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

Anzupgo

Delgocitinib

Procedure no: EMA/PAM/0000280076

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	25 August 2025	27 June 2025
☐	CHMP comments	8 September 2025	n/a
☐	Updated CHMP Rapporteur AR	11 September 2025	n/a
☒	CHMP outcome	18 September 2025	18 September 2025

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1. Introduction

On 13 June 2025, the MAH submitted a completed paediatric 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 study LP0133-1426: "A phase 3 clinical trial to evaluate efficacy and safety of twice-daily applications of delgocitinib cream 20 mg/g compared with cream vehicle for a 16-week treatment period in adolescents 12-17 years of age with moderate to severe chronic hand eczema (DELTA TEEN)" is part of a clinical development program.

The MAH is planning to submit a type II variation to amend the product information based on the DELTA TEEN results by 03 December 2025.

A line listing of the concerned study is annexed.

2.2. Information on the pharmaceutical formulation used in the study

The same cream formulation has been used in all phase 3 clinical trials by the MAH. As the excipients used in the topical cream formulation of delgocitinib cream are considered safe for paediatric subjects, a paediatric specific formulation has not been considered necessary by the MAH.

2.3. Clinical aspects

2.3.1. Introduction

The MAH submitted a clinical trial report for:

- Study LP0133-1426 "A phase 3 clinical trial to evaluate efficacy and safety of twice-daily applications of delgocitinib cream 20 mg/g compared with cream vehicle for a 16-week treatment period in adolescents 12-17 years of age with moderate to severe chronic hand eczema (DELTA TEEN)"

2.3.2. Clinical study

Only topline results are described below, as the evaluation of Trial DELTA TEEN and possible modifications to the product information will be conducted once the complete variation package, including relevant clinical summaries, is submitted.

Clinical study number and title

Study LP0133-1426: "A phase 3 clinical trial to evaluate efficacy and safety of twice-daily applications of delgocitinib cream 20 mg/g compared with cream vehicle for a 16-week treatment period in adolescents 12-17 years of age with moderate to severe chronic hand eczema (DELTA TEEN)"

Description

Trial 1426 is the first trial to evaluate the efficacy and safety of delgocitinib cream 20 mg/g in adolescents 12-17 years of age with moderate to severe chronic hand eczema (CHE) for whom topical corticosteroids (TCS) are inadequate or inappropriate.

Methods

Study participants

The key eligibility criteria in Trial 1426 were the same as those in the pivotal trials, except the inclusion criteria regarding age (12-17 years of age in Trial 1426 and age 18 years or above in the pivotal trials) and a HESD itch score (weekly average) of ≥4 points at baseline (included in the pivotal trials, but not in Trial 1426). Further, the trial design of Trial 1426 was also similar to that of the pivotal trials (randomised, double-blind, vehicle-controlled phase 3 trials in subjects with moderate to severe CHE who were treated with delgocitinib cream 20 mg/g or cream vehicle twice daily for 16 weeks).

Results

Efficacy results

The results of the hierarchically evaluated primary and key secondary endpoints in Trial 1426 are presented in Table 1. Identical primary and key secondary endpoints were also evaluated in the testing hierarchy in the pivotal trials. These endpoints are based on efficacy assessments that cover different aspects of CHE, including objective measures of CHE (severity and extent of CHE, as assessed by the IGA-CHE and HECSI instruments), and subjective measures of CHE (severity of CHE signs and symptoms, as assessed by the HESD instrument).

Table 1. Summary of efficacy results for the primary and key secondary endpoints in Trial 1426

Assessment Binary endpoints	Delgocitinib cream 20 mg/g Responders/N (%)	Cream vehicle Responders/N (%)	Treatment difference in percentage (95% credibility interval)[a]	Probability[b]
IGA-CHE				
Primary endpoint				
IGA-CHE TS at Week 16	47/74 (63.5%)	7/24 (29.2%)	37.9% (13.5% to 58.2%)	0.999
HECSI				
Key secondary endpoint				
HECSI-90 at Week 16	53/74 (71.6%)	9/24 (37.5%)	36.4% (12.3% to 59.9%)	0.999
HESD				
Key secondary endpoints				
Reduction of HESD itch score (weekly average) of ≥4 points from baseline at Week 16[c]	35/54 (64.8%)	7/19 (36.8%)	31.7% (5.6% to 51.1%)	0.989
Reduction of HESD pain score (weekly average) of ≥4 points from baseline at Week 16[d]	31/49 (63.3%)	5/15 (33.3%)	31.2% (8.7% to 49.4%)	0.994
Reduction of HESD score (weekly average) of ≥4 points from baseline at Week 16[e]	30/54 (55.6%)	5/16 (31.3%)	25.1% (3.9% to 42.3%)	0.986

Abbreviation: HECSI-90 = at least 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; N = number of subjects with data available at baseline.

Notes: The Bayesian analysis of the composite estimand for the primary and key secondary endpoints were considered the confirmatory evidence for the trial and were evaluated hierarchically. **a** = The 95% credibility interval is generated as the 2.5% and 97.5% quantiles of the difference in posterior distributions. Delgocitinib cream 20 mg/g is considered superior to cream vehicle if the 2.5% percentile of the posterior distribution of the treatment difference is ≥0. **b** = Probability that the difference in posterior distributions between delgocitinib cream 20 mg/g minus cream vehicle is larger than zero.. **c** = Among subjects with a baseline HESD itch score (weekly average) ≥4 points. **d** = Among subjects with a baseline HESD pain score (weekly average) ≥4 points. **e** = Among subjects with a baseline HESD score (weekly average) ≥4 points.

Safety results

The overall summary the AEs is shown in Table 2.

Table 2. AEs - overall summary – SAF

Overall summary	Delgocitinib cream 20 mg/g (N=74, PYO=25.76)			Cream vehicle (N=24, PYO=8.18)		
	n (%)	E	R	n (%)	E	R
AEs	37 (50.0%)	77	298.88	8 (33.3%)	19	232.33
SAEs	0	0		0	0	
Deaths	0	0		0	0	
Severity						
Mild	32 (43.2%)	48	186.31	6 (25.0%)	7	85.60
Moderate	13 (17.6%)	29	112.56	6 (25.0%)	9	110.05
Severe	0	0		3 (12.5%)	3	36.68
Related to IMP[a]	2 (2.7%)	2	7.76	2 (8.3%)	3	36.68
AEs leading to withdrawal from trial or permanent discontinuation of IMP	2 (2.7%)	2	7.76	1 (4.2%)	1	12.23
AEs leading to withdrawal from trial	2 (2.7%)	2	7.76	0	0	
AEs leading to permanent discontinuation of IMP	2 (2.7%)	2	7.76	1 (4.2%)	1	12.23
Outcome						
Not recovered/Not resolved	3 (4.1%)	4	15.53	2 (8.3%)	2	24.46
Recovering/Resolving	1 (1.4%)	1	3.88	1 (4.2%)	1	12.23
Recovered/Resolved	36 (48.6%)	72	279.47	7 (29.2%)	16	195.65
Lesional/perilesional[b] AEs	8 (10.8%)	8	31.05	2 (8.3%)	3	36.68
Most frequently reported SOC						
Infections and infestations	27 (36.5%)	36	139.73	7 (29.2%)	8	97.82
Most frequently reported AEs[c] by PT						
PT nasopharyngitis	10 (13.5%)	12	46.58	4 (16.7%)	4	48.91
PT upper respiratory tract infection	5 (6.8%)	5	19.41	0	0	
PT headache	4 (5.4%)	4	15.53	1 (4.2%)	1	12.23

Abbreviations: AE = adverse event; E = number of events; IMP = investigational medicinal product; N = number of subjects; n = number of subjects with events; PT = preferred term; PYO = patient years of observation; R = rate (E/PYO×100); SAE = serious adverse event; SAF = safety analysis set; SOC = system organ class; % = percentage of subjects with events.

Notes: **a** = Considered possibly or probably related by the investigator. **b** = ≤2 cm from the border of lesion(s) treated with IMP. **c** = Reported in ≥5% of subjects.

2.3.3. Discussion on clinical aspects

In accordance with Article 46 of Regulation (EC) No 1901/2006, as amended, the MAH has submitted the final report of study LP0133-1426. The study LP0133-1426 (DELTA TEEN) is a phase 3 clinical trial to evaluate efficacy and safety of twice-daily applications of delgocitinib cream 20 mg/g compared with cream vehicle for a 16-week treatment period in adolescents 12-17 years of age with moderate to severe chronic hand eczema (CHE).

After finalisation of this procedure, the MAH intends to submit a type II variation by 03 December 2025 to apply for an extension of the indication to include treatment of adolescents aged 12-17 years with moderate to severe CHE for whom TCS is medically inadvisable or inappropriate.

In this procedure, only the topline results of the DELTA TEEN study results are outlined, as presented by the MAH. The evaluation of Trial 1426 and possible modifications to the product information will be conducted once the complete variation package, including relevant clinical summaries, is submitted for assessment.

3. CHMP's overall conclusion and recommendation

☒ **Fulfilled:**

No further action required. Nevertheless, the MAH committed to submit a type II variation with the DELTA TEEN results to support an extension of the indication in the adolescent population with CHE. The CHMP will assess the full dataset in further details in the context of this type II variation before any conclusion on the product information amendments can be made.

Annex. Line listing of all the studies included in the development program

The studies should be listed by chronological date of completion:

Clinical studies

Product Name: Anzupgo Active substance: delgocitinib

Study title	Study number	Date of completion	Date of submission of final study report
A phase 3 clinical trial to evaluate efficacy and safety of twice-daily applications of delgocitinib cream 20 mg/g compared with cream vehicle for a 16-week treatment period in adolescents 12-17 years of age with moderate to severe chronic hand eczema (DELTA TEEN)	LP0133-1426	17-Dec-2024	13-Jun-2025