHE TS = IGA-CHE treatment success i.e. an IGA-CHE score of 0 (clear) or 1 (almost clear) with a ≥2-step improvement from baseline.

Safety results

According to the MAH, there were no safety concerns for the adolescent participant in Trial 2283, based on the evaluation of AEs, laboratory data, vital signs, and ECG for up to 16 weeks of treatment and up to 36 weeks of as needed treatment with delgocitinib cream 20 mg/g.

3 AEs were reported for the adolescent. The AEs were reported during the 16-week treatment period and were based on abnormal laboratory values. All 3 AEs were mild, assessed as not related to IMP by the investigator, did not require any treatment, and no action was taken with the IMP. 2 out of 3 events were resolved at the end of the trial.

2.3.3. Discussion on clinical aspects

Trial 2283 was a study conducted in CHE including both adults and adolescents to support MAA of delgocitinib in China. One adolescent was enrolled in the study. To adhere to the requirements from Article 46 of the Paediatric Regulation, the MAH has now submitted the results from this one adolescent patient randomised to the study.

No relevant conclusions can be drawn from the results in one adolescent patient enrolled in Trial 2283; no further regulatory action is requested. The potential extension of indication of delgocitinib in adolescents with CHE is currently being evaluated based on Study LP0133-1426 DELTA TEEN (EMA/VR/0000315280).

3. CHMP overall conclusion and recommendation

☒ **Fulfilled:**

No regulatory action required.