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MEDIA UPDATE

Cosentyx® (secukinumab) receives expanded approvals in EU for use in childhood arthritic conditions

- *Approvals based on data from the JUNIPERA trial, showing that Cosentyx® (secukinumab) reduced the risk of flare and disease activity compared to placebo over 2 years in pediatric patients[1] with enthesitis-related arthritis (ERA) and psoriatic arthritis (PsA)*

- *Safety in these pediatric populations was consistent with the known safety profile across approved adult and pediatric indications[1,2]*

- *Since its initial approval in 2015, Cosentyx has a proven sustained efficacy profile across several systemic inflammatory conditions and has been used to treat more than 700,000 patients worldwide[1–11]*

Basel, June 27, 2022 — Novartis today announced the European Commission (EC) has approved 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[1].

“The approval of Cosentyx is very positive news for children affected by JPsA and ERA across Europe. We are now able to offer a new therapeutic target, which was not on the market for this disease in children and also offers a lower frequency of administration. Cosentyx adds to the body of other approved treatments that may provide children and adolescent patients, with the opportunity to participate in all daily activities, and even sports,” said Ivan Foeldvari, M.D., Hamburg Centre for Pediatric Rheumatology, Germany.

ERA and JPsA are two forms of juvenile idiopathic arthritis (JIA) and 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[13,14]. 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, these diseases can lead to high levels of pain and disability[12–15].

“Cosentyx could now provide a treatment option for eligible patients who continue to struggle with the painful symptoms which negatively impact their quality of life, such as inflammation of the joints, swollen fingers and toes,” said Todd Fox, Global Head of Medical Affairs Immunology at Novartis. “This approval represents an important step in our ambition to expand Cosentyx to 10 indications for children and adults living with rheumatic and dermatologic diseases.”

The approval is based on data from the Phase III JUNIPERA trial, a 2-year, three-part, double-blind, placebo-controlled, randomized withdrawal trial showing significantly longer time to flare in Cosentyx versus placebo in pediatric patients with ERA and JPsA[16]. Safety in this pediatric population was consistent with the known safety profile of Cosentyx across approved adult and pediatric indications[1,2].

Novartis is working closely with regulatory agencies to ensure that eligible European patients can start benefitting from Cosentyx as quickly as possible. In July 2020, Cosentyx received European Medicines Agency 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[1,17]. In 2021, Cosentyx was also approved in Japan for pediatric psoriasis[18]. Cosentyx was also approved in the US in December 2021 and earlier this year 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 EC approval is based on data from the Phase III JUNIPERA trial, 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 the modified International League of Associations for Rheumatology classification criteria[16]. The primary endpoint of the trial was time to flare in the treatment period 2 (Week 12 to Week 104)[16]. The trial 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% confidence interval: 0.13 to 0.63; P<0.001). A total of 21 patients in the placebo group experienced a flare (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 trial[1,10]. 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[2].

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)[1,20]. 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 in adult patients with moderate to severe plaque psoriasis, PsA, AS and nr-axSpA[3–5,7–9,21]. These data strengthen the position of Cosentyx as a treatment option in these conditions, and are supported by more than 700,000 patients treated worldwide since launch in 2015[1,11,22].

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