EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

11 December 2025
EMADOC-1700519818-2769286
Human Medicines Division

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

Cosentyx

Secukinumab

Procedure no: EMA/PAM/0000301644

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**
☐	Start of procedure	13 October 2025	13 October 2025
☐	CHMP Rapporteur Assessment Report	17 November 2025	13 November 2025
☐	CHMP members comments	1 December 2025	n/a
☐	Updated CHMP Rapporteur Assessment Report	4 December 2025	n/a
☒	CHMP adoption of conclusions:	11 December 2025	11 December 2025

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1. Introduction

On 15 September 2025, the MAH submitted completed paediatric study for Cosentyx, 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 No. CAIN457A2406 (also referred as Study A2406) is a stand-alone study.

2.2. Information on the pharmaceutical formulation used in the study

The patients received Cosentyx 75 mg, 150 mg or 300 mg, which are all approved strengths for treating pediatric plaque psoriasis in China.

2.3. Clinical aspects

2.3.1. Introduction

The MAH submitted a final report for:

- Study No. CAIN457A2406: "*A real-world, prospective, multicenter study to assess the safety and effectiveness of secukinumab (Cosentyx) in patients aged 6 to less than 18 years with moderate to severe chronic plaque psoriasis in China*"

Foe further details, see below.

2.3.2. Clinical study

Clinical study number and title

Study No. CAIN457A2406: "*A real-world, prospective, multicenter study to assess the safety and effectiveness of secukinumab (Cosentyx) in patients aged 6 to less than 18 years with moderate to severe chronic plaque psoriasis in China*"

Description

This was a non-interventional, prospective, multi-center, real-world setting study, aiming to provide safety and effectiveness data in Chinese pediatric patients with moderate to severe chronic plaque psoriasis treated with Cosentyx for up to 52 weeks. Data from medical records, including safety and effectiveness information on Cosentyx (e.g., AE, SAE, physical examinations, laboratory tests, disease assessments, etc.) were collected in real clinical practice at each routine visit.

- First patient first visit: 08-Sep-2022
- Last patient last visit: 27-Feb-2025

Methods

Study participants

Chinese pediatric patients with moderate to severe chronic plaque psoriasis who were about to initiate Cosentyx or had started Cosentyx within 4 weeks of enrollment and met the eligibility criteria were enrolled.

Key inclusion criteria:

- Written assent and informed consent must be obtained as per local regulations prior to any study procedures
- Diagnosed with moderate to severe plaque psoriasis
- Initiating treatment with Cosentyx or having started Cosentyx treatment within the last 4 weeks in routine clinical practice, and its prescription is independent of this study.
- Aged 6 to less than 18 years at the time they are prescribed Cosentyx.
- Have valid Psoriasis Area and Severity Index (PASI) and Investigator's Global Assessment, modified 2011 (IGA mod 2011) score at the time they are prescribed Cosentyx.

Key exclusion criteria:

- Patients previously treated with other biologics.
- Patients participating in other clinical trials or who previously participated in clinical trials within 30 days before Cosentyx initiation or a period of 5 half-lives of the investigational drug, whichever is longer.
- Patients in conditions which, in the judgment of the clinical investigator, render the patient unsuitable for the study.

Treatments

The dosage of secukinumab used was up to the judgement of the investigator, with no restriction or any other involvement by the MAH. The MAH did not provide the study treatment to patients.

Objective(s)

To provide safety and effectiveness data of secukinumab in Chinese children and adolescents (6 to <18 years) with moderate to severe chronic plaque psoriasis in a real-world setting to meet the regulatory requirements by Center for Drug Evaluation (CDE).

Outcomes/endpoints

Primary endpoint:

- AEs/SAEs/AESIs type and frequency during the 52-week observation period

Secondary endpoints:

- Proportion of patients who achieved PASI 75 response score at Week 12
- Proportion of patients who achieved IGA mod 2011 0 or 1 response at Week 12
- Proportion of patients who achieved PASI 90/100 response at Week 12
- Proportion of patients who achieved PASI 75/90/100 response/IGA mod 2011 0 or 1 response over time up to Week 52
- Absolute value change from baseline of PASI score/IGA mod 2011 score over time up to Week 52

Exploratory endpoints:

- Absolute and percentage change from baseline of Children's Dermatology Life Quality Index (CDLQI) score over time up to Week 52
- Proportion of patients who achieved CDLQI 0 or 1 over time up to Week 52
- Height, weight measurement, vital signs, laboratory testing at each visit up to Week 52

Sample size

The sample size for this study was calculated to ensure an adequate number of patients for the safety analysis. In the pooled global pediatric studies, CAIN457A2311 and CAIN457A2310, the incidence of SAE was 5.6%. Assuming no background incidence of SAEs, the probability of observing one or more SAE in 42 patients with an anticipated incidence rate of 5.6% was approximately 90%.

Randomisation and blinding (masking)

This was a non-interventional (non-randomised) real-world study and data were collected from routine clinical practice without additional mandated visits, examinations, laboratory tests, or procedures.

Statistical Methods

There were no statistical hypotheses and inference in this study. Descriptive statistics were applied.

Results

Patient disposition

A total of 42 patients were enrolled in the study across participating sites (Table 1).

Table 1. Patient disposition (Enrolled Set)

	ENR [1] (N=42)
Patients in safety analysis set, n (%) [2]	42 (100.0)
Patients in effectiveness analysis set, n (%) [3]	41 (97.6)
Study completion, n (%)	37 (88.1)
Study not completion, n (%)	5 (11.9)
Primary Reason for not completion, n (%)	
Discontinuation determined by investigator - lack of effectiveness	0 (0.0)
Patient or guardian decision	4 (9.5)
Switch to other biologics during the study	0 (0.0)
Adverse Event	0 (0.0)
Special Conditions	0 (0.0)
Death	0 (0.0)
Other, Patient Lost To Follow-Up	1 (2.4)
Treatment discontinuation, n (%)	3 (7.1)
Reason for treatment discontinuation, n (%)	
Discontinuation determined by investigator - lack of effectiveness	0 (0.0)
Patient or guardian decision	3 (7.1)
Switch to other biologics during the study	0 (0.0)
Adverse Event	0 (0.0)
Special Conditions	0 (0.0)
Death	0 (0.0)
Other	0 (0.0)

ENR = enrolled set, % = percentage of patients (n) based on enrolled set.
Study Completion: Patients who completed the Week 52 visit were classified as study completion patients.
Treatment discontinuation: Patients who did not receive the Week 52 study treatment were categorized as treatment discontinuation patients. If a patient did not complete the study for any reason and their treatment status remained unknown (no treatment received/prescribed/discontinuation records), they were not counted under treatment discontinuation.
[1] Consists of all patients whose parent/legal guardian provide written informed consent.
[2] Consists of all enrolled patients who take at least one dose of Cosentyx® prescribed by the investigator in the routine clinical visit.
[3] Consists of all enrolled patients who take at least one dose of Cosentyx® prescribed by the investigator in the routine clinical visit and have at least one post-baseline effectiveness endpoint assessment besides baseline.
Source: Table 14.1-1.1

Protocol deviations

In total, 3 critical protocol deviations were identified during the study. These included: noncompliance with SAE reporting procedures; enrollment of a patient who met the exclusion criteria due to prior biologic treatment; and enrollment of a patient who lacked valid baseline PASI and IGA mod 2011 assessments when prescribed Cosentyx, thus not meeting the inclusion criteria.

Baseline data

The mean (SD) age of the patients was 11.9 (3.53) years, with 61.9% (26/42) patients in the age group ≥12 years. 54.8% of the patients (n=23) were male. At baseline, the mean (SD) body weight was 53.6 (22.32) kg and 54.8% (23/42) of patients were in the ≥50 kg weight category.

All enrolled patients (N=42, 100.0%) were diagnosed with plaque psoriasis, and 4 (9.5%) of them were also classified as having guttate psoriasis. The most frequently reported special area of psoriasis involvement was the scalp (n=39, 92.9%). No patients reported involvement of the nail or genitals.

The mean (SD) baseline BSA was 20.9 (17.57). Among the 41 patients who had a baseline PASI score, the mean (SD) PASI score was 14.7 (9.34). Baseline IGA mod 2011 scores were available for 41 patients, with a mean (SD) of 3.1 (0.56); 37 (88.1%) patients had a score of 3 or higher at baseline, including 28 (66.7%) with a score of 3 and 9 (21.4%) with a score of 4. At baseline, 45.2% (19/42) of

patients met the criteria for moderate to severe psoriasis in global pivotal studies (BSA ≥10%, PASI ≥12, and IGA mod 2011 ≥3).

Number analysed

All 42 enrolled patients received at least one dose of Cosentyx and were included in the safety analysis set. Of these, 41 patients had at least one post-baseline PASI or IGA assessment and were included in the effectiveness analysis set (Table 1).

Exposure

A similar proportion of the patients received an initial dosage of Cosentyx of either 150 mg (n=18, 42.9%) or 300 mg (n=20, 47.6%). Four patients (9.5%) reported an initial dosage of 75 mg. The mean duration of Cosentyx treatment in the overall patient population was 346.2 days (SD=76.16).

Safety results

Safety and efficacy data were summarized using descriptive summary statistics. No formal statistical testing was done. Frequencies and percentages were provided for categorical variables. Mean, standard deviation (SD), median, minimum and maximum were provided for continuous variables. The safety analysis set was used for primary and exploratory objectives, and consisted of all enrolled patients who received at least one dose of Cosentyx.

The analysis of primary endpoints was based on the frequency and percentage of Treatment-emergent adverse events (TEAEs)/Serious TEAEs/TEAEs of special interests during the 52-week observation period for the safety analysis set. All AEs were coded by System Organ Class (SOC) and Preferred Term (PT) of the MedDRA (version 27.1).

Overview of treatment-emergent adverse events

An overall summary of patients with TEAEs is presented in Table 2. Thirty-one (73.8%) patients experienced TEAEs during the observation period. Only 1 patient (2.4%) experienced a treatment-emergent SAE, and no deaths occurred during the study. No patients discontinued treatment or withdrew from the study due to an AE.

Table 2. Overall summary of TEAEs (Safety Analysis Set)

	AIN457 (N=42)			
	n (%)	95% CI [1]	EX (EAIR) [2]	95% CI [3]
Patients with any TEAEs	31 (73.81)	(57.68, 85.61)	19.31 (1.61)	(1.09, 2.28)
Patients with any TEAEs leading to study discontinuation	0 (0.00)	-	0 (0.00)	-
Patients with any TEAEs leading to treatment discontinuation	0 (0.00)	-	0 (0.00)	-
Patients with any treatment emergent SAE	1 (2.38)	(0.12, 14.10)	39.43 (0.03)	(0.00, 0.14)
Patients with fatal TEAEs	0 (0.00)	-	0 (0.00)	-

[1] 95% CI of percentage was obtained from score method with continuity correction.

[2] For patients with any AE, exposure time is censored at time of first event. For patients without any AE, exposure time = (end of treatment – first dosing date + 1) / 365.25.

[3] 95% CI of EAIR was obtained from exact method.

Source: [Study A2406 Final CSR-Table 14.3.1-1.1]

Analysis of adverse events

A summary of TEAEs by SOC and PT is presented in Table 3. The most frequently reported (≥20% of patients) SOCs for TEAEs were infections and infestations (n=20, 47.6%) and skin and subcutaneous tissue disorders (n=10, 23.8%). Within the SOC of infections and infestations, the most frequently reported (≥5% of patients) PTs were upper respiratory tract infection (n=10, 23.8%), bronchitis (n=5, 11.9%), influenza (n=3, 7.1%) and tonsillitis (n=3, 7.1%). Within the SOC of skin and subcutaneous tissue disorders, the most frequently reported (≥5% of patients) PT was acne (n=4, 9.5%). Two occurrences of mycoplasma infection, both of mild severity and not related to study treatment, were reported in one patient.

Table 3. Summary of TEAEs by SOC and PT (Safety Analysis Set)

	AIN457 (N=42)			
	n (%)	95% CI [2]	EX (EAIR) [3]	95% CI [4]
Patients with any TEAEs [1]	**31 (73.81)**	**(57.68, 85.61)**	**19.31 (1.61)**	**(1.09, 2.28)**
Infections and infestations	**20 (47.62)**	**(32.29, 63.38)**	**29.27 (0.68)**	**(0.42, 1.06)**
Upper respiratory tract infection	10 (23.81)	(12.59, 39.80)	36.01 (0.28)	(0.13, 0.51)
Bronchitis	5 (11.90)	(4.47, 26.43)	38.98 (0.13)	(0.04, 0.30)
Influenza	3 (7.14)	(1.86, 20.55)	38.36 (0.08)	(0.02, 0.23)
Tonsillitis	3 (7.14)	(1.86, 20.55)	38.78 (0.08)	(0.02, 0.23)
COVID-19	2 (4.76)	(0.83, 17.42)	37.99 (0.05)	(0.01, 0.19)
Pharyngitis	2 (4.76)	(0.83, 17.42)	39.26 (0.05)	(0.01, 0.18)
Pneumonia	2 (4.76)	(0.83, 17.42)	38.99 (0.05)	(0.01, 0.19)
Ear infection	1 (2.38)	(0.12, 14.10)	38.94 (0.03)	(0.00, 0.14)
Folliculitis	1 (2.38)	(0.12, 14.10)	39.49 (0.03)	(0.00, 0.14)
Mycoplasma infection	1 (2.38)	(0.12, 14.10)	39.61 (0.03)	(0.00, 0.14)
Nasopharyngitis	1 (2.38)	(0.12, 14.10)	39.40 (0.03)	(0.00, 0.14)
Paronychia	1 (2.38)	(0.12, 14.10)	39.49 (0.03)	(0.00, 0.14)
Pulpitis dental	1 (2.38)	(0.12, 14.10)	39.22 (0.03)	(0.00, 0.14)
Respiratory tract infection	1 (2.38)	(0.12, 14.10)	39.28 (0.03)	(0.00, 0.14)
Sinusitis	1 (2.38)	(0.12, 14.10)	39.77 (0.03)	(0.00, 0.14)
Vulvitis	1 (2.38)	(0.12, 14.10)	39.03 (0.03)	(0.00, 0.14)
Skin and subcutaneous tissue disorders	**10 (23.81)**	**(12.59, 39.80)**	**32.70 (0.31)**	**(0.15, 0.56)**
Acne	4 (9.52)	(3.10, 23.55)	37.26 (0.11)	(0.03, 0.27)
Dry skin	2 (4.76)	(0.83, 17.42)	37.97 (0.05)	(0.01, 0.19)
Pruritus	2 (4.76)	(0.83, 17.42)	38.51 (0.05)	(0.01, 0.19)
Dermatitis	1 (2.38)	(0.12, 14.10)	39.38 (0.03)	(0.00, 0.14)
Dermatitis contact	1 (2.38)	(0.12, 14.10)	39.00 (0.03)	(0.00, 0.14)
Rash	1 (2.38)	(0.12, 14.10)	39.32 (0.03)	(0.00, 0.14)
Urticaria	1 (2.38)	(0.12, 14.10)	38.82 (0.03)	(0.00, 0.14)
Urticaria papular	1 (2.38)	(0.12, 14.10)	38.85 (0.03)	(0.00, 0.14)
General disorders and administration site conditions	**5 (11.90)**	**(4.47, 26.43)**	**35.99 (0.14)**	**(0.05, 0.32)**
Pyrexia	5 (11.90)	(4.47, 26.43)	35.99 (0.14)	(0.05, 0.32)
Investigations	**5 (11.90)**	**(4.47, 26.43)**	**37.56 (0.13)**	**(0.04, 0.31)**
Blood bilirubin increased	2 (4.76)	(0.83, 17.42)	39.16 (0.05)	(0.01, 0.18)
Blood bilirubin unconjugated increased	1 (2.38)	(0.12, 14.10)	39.85 (0.03)	(0.00, 0.14)
Blood uric acid increased	1 (2.38)	(0.12, 14.10)	38.95 (0.03)	(0.00, 0.14)
Eosinophil count increased	1 (2.38)	(0.12, 14.10)	38.95 (0.03)	(0.00, 0.14)
Protein urine present	1 (2.38)	(0.12, 14.10)	39.93 (0.03)	(0.00, 0.14)
Respiratory, thoracic and mediastinal disorders	**5 (11.90)**	**(4.47, 26.43)**	**36.98 (0.14)**	**(0.04, 0.32)**

	AIN457 (N=42)			
	n (%)	95% CI [2]	EX (EAIR) [3]	95% CI [4]
Cough	4 (9.52)	(3.10, 23.55)	37.78 (0.11)	(0.03, 0.27)
Nasal dryness	1 (2.38)	(0.12, 14.10)	39.44 (0.03)	(0.00, 0.14)
Oropharyngeal pain	1 (2.38)	(0.12, 14.10)	39.01 (0.03)	(0.00, 0.14)
Rhinitis allergic	1 (2.38)	(0.12, 14.10)	39.18 (0.03)	(0.00, 0.14)
Vasomotor rhinitis	1 (2.38)	(0.12, 14.10)	39.27 (0.03)	(0.00, 0.14)
Gastrointestinal disorders	**4 (9.52)**	**(3.10, 23.55)**	**36.73 (0.11)**	**(0.03, 0.28)**
Abdominal pain	2 (4.76)	(0.83, 17.42)	38.62 (0.05)	(0.01, 0.19)
Dental caries	1 (2.38)	(0.12, 14.10)	39.25 (0.03)	(0.00, 0.14)
Diarrhoea	1 (2.38)	(0.12, 14.10)	38.84 (0.03)	(0.00, 0.14)
Vomiting	1 (2.38)	(0.12, 14.10)	38.90 (0.03)	(0.00, 0.14)
Injury, poisoning and procedural complications	**2 (4.76)**	**(0.83, 17.42)**	**38.71 (0.05)**	**(0.01, 0.19)**
Ankle fracture	1 (2.38)	(0.12, 14.10)	39.09 (0.03)	(0.00, 0.14)
Ligament injury	1 (2.38)	(0.12, 14.10)	39.09 (0.03)	(0.00, 0.14)
Osteochondral fracture	1 (2.38)	(0.12, 14.10)	39.09 (0.03)	(0.00, 0.14)
Perineal injury	1 (2.38)	(0.12, 14.10)	39.43 (0.03)	(0.00, 0.14)
Musculoskeletal and connective tissue disorders	**2 (4.76)**	**(0.83, 17.42)**	**38.41 (0.05)**	**(0.01, 0.19)**
Arthralgia	2 (4.76)	(0.83, 17.42)	38.41 (0.05)	(0.01, 0.19)
Ear and labyrinth disorders	**1 (2.38)**	**(0.12, 14.10)**	**39.23 (0.03)**	**(0.00, 0.14)**
Tympanic membrane perforation	1 (2.38)	(0.12, 14.10)	39.23 (0.03)	(0.00, 0.14)
Hepatobiliary disorders	**1 (2.38)**	**(0.12, 14.10)**	**38.96 (0.03)**	**(0.00, 0.14)**
Hepatic function abnormal	1 (2.38)	(0.12, 14.10)	38.96 (0.03)	(0.00, 0.14)
Metabolism and nutrition disorders	**1 (2.38)**	**(0.12, 14.10)**	**39.33 (0.03)**	**(0.00, 0.14)**
Hyperuricaemia	1 (2.38)	(0.12, 14.10)	39.33 (0.03)	(0.00, 0.14)
Psychiatric disorders	**1 (2.38)**	**(0.12, 14.10)**	**39.60 (0.03)**	**(0.00, 0.14)**
Attention deficit hyperactivity disorder	1 (2.38)	(0.12, 14.10)	39.60 (0.03)	(0.00, 0.14)

[1] SOC and PT are coded by MedDRA version 27.1. A patient can have one or more PTs reported under a SOC. Results are sorted by overall descending frequency of SOC and then by overall descending frequency of PT within a SOC. If multiple PTs have the same frequency within a SOC, they are sorted alphabetically.

[2] 95% CI of percentage was obtained from score method with continuity correction.

[3] For patients with any AE, exposure time is censored at time of first event. For patients without any AE, exposure time = (end of treatment – first dosing date + 1) / 365.25.

[4] 95% CI of EAIR was obtained from exact method.

Source: [Study A2406 Final CSR-Table 14.3.1-1.2.1]

TEAEs by maximum severity

No severe TEAEs were reported. Seventeen patients (40.5%) had events of mild severity and 14 (33.3%) had events of moderate severity.

TEAEs related to study drug

Sixteen patients (38.1%) experienced at least one TEAE suspected to be related to study treatment by the investigator. The most commonly reported treatment related TEAEs were in the SOC of infections

and infestations (n=9, 21.4%); among those, the most commonly reported PT was upper respiratory tract infection (n=6, 14.3%).

TEAEs leading to discontinuation

No TEAEs led to study discontinuation or treatment discontinuation in the study (Table 2).

Deaths

No deaths were reported during the study (Table 2).

SAEs

Only 1 patient (2.4%) experienced a treatment-emergent SAE during the study (Table 2), namely pneumonia (Table 4). The SAE of pneumonia was of moderate severity and was not suspected to be related to the study drug. No changes were made to the study treatment, and the patient achieved complete recovery. The event required hospitalization but did not result in study discontinuation.

Table 4. Summary of treatment-emergent serious adverse events by SOC and PT (Safety Analysis Set)

	AIN457 (N=42)			
	n (%)	95% CI [2]	EX (EAIR) [3]	95% CI [4]
Patients with any treatment-emergent SAE [1]	1 (2.38)	(0.12, 14.10)	39.43 (0.03)	(0.00, 0.14)
Infections and infestations	1 (2.38)	(0.12, 14.10)	39.43 (0.03)	(0.00, 0.14)
Pneumonia	1 (2.38)	(0.12, 14.10)	39.43 (0.03)	(0.00, 0.14)

[1] SOCs and PTs are coded by MedDRA version 27.1.

[2] 95% CI of percentage was obtained from score method with continuity correction.

[3] For patients with any AE, exposure time is censored at time of first event. For patients without any AE, exposure time = (end of treatment – first dosing date + 1) / 365.25.

[4] 95% CI of EAIR was obtained from exact method.

Source: [Study A2406 Final CSR-Table 14.3.1-2.2.1]

Adverse events of special interest (AESI)

AESIs are summarized by risk name and PT based on absolute and relative frequencies for treatment-emergent AEs during the observation period in Table 5.

Infections and infestations were reported in 20 patients (47.6%; 95% CI: 32.3, 63.4). Within this risk category, the most frequently reported (≥5% of patients) PTs were upper respiratory tract infection (n=10, 23.8%), bronchitis (n=5, 11.9%), influenza (n=3, 7.1%), and tonsillitis (n=3, 7.1%).

Hypersensitivity events were reported in 5 patients (11.9%; 95% CI: 4.47, 26.43), and were all single events by PT. No cases of Hepatitis B reactivation, neutropenia, inflammatory bowel disease, malignancy, MACE, suicidal ideation and behavior were reported during the 52 weeks observation period.

Table 5. Summary of treatment-emergent AESIs by risk name and PT (Safety Analysis Set)

Risk Name / Preferred Term	AIN457 (N=42)	
	n (%)	95% CI [2]
Patients with any TEAEs of special interest [1]	**22 (52.38)**	**(36.62, 67.71)**
Infections and Infestations	**20 (47.62)**	**(32.29, 63.38)**
Upper respiratory tract infection	10 (23.81)	(12.59, 39.80)
Bronchitis	5 (11.90)	(4.47,26.43)
Influenza	3 (7.14)	(1.86,20.55)
Tonsillitis	3 (7.14)	(1.86, 20.55)
COVID-19	2 (4.76)	(0.83, 17.42)
Pharyngitis	2 (4.76)	(0.83, 17.42)
Pneumonia	2 (4.76)	(0.83, 17.42)
Ear infection	1 (2.38)	(0.12, 14.10)
Folliculitis	1 (2.38)	(0.12, 14.10)
Mycoplasma infection	1 (2.38)	(0.12, 14.10)
Nasopharyngitis	1 (2.38)	(0.12, 14.10)
Paronychia	1 (2.38)	(0.12, 14.10)
Pulpitis dental	1 (2.38)	(0.12, 14.10)
Respiratory tract infection	1 (2.38)	(0.12, 14.10)
Sinusitis	1 (2.38)	(0.12, 14.10)
Vulvitis	1 (2.38)	(0.12, 14.10)
Hypersensitivity	**5 (11.90)**	**(4.47, 26.43)**
Dermatitis	1 (2.38)	(0.12, 14.10)
Dermatitis contact	1 (2.38)	(0.12, 14.10)
Rash	1 (2.38)	(0.12, 14.10)
Rhinitis allergic	1 (2.38)	(0.12, 14.10)
Urticaria	1 (2.38)	(0.12, 14.10)
Urticaria papular	1 (2.38)	(0.12, 14.10)

[1] PTs are coded by MedDRA version 27.1). PTs are sorted within risk level in descending order of frequency. A patient with multiple occurrences of a level is counted only once for the same risk.

[2] 95% CI of percentage was obtained from score method with continuity correction.

Source: [Study A2406 Final CSR-Table 14.3.1-2.3]

Clinical laboratory evaluations

Laboratory assessment results were mostly within normal range. Clinically significant and treatment-associated abnormalities were not observed.

Physical examination and vital signs

No clinically significant abnormalities were observed in vital signs throughout the study. Mean height increased from 152.47 cm (SD=20.384) at baseline to 159.82 cm (SD=20.349) at Week 52, and mean weight increased from 53.61 kg (SD=22.317) to 57.13 kg (SD=21.252).

Efficacy results

PASI 75/90/100 and IGA mod 2011 response at week 12

Thirty-seven patients (90.2%) had PASI assessments available at both baseline and Week 12. Of these patients, 94.6% (n=35; 95% CI: 81.8, 99.3) achieved PASI 75, 86.5% (n=32; 95% CI: 71.2, 95.5) achieved PASI 90, and 70.3% (n=26; 95% CI: 53.0, 84.1) achieved PASI 100.

Thirty-seven patients (90.2%) had an IGA mod 2011 assessment at Week 12. Of these patients, 91.9% (n=34; 95% CI: 78.1, 98.3) achieved an IGA mod 2011 0/1 response.

PASI 75/90/100 and IGA mod 2011 response over time up to week 52

At Week 52, among 33 patients (80.5%) with available data, 100% achieved PASI 75, 78.8% achieved PASI 90, and 57.6% achieved PASI 100.

Altogether 78.8% (n=26) of patients achieved IGA mod 2011 0 or 1 response at Week 52.

PASI score and IGA mod 2011 score over time

At baseline, the mean PASI score was 14.66 (SD=9.34). Improvements in percentage change from baseline began as early as Week 4, and mean PASI scores declined to 0.46 at Week 12, remaining low through Week 52 (0.56).

The mean IGA mod 2011 scores decreased from baseline to Week 12 and remained low through to Week 52. The mean percentage change from baseline showed consistent improvement over time. Correspondingly, the proportion of patients achieving IGA mod 2011 0 or 1 scores increased over time, reaching 83.0% at Week 12 and maintaining 63.4% at Week 52.

Exploratory efficacy endpoints

Improvements in CDLQI response rates were observed over time. At Week 4, 39.0% (16/41) of patients achieved a CDLQI 0 or 1 response. The proportion increased over time, reaching 77.8% (28/36) at Week 12 and maintaining 75.0% (21/28) at Week 52.

Mean CDLQI scores decreased from 7.0 (SD=4.77) at baseline to 1.2 (SD=2.25) at Week 12 and remained low through to Week 52. Correspondingly, the mean percentage change from baseline reached −82.4% (SD=33.65) at Week 12 and ranged between −80.6% (SD=44.45) and −85.1% (SD=28.96) across later visits.

2.3.3. Discussion on clinical aspects

The MAH has submitted a final CSR for Study No. CAIN457A2406 (Study A2405): "*A real-world, prospective, multicenter study to assess the safety and effectiveness of secukinumab (Cosentyx) in patients aged 6 to less than 18 years with moderate to severe chronic plaque psoriasis in China*". This

is a standalone submission, in accordance with Article 46 of regulation (EC) No 1901/2006, as amended.

CAIN457A2406 study was a small (n=42) non-interventional study conducted in a real world setting, which limits the overall conclusions that can be drawn.

Safety: All 42 enrolled patients (100.0%) received at least one dose of Cosentyx in routine clinical practice and were included in the Safety Analysis Set. Thirty-one (73.8%) patients experienced TEAEs during the observation period. Only 1 patient (2.4%) experienced a treatment-emergent SAE (not related to study drug), and no deaths occurred during the study. No patients discontinued treatment or withdrew from the study due to an AE.

Sixteen patients (38.1%) experienced at least one TEAE suspected to be related to study treatment by the investigator. The most commonly reported treatment related TEAEs were in the SOC of infections and infestations (21.4%). Regarding AESIs, infections and infestations were reported in 20 patients (47.6%) and hypersensitivity events were reported in 5 patients (11.9%). In conclusion, the safety profile in the study is in line with the current Cosentyx SmPC.

Efficacy: Altogether 41 patients with at least one post-baseline PASI or IGA assessment were in included in the efficacy evaluation (i.e. Effectiveness Analysis Set). The observed PASI75/90/100 and IGA mod 2011 responses at week 12 were 94.6/86.5/70.3% and 91.9%, respectively, and were well maintained throughout week 52. Improvements were also seen in quality of life, as measured by CDLQI. The caveats of the observational study design and differences in the patient population when compared to the pivotal pediatric psoriasis studies are acknowledged. Nevertheless, the CAIN457A2406 study results continue to support the benefits of secukinumab in this patient group.

No relevant new information can be drawn from the safety or efficacy data in the CAIN457A2406 study and no changes to the product information are proposed. This is endorsed.

The benefit-risk of secukinumab in pediatric psoriasis patients remains positive.

3. CHMP overall conclusion and recommendation

The submitted final CSR for study CAIN457A2406 fulfills the requirement of the Article 46 of regulation (EC) No 1901/2006, as amended.

☒ **Fulfilled:**

No regulatory action required.