Novartis International AG
Novartis Global Communications
CH-4002 Basel
Switzerland

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MEDIA & INVESTOR RELEASE

Novartis Cosentyx® (secukinumab) receives positive CHMP opinion for expanded use in childhood arthritic conditions

- *Positive opinion could expand the role of Cosentyx® (secukinumab) in reducing flare risk in pediatric enthesitis-related arthritis (ERA) and psoriatic arthritis (PsA) patients in the EU*
- *Safety in these pediatric populations was consistent with the known safety profile across approved adult and pediatric indications*
- *Since its initial approval, Cosentyx has a proven sustained efficacy profile across several systemic inflammatory conditions and has treated more than 700,000 patients worldwide* [1-11]

Basel, May 20, 2022 — Novartis today announced the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has adopted a positive opinion for Cosentyx® (secukinumab), used alone or in combination with methotrexate, in the juvenile idiopathic arthritis (JIA) categories of enthesitis-related arthritis (ERA) and juvenile psoriatic arthritis (JPsA) in patients 6 years and older whose disease has responded inadequately to, or who cannot tolerate, conventional therapy[8].

“JIA is the most common childhood rheumatic disease, affecting millions of children worldwide. Unfortunately, due to the limitations of current or available treatment options, some patients continue to experience symptoms, with an impact on their life. If approved in Europe, Cosentyx could offer a much-needed, additional effective treatment for the underserved ERA and JPsA patient populations,” said Ivan Foeldvari, M.D., Hamburg Centre for Pediatric Rheumatology, Germany.

ERA and JPsA are progressive, debilitating autoimmune diseases[12-14]. ERA is characterized by joint swelling and pain where tendons and ligaments attach to bone and may present with lower back pain or tenderness at the palpation of the hips[13-15]. JPsA is characterized by joint swelling and skin psoriasis and may present with nail changes, inflammation of fingers and/or toes or psoriatic skin changes in a first-degree relative. If left untreated, they can lead to high levels of pain and disability[12-15].

“The positive CHMP opinion reinforces that children and adults living with immunologic rheumatic and dermatological diseases, and the physicians who treat them, may feel confident in the management of these diseases with Cosentyx,” said Todd Fox, Global Head of Medical Affairs Immunology at Novartis. “We’re committed to bringing innovative treatments to young people living with rheumatic diseases across the world. With recent approvals in the US, Japan and Brazil, we are one step closer in our ambition to expand Cosentyx to 10 indications in areas of high unmet need.”

The positive CHMP opinion is based on data from the Phase III JUNIPERA study, a 2-year, three-part, double-blind, placebo-controlled, randomized withdrawal trial showing significantly longer time to flare in Cosentyx vs placebo (P<.001) in pediatric ERA and JPsA patients[16]. Safety in this pediatric population was consistent with the known safety profile of Cosentyx across approved adult and pediatric indications[9].

This CHMP recommendation supports Novartis ongoing commitment to the pediatric community across a range of inflammatory conditions. In July 2020, Cosentyx received EMA approval as a first-line systemic treatment for pediatric psoriasis in patients aged 6-18 years old and recently received approval in the US and China[8, 17]. In 2021, Cosentyx was also approved in Japan to treat both PsA and psoriasis in pediatric patients aged 6 years or older, as well as those with generalized pustular psoriasis[18]. Earlier this year, Cosentyx was also approved in Brazil to treat ERA in patients 4 years or older and JPsA in patients aged 2 years and older[19].

About the JUNIPERA trial

The positive CHMP opinion is based on data from the Phase III JUNIPERA study, a 2-year, three-part, double-blind, placebo-controlled, randomized withdrawal trial that enrolled 86 children and adolescents aged 2–18 years old with a confirmed diagnosis of ERA or JPsA according to a modified International League of Associations for Rheumatology classification criteria[16]. The primary endpoint of the study was time to flare in the treatment period 2 (Week 12 to Week 104)[16]. The study met its primary endpoint and demonstrated a statistically significant longer time to disease flare in treatment period 2 for ERA and JPsA with secukinumab versus placebo. The risk of flare was reduced by 72% for patients on secukinumab compared with patients on placebo in treatment period 2 (Hazard ratio=0.28, 95% CI: 0.13 to 0.63, p<0.001). A total of 21 patients in the placebo group experienced a flare event (11 JPsA and 10 ERA) compared with 10 patients in the secukinumab group (4 JPsA and 6 ERA) during the placebo-controlled treatment period 2 of the study[8, 10]. Safety in this pediatric population was consistent with the known safety profile of Cosentyx for the treatment of adult and pediatric plaque psoriasis, PsA and axial spondyloarthritis[9].

About Cosentyx

Cosentyx is the first and only fully human biologic that directly inhibits interleukin-17A, an important cytokine involved in the inflammation of psoriatic arthritis (PsA), moderate to severe plaque psoriasis, ankylosing spondylitis (AS) and non-radiographic axial spondyloarthritis (nr-axSpA)[8, 20]. Cosentyx is a proven medicine and has been studied clinically for more than 14 years. The medicine is backed by robust evidence, including 5 years of clinical data in adults supporting long-term safety and efficacy across moderate to severe plaque psoriasis, PsA and AS[1-3, 5-7, 21]. These data strengthen the position of Cosentyx as a treatment across AS, nr-axSpA, PsA and moderate to severe plaque psoriasis, supported by more than 700,000 patients treated worldwide since launch in 2015[8, 11, 22].

Disclaimer

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About Novartis
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Novartis Media Relations
E-mail: media.relations@novartis.com

Michael Meo
Novartis US External Communications
+1 862 274 5414 (direct)
michael.meo@novartis.com

Rachel Fink-Thoma
Novartis Pharma Communications
+41 97789486 (direct)
rachel.fink@novartis.com

Julie Masow
Novartis US External Communications
+1 862 579 8456
julie.masow@novartis.com

Novartis Investor Relations
Central investor relations line: +41 61 324 7944
E-mail: investor.relations@novartis.com

Central		North America	
Samir Shah	+41 61 324 7944	Sloan Simpson	+1 862 345 4440
Thomas Hungerbuehler	+41 61 324 8425	Alina Levchuk	+1 862 778 3372
Isabella Zinck	+41 61 324 7188	Parag Mahanti	+1 973-876-4912

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