

MEDIA UPDATE

Novartis presents positive Phase III results for Cosentyx® in children with active enthesitis-related arthritis (ERA) and juvenile psoriatic arthritis (JPsA) at ACR 2021

- *Treatment with Cosentyx® (secukinumab) resulted in a 72% reduced flare risk versus placebo, with improvement in disease activity over two years across both enthesitis-related arthritis (ERA) and juvenile psoriatic arthritis (JPsA)¹. Safety in this pediatric population was consistent with the known safety profile of Cosentyx¹*
- *Novartis has filed regulatory submissions for Cosentyx in ERA and JPsA [categories of juvenile idiopathic arthritis (JIA)] in the US and Europe with decisions anticipated in the coming months. The US Food and Drug Administration (FDA) granted a Priority Review for both indications*
- *There are approximately 2 million children worldwide who are currently diagnosed with JIA^{2,3}. The categories of JPsA and ERA are progressive, chronic, debilitating diseases and, if approved, Cosentyx would be the first biologic for ERA patients in the US^{4,5}*

Basel, November 08, 2021 — Novartis, a leader in rheumatology and immuno-dermatology, today announced new analyses from the two-year positive Phase III JUNIPERA study, which demonstrated the treatment response of Cosentyx® (secukinumab) in children and adolescents with enthesitis-related arthritis (ERA) and juvenile psoriatic arthritis (JPsA) – two categories of juvenile idiopathic arthritis (JIA). The safety profile was consistent with that of Cosentyx in adults with plaque psoriasis, psoriatic arthritis, non-radiographic axial spondyloarthritis and ankylosing spondylitis¹. These data will be highlighted as an oral presentation at the American College of Rheumatology (ACR) Convergence all-virtual annual meeting, November 3–10, 2021¹. Initial results from the Phase III JUNIPERA trial were previously presented at the European Alliance of Associations for Rheumatology (EULAR) 2021 European Congress of Rheumatology in June⁶.

Two-year results from JUNIPERA demonstrated that patients treated with Cosentyx had a significantly longer time to flare, showing a 72% reduction in the risk of flare ($P < .001$) versus placebo, in children and adolescents ages two to 17 years old with active ERA ($n=52$; mean age: 13.7) and active JPsA ($n=34$; mean age: 12.2)¹. At Week one, over 30% of patients showed improvement with Cosentyx (JIA American College of Rheumatology [ACR] 30) and nearly 90% achieved JIA ACR 30 by the end of the first treatment period (12 weeks)¹. Additionally, by Week 12, nearly 35% of patients ($N=86$) achieved JIA ACR inactive disease status. Improvements in disease activity, as measured by the mean juvenile arthritis disease activity score (JADAS 27), were observed at Week one, reaching low disease activity from

Week 12 through Week 104¹. Safety in this pediatric population was consistent with the known safety profile of Cosentyx¹.

“If left untreated, ERA and JPsA can have a substantial negative impact on quality of life and may lead to deformities and long-term disability for children and adolescents who live with these conditions,” said Dr. Hermine Brunner, Cincinnati Children’s Hospital Medical Center and lead investigator of the JUNIPERA study. “It is promising that the JUNIPERA study shows that secukinumab demonstrated marked responses in patients with ERA and JPsA, a population that currently has limited treatment options available to help improve joint inflammation, dactylitis and enthesitis.”

Novartis has filed regulatory submissions for Cosentyx in ERA and JPsA in Europe and the US. Final decisions by the European Medicines Agency (EMA) and the US Food and Drug Administration (FDA) are anticipated in the coming months. If approved, Cosentyx would be the first biologic treatment for children living with ERA in the US.

“With more than 500,000 patients treated worldwide since launch, these JUNIPERA data further reinforce the known efficacy and safety of Cosentyx for children and adults living with rheumatologic and dermatologic conditions,” said Todd Fox, Global Head of Medical Affairs Immunology, Hepatology and Dermatology at Novartis. “We are committed to bringing Cosentyx to young people living with inflammatory rheumatic diseases as quickly as possible, as part of our ambition to expand Cosentyx to 10 indications.”

In July 2020, Cosentyx received EU approval as a first-line systemic treatment for pediatric psoriasis and recently received approval in the US and China⁷⁻⁹. In Japan, Cosentyx has also been approved to treat psoriatic arthritis as well as psoriasis in pediatric patients aged 6 years or older, as well as generalized pustular psoriasis¹⁰.

About the JUNIPERA Study

JUNIPERA is a two-year, three-part, double-blind, placebo-controlled, randomized-withdrawal, Phase III study that enrolled 86 children and adolescents aged 2 to 17 years with a confirmed diagnosis of JPsA or ERA according to the International League of Associations for Rheumatology classification criteria¹¹. Patients were given open-label secukinumab 75 mg/150 mg (prefilled syringe at doses of 75 mg in patients <50 kg and 150 mg in patients ≥50 kg) up until Week 12¹¹. In this treatment period 1, patients achieving at least JIA ACR 30 response then progressed onto treatment period 2 where patients were allocated to one of two arms: secukinumab 75 mg/150 mg (depending on bodyweight) or placebo and responses observed up until Week 104¹¹. The primary endpoint of the study was time to flare in the treatment period 2 (Week 12 to Week 104)¹¹. Secondary endpoints in treatment period 1 (up to Week 12) included evaluation of JIA ACR 30/50/70/90/100 responses and each JIA ACR core component, change from baseline of the JADAS, and total enthesitis and dactylitis count¹¹.

About Cosentyx® (secukinumab)

Cosentyx is the first and only fully-human biologic that directly inhibits interleukin-17A (IL-17A), an important cytokine involved in the inflammation of psoriatic arthritis, (PsA), moderate to severe plaque psoriasis, (PsO), ankylosing spondylitis (AS) and non-radiographic axial spondyloarthritis (nr-axSpA)^{12,13}. Cosentyx is a proven medicine and has been studied clinically for more than 14 years. The medicine is backed by robust evidence, including five years of clinical data in adults supporting long-term safety and efficacy across moderate to severe PsO, PsA and AS¹⁴⁻²⁰. These data strengthen the position of Cosentyx as a treatment across AS and nr-axSpA, PsA and moderate to severe PsO, supported by more than 500,000 patients treated worldwide since launch in 2015^{7,21,22}

Disclaimer

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About Novartis

Novartis is reimagining medicine to improve and extend people’s lives. As a leading global medicines company, we use innovative science and digital technologies to create transformative treatments in areas of great medical need. In our quest to find new medicines, we consistently rank among the world’s top companies investing in research and development. Novartis products reach nearly 800 million people globally and we are finding innovative ways to expand access to our latest treatments. About 108,000 people of more than 140 nationalities work at Novartis around the world. Find out more at <https://www.novartis.com>.

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