NOVARTIS

CAIN457A2406 Study Results Abstract for Public Disclosure

Title

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

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NIS Type

Novartis Drug NIS

Keywords

Plaque psoriasis, secukinumab, pediatric, IL-17 inhibitor, safety, effectiveness

Rationale and background

Cosentyx® (secukinumab) is a recombinant high-affinity fully human monoclonal anti-human interleukin-17A (IL-17A) antibody of the IgG1 (Immunoglobulin G)/ kappa isotype that selectively binds to and neutralizes the proinflammatory cytokine interleukin-17A (IL-17A).

Based on the data generated from a China-centric Phase III randomized double-blind placebo control adult study CAIN457A2318 and pivotal studies CAIN457A2302, CAIN457A2303, CAIN457A2308, and CAIN457A2309, Cosentyx® was originally approved for the treatment of adult patients with moderate to severe plaque psoriasis by the Center for Drug Evaluation (CDE) in China on 28 Mar 2019. Based on the positive results from 2 global pivotal pediatric studies, CAIN457A2310 and CAIN457A2311, CDE approved expanding the patient population to 6 to less than 18 years old children in August 2021, contingent upon the conduct of a post-marketing study, which would: (1) collect the efficacy and safety data in Chinese pediatric patients in clinical practice, and (2) supplement the evidence of clinical efficacy and safety of Cosentyx® observed in the global pivotal pediatric studies. In China, the approved strengths for treating pediatric plaque psoriasis patients include 75mg, 150mg and 300mg.

This non-interventional study (NIS) is aimed to provide safety and effectiveness information of Cosentyx® in Chinese pediatric plaque psoriasis patients (from 6 to less than 18 years old) in a real-world setting, as well as to meet the regulatory requirement by CDE.

Research question and objectives

Primary Objective

- To evaluate the safety and tolerability of Cosentyx® as assessed by adverse events (AEs), serious adverse events (SAEs) and adverse event of special interests (AESIs) in clinical use in Chinese patients aged 6 to less than 18 years with moderate to severe plaque psoriasis over a 52-week observation period

Secondary Objectives

- To evaluate the effectiveness of Cosentyx® in clinical use with respect to Psoriasis Area and Severity Index (PASI 75) response at Week 12
- To evaluate the effectiveness of Cosentyx® in clinical use with respect to Investigator's Global Assessment, modified 2011 (IGA mod 2011) 0 or 1 response at Week 12
- To evaluate the effectiveness of Cosentyx® in clinical use with respect to PASI 90/100 response at Week 12

- To evaluate the effectiveness of Cosentyx® in clinical use with respect to PASI 75/90/100 response and IGA mod 2011 0 or 1 response over time up to Week 52
- To evaluate the effectiveness of Cosentyx® with respect to PASI score/ IGA mod 2011 score over time up to Week 52

Study design

This is a non-interventional, prospective, multicenter real-world setting study, aiming to provide safety and effectiveness data in Chinese pediatric patients with moderate to severe plaque psoriasis treated with Cosentyx® for up to 52 weeks. Approximately 42 patients who were about to initiate Cosentyx® or had started Cosentyx® within the last 4 weeks and met the eligibility criteria were enrolled. Patients were followed via routine visits in real clinical practice up to 52 weeks. Data from regular medical records, including safety and effectiveness information of Cosentyx® (e.g., AE, SAE, physical examinations, laboratory tests, disease assessments, etc.) were collected at each visit. No additional study visits, examinations, laboratory tests or procedures were mandated throughout the study.

Setting

The assent and informed consent were achieved with the premise of a clinical decision to initiate Cosentyx®. All patients in the participating sites were offered the opportunity to participate in this study, and if eligible, were enrolled in the study after assent and informed consent was signed. All relevant medical data and records for the patients enrolled were collected and recorded prospectively for up to 52 weeks.

Subjects and study size, including dropouts

A total of 42 patients who were diagnosed with moderate to severe plaque psoriasis and aged 6 to less than 18 years were enrolled. All patients in the participating sites, who were about to initiate Cosentyx® or have had started Cosentyx® within the last 4 weeks and met all of the following criteria were eligible for inclusion in this study:

- 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 PASI and IGA mod 2011 score at the time they are prescribed Cosentyx®

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 renders the patient unsuitable for the study

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 SAEs was 5.6%. Assuming no background incidence of SAEs, the probability of observing 1 or more SAE in 42 patients with an anticipated incidence rate of 5.6% is approximately 90%.

Variables and data sources

The type and frequency of AE, AESI and SAE were used as variables to evaluate the primary objective. The PASI 75 / PASI 90 / PASI 100 and IGA mod 2011 0 or 1 response, PASI score and IGA score over time were used as variables to evaluate the secondary objectives. The study collected data from medical records documented in routine clinical visits.

The data included but were not limited to:

- Cosentyx® dosage and administration date
- Patient demographics
- Psoriasis history, including prior therapies
- Medical history and prior medications/ surgery/ medical procedures
- Concomitant medications
- Physical examination information including vital signs, height and weight
- Laboratory tests
- PASI/IGA mod 2011
- AE/SAE

The study was a NIS and did not impose a therapy protocol, diagnostic/ therapeutic procedures, or a visit schedule. The assessment schedule guidance provided only the most likely pattern of routine clinical practice for most pediatric patients treated with Cosentyx®. Recommended visit window period was ± 2 weeks for Week 4, 8, 12, and ± 4 weeks for Week 24, 36, and 52. The treating physician was asked to complete – if possible – the appropriate case report form (CRF) at every patient visit. Laboratory values were collected as part of routine clinical visits. Designated investigator staff entered the data required by the protocol at every visit wherever possible into Electronic Case Report Forms (eCRFs).

Statistical methods

There were no statistical hypotheses and inferences in this study. Descriptive statistics were provided.

Continuous variables were presented as mean, standard deviation (SD), median, first and third quartiles (Q1, Q3), minimum, and maximum.

Categorical variables were summarized as counts and percentage (%) of patients in each category.

Analysis sets in this study were defined as enrolled set (ENR), safety analysis set (SS), and effectiveness analysis set (EFF). ENR consisted of all patients whose parent/legal guardian provided written informed consent, SS consisted of all enrolled patients who took at least one dose of Cosentyx® prescribed by the investigator in the routine clinical visit, while EFF consisted of all enrolled patients who took at least one dose of Cosentyx® prescribed by the investigator in the routine clinical visit with baseline and at least one post-baseline effectiveness endpoint assessments (e.g., PASI or IGA mod 2011).

Patient disposition was summarized based on ENR. Demographic and other baseline characteristics were summarized for SS. Medical history was summarized by system organ class (SOC) and preferred term (PT) of the Medical Dictionary for Regulatory Activities (MedDRA) (version 27.1). Information related to Cosentyx® treatment was summarized for the SS. The information of prior and concomitant medication / prior and concomitant non-medication therapies/procedures were also presented for the SS.

All AEs were summarized based on the SS. The primary endpoints were analyzed based on the frequency and percentage of treatment-emergent adverse events (TEAEs), treatment-emergent SAEs, and TEAEs of special interest during a 52-week observation period. TEAE, SAE and TEAE of special interests leading to dose changes, drug interruptions, study discontinuations, and treatment discontinuations were also summarized by SOC and PT.

The effectiveness evaluations were performed based on the EFF. Frequency and response rate were presented for PASI 75, PASI 90, PASI 100 and IGA mod 2011 0 or 1 response at Week 12 for EFF. Additionally, frequency and response rates were also presented for PASI 75, PASI 90, PASI 100 and IGA mod 2011 0 or 1 response by visit for EFF. Descriptive statistics for observed baseline, change from baseline (CHG) and percentage change from baseline (PCHG) values were displayed at each visit for PASI by body area for EFF. Furthermore, descriptive statistics for observed baseline, CHG and PCHG values were also displayed at each visit for IGA mod 2011 for EFF.

Results

Of the 42 enrolled patients with moderate to severe plaque psoriasis, 37 (88.1%) completed the study through Week 52. TEAEs occurred in 31 (73.8%) patients, with 17 (40.5%) patients experienced mild and 14 (33.3%) patients experienced moderate TEAEs in severity. No patients experienced severe TEAEs, and no treatment discontinuations were attributed to AEs. The most frequent reported TEAEs by primary SOC were infections and infestations (47.6%), skin and subcutaneous tissue disorders (23.8%), and general disorders and administration site conditions (11.9%). One treatment-emergent SAE (pneumonia, 2.4%) was reported and was not considered related to study drug by the investigator. The exposure adjusted incidence rate (EAIR) of TEAEs and treatment-emergent SAEs was 1.61 and 0.03 per patient-year, respectively. The majority of adverse events of special interest were related to infections and infestations. No cases of Hepatitis B reactivation, neutropenia, major adverse cardiovascular events (MACE), suicidal ideation and behavior, or inflammatory bowel disease were reported.

Discussion

The safety profile of Cosentyx® observed in this study (A2406) was in line with the known safety profile observed in global pediatric psoriasis studies, with no new safety signals identified. All TEAEs were mild or moderate, and the single treatment-emergent SAE reported (pneumonia) was not attributed to the study drug as judged by the investigator. The overall EAIRs of TEAEs was 1.61 per patient-year and treatment- emergent SAEs was 0.03 per patient-year.

Effectiveness outcomes showed high and sustained responses across all endpoints.

The results from this study further support the safety of Cosentyx® and reinforcing the role of Cosentyx® in improving both clinical outcomes and quality of life of Chinese pediatric patients in real-world clinical practice.

Conclusion

This prospective, observational study demonstrated that Cosentyx® was generally well tolerated in Chinese pediatric patients with moderate to severe plaque psoriasis in a real-world clinical setting. All AEs were mild or moderate in severity, and no new safety signals emerged during the 52-week observation period.

High response rates were observed in effectiveness outcomes (PASI, IGA,) at Week 12 and sustained through Week 52. These findings further support the favorable benefit–risk profile of Cosentyx® in pediatric patients and fulfill post-marketing regulatory requirements in China by providing local real-world evidence.

List of abbreviations

AE	Adverse Event
AESI	Adverse Event of Special Interest
CAIN	Cosentyx® Clinical Trial Identifier
CDE	Center for Drug Evaluation (China)
CHG	Change from Baseline
CRF	Case Report Form
EAIR	Exposure-Adjusted Incidence Rate
EFF	Effectiveness Analysis Set
ENR	Enrolled Set
IGA mod 2011	Investigator's Global Assessment, modified 2011
IL-17A	Interleukin-17A
MACE	Major Adverse Cardiovascular Events
MedDRA	Medical Dictionary for Regulatory Activities
NIS	Non-interventional Study
PASI	Psoriasis Area and Severity Index
PCHG	Percentage Change from Baseline
PT	Preferred Term
Q1, Q3	First Quartile, Third Quartile
SAE	Serious Adverse Event
SD	Standard Deviation
SOC	System Organ Class
TEAE	Treatment-Emergent Adverse Event