In JUNIPERA in biologic-naive patients

COSENTYX® (secukinumab) gives kids...

Time to flare in Treatment Period 2 in JPsA and ERA (**primary end point**)[1]

- **72%** risk reduction in time to flare vs placebo (N=75) (HR=0.28, 95% CI: 0.13-0.63)

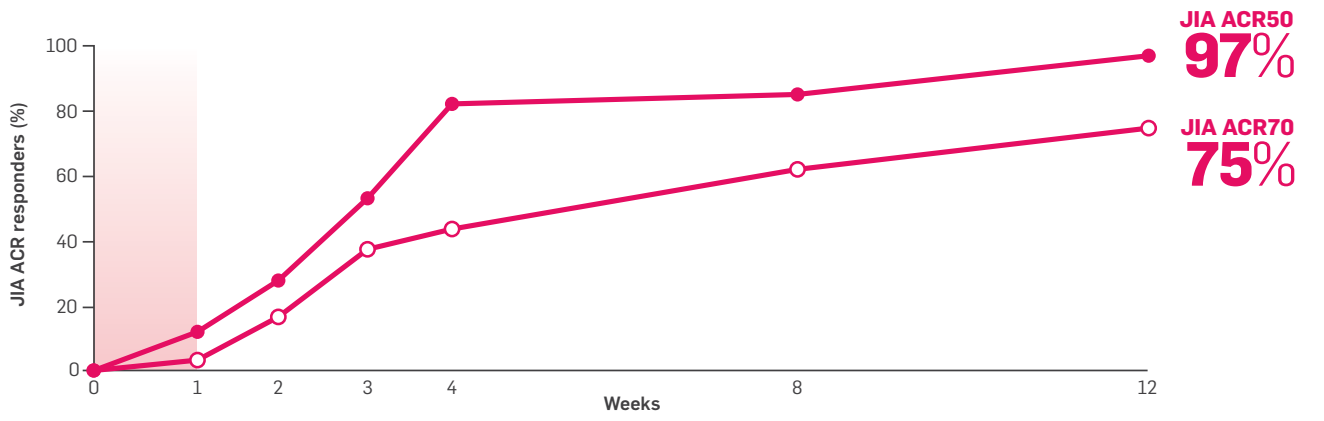
The median time to disease flare was not reached in the COSENTYX group and was 453 days in the placebo group (KM estimate).[1]

Significantly longer time to flare in JPsA in Treatment Period 2[2]

- **85%** reduced risk of flare vs placebo (N=31) (HR=0.15, 95% CI: 0.04-0.56)*

Time to flare in the individual JPsA subtype was an exploratory end point in Treatment Period 2.[1]

Results seen in Treatment Period 1 in JPsA (N=34)[1]



JIA ACR50/70 were secondary end points in both open-label, single-arm, Treatment Period 1 and in Treatment Period 2. No clinical or statistical conclusions can be drawn.[1]

Results observed up to Year 2 in JPsA[1,3]

- **73%/67%** of patients on COSENTYX **(N=15)** and 56%/31% of patients on placebo **(N=16)** achieved JIA ACR50/70 at the end of Treatment Period 2 (as observed)

Disease flare was defined as a ≥30% worsening in ≥3 of the 6 JIA ACR response criteria, and ≥30% improvement in ≤1 of the 6 JIA ACR response criteria and ≥2 active joints.[2]

JIA ACR50/70 are defined as 50%/70% improvement from baseline in ≥3 of the 6 ACR response criteria, with ≤1 variable worsening >30%.[1]

*During Treatment Period 2, a total of 11 patients with JPsA in the placebo group experienced a flare event compared with 4 patients with JPsA in the COSENTYX group.[2]

ACR=American College of Rheumatology; CI=confidence interval; ERA=enthesitis-related arthritis; HR=hazard ratio; JIA=juvenile idiopathic arthritis; JPsA=juvenile psoriatic arthritis; KM=Kaplan-Meier.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

COSENTYX® (secukinumab) is contraindicated in patients with a previous serious hypersensitivity reaction to secukinumab or to any of the excipients in COSENTYX. Cases of anaphylaxis have been reported during treatment with COSENTYX.

Please see additional Important Safety Information on next and last pages.

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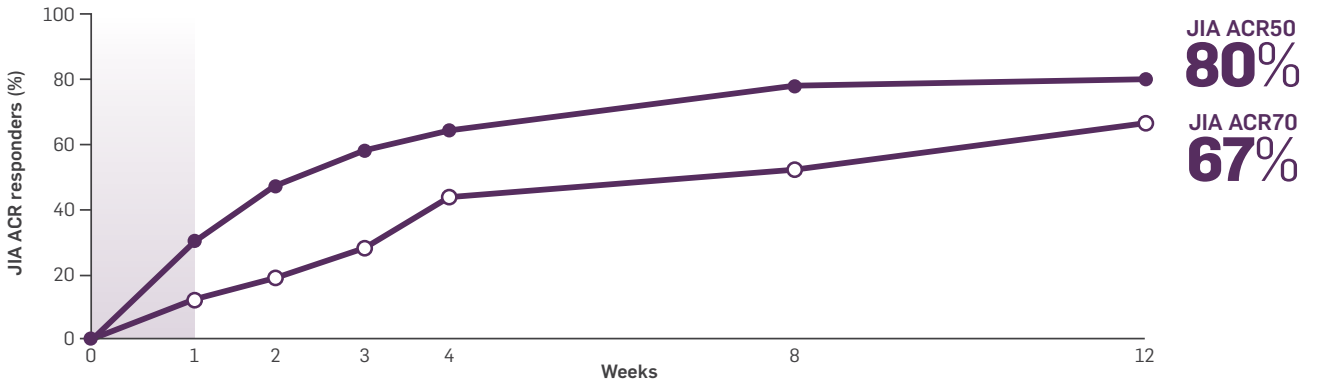
...more time to be kids

Longer time to flare in ERA in Treatment Period 2[2]

- **53%** reduced risk of flare vs placebo (N=44) (HR=0.47, 95% CI: 0.17-1.32)*

Time to flare in ERA vs placebo (exploratory end point) did not reach statistical significance. Supplementary analyses provided confirmatory evidence of the treatment effect in ERA.[2]

Results seen in Treatment Period 1 in ERA (N=52)[1]



JIA ACR50/70 were secondary end points in both open-label, single-arm, Treatment Period 1 and in Treatment Period 2. No clinical or statistical conclusions can be drawn.[1]

Results observed up to Year 2 in ERA[1,3]

- **82%/68%** of patients on COSENTYX® **(N=22)** and 68%/55% of patients on placebo **(N=22)** achieved JIA ACR50/70 at the end of Treatment Period 2 (as observed)

*During Treatment Period 2, a total of 10 patients with ERA in the placebo group experienced a flare event compared with 6 patients with ERA in the COSENTYX group.[2]

IMPORTANT SAFETY INFORMATION (cont)

WARNINGS AND PRECAUTIONS

Infections

COSENTYX may increase the risk of infections. In clinical trials, a higher rate of infections was observed in COSENTYX treated subjects compared to placebo-treated subjects. In placebo-controlled clinical trials in subjects with moderate to severe plaque psoriasis, higher rates of common infections, such as nasopharyngitis (11.4% versus 8.6%), upper respiratory tract infection (2.5% versus 0.7%) and mucocutaneous infections with candida (1.2% versus 0.3%) were observed with COSENTYX compared with placebo. A similar increase in risk of infection was seen in placebo-controlled trials in subjects with psoriatic arthritis, ankylosing spondylitis and non-radiographic axial spondyloarthritis. The incidence of some types of infections appeared to be dose-dependent in clinical studies. In the postmarketing setting, serious and some fatal infections have been reported in patients receiving COSENTYX.

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Exercise caution when considering the use of COSENTYX in patients with a chronic infection or a history of recurrent infection.

Instruct patients to seek medical advice if signs or symptoms suggestive of an infection occur. If a patient develops a serious infection, monitor the patient closely and discontinue COSENTYX until the infection resolves.

Pre-treatment Evaluation for Tuberculosis

Evaluate patients for tuberculosis (TB) infection prior to initiating treatment with COSENTYX. Avoid administration of COSENTYX to patients with active TB infection. Initiate treatment of latent TB prior to administering COSENTYX. Consider anti-TB therapy prior to initiation of COSENTYX in patients with a past history of latent or active TB in whom an adequate course of treatment cannot be confirmed. Monitor patients closely for signs and symptoms of active TB during and after treatment.

Inflammatory Bowel Disease

Caution should be used when prescribing COSENTYX to patients with inflammatory bowel disease. Exacerbations, in some cases serious, occurred in COSENTYX treated subjects during clinical trials in plaque psoriasis, psoriatic arthritis, ankylosing spondylitis and non-radiographic axial spondyloarthritis. In addition, new onset inflammatory bowel disease cases occurred in clinical trials with COSENTYX. In an exploratory trial in 59 subjects with active Crohn's disease, there were trends toward greater disease activity and increased adverse events in the secukinumab group as compared to the placebo group. Patients who are treated with COSENTYX should be monitored for signs and symptoms of inflammatory bowel disease.

Hypersensitivity Reactions

Anaphylaxis and cases of urticaria occurred in COSENTYX treated subjects in clinical trials. If an anaphylactic or other serious allergic reaction occurs, administration of COSENTYX should be discontinued immediately and appropriate therapy initiated.

The removable caps of the COSENTYX Sensoready® pen and the COSENTYX 1 mL and 0.5 mL prefilled syringes contain natural rubber latex, which may cause an allergic reaction in latex-sensitive individuals. The safe use of the COSENTYX Sensoready pen or prefilled syringe in latex-sensitive individuals has not been studied.

Immunizations

Prior to initiating therapy with COSENTYX, consider completion of all age appropriate immunizations according to current immunization guidelines. COSENTYX may alter a patient's immune response to live vaccines. Avoid use of live vaccines in patients treated with COSENTYX.

MOST COMMON ADVERSE REACTIONS

Most common adverse reactions (>1%) are nasopharyngitis, diarrhea, and upper respiratory tract infection.

INDICATIONS

COSENTYX is indicated for the treatment of moderate to severe plaque psoriasis in patients 6 years and older who are candidates for systemic therapy or phototherapy.

COSENTYX is indicated for the treatment of active psoriatic arthritis (PsA) in patients 2 years of age and older.

COSENTYX is indicated for the treatment of adult patients with active ankylosing spondylitis (AS).

COSENTYX is indicated for the treatment of adult patients with active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation.

COSENTYX is indicated for the treatment of active enthesitis-related arthritis (ERA) in patients 4 years of age and older.

References: 1. Data on file. CAIN457F2304 Clinical Study Report. Novartis Pharmaceuticals Corp; June 2020. **2.** Cosentyx. Prescribing Information. Novartis Pharmaceuticals Corp; [December 2021]. **3.** Data on file. CAIN457F2304 Data Analysis Report. Novartis Pharmaceuticals Corp; February 2022.

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Novartis Pharmaceuticals Corporation
East Hanover, New Jersey 07936-1080