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## MEDIA & INVESTOR RELEASE

# Novartis Cosentyx® receives FDA approval for the treatment of children and adolescents with enthesitis-related arthritis and psoriatic arthritis

- *New approvals are based on JUNIPERA trial data showing Cosentyx® (secukinumab) demonstrated reduced flare risk versus placebo and improvement in disease activity observed over two years across both enthesitis-related arthritis (ERA) and psoriatic arthritis (PsA) in pediatric patients*[1]

- *Safety in these pediatric populations was consistent with the known safety profile of Cosentyx*[2]

- *Cosentyx is the only biologic treatment approved for children and adolescents for both ERA (4 years of age and older) and PsA (2 years of age and older) in the US*

**Basel, December 22, 2021** — Novartis, a leader in rheumatology and immuno-dermatology, today announced the US Food and Drug Administration (FDA) has approved Cosentyx® (secukinumab) for the treatment of active enthesitis-related arthritis (ERA) in patients four years and older, and active juvenile psoriatic arthritis (JPsA) in patients two years and older[1]. Cosentyx is now the first biologic indicated for ERA, and the only biologic treatment approved for both ERA and PsA in pediatric patients in the US. These are the second and third approvals for Cosentyx in a pediatric population in the US, and Cosentyx now has a total of five indications across rheumatology and dermatology[1].

“Prior research suggests that despite receiving treatment, some children and adolescents with PsA or ERA can continue to experience symptoms,” said Hermine Brunner, M.D., Cincinnati Children’s Hospital. “The findings from the Phase III JUNIPERA trial show that pediatric patients treated with secukinumab demonstrated marked responses throughout the treatment period. This approval is positive news for some patients who continue to struggle with painful symptoms like inflammation of the joints and swollen fingers and toes.”

ERA and JPsA, subtypes of juvenile idiopathic arthritis (JIA), are autoimmune diseases[3-5]. ERA is characterized by joint swelling and pain where tendons and ligaments attach to bone and may present with low back pain or tenderness at the palpation of the hips[5]. 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[6]. If left untreated, they can lead to high levels of pain and disability[3-5].

“This marks the second and third US pediatric approval this year for Cosentyx, following pediatric psoriasis approval and further reinforces the proven efficacy and safety of the therapy. With more than 500,000 adult and pediatric patients treated worldwide since launch, healthcare professionals and patients can feel confident in Cosentyx,” said Todd Fox, Global

Head of Medical Affairs Immunology, Hepatology and Dermatology at Novartis. “Furthermore, we are pleased to build on our strong heritage of bringing innovative treatments to young people living with rheumatic diseases, which began with the FDA approval of Ilaris. We are committed to bringing Cosentyx to this pediatric community globally as part of our ambition to expand Cosentyx to 10 indications in areas of high unmet need.”

The approved pediatric dosing for Cosentyx in children and adolescents is 75 mg (15 kg or more to less than 50 kg) or 150 mg (50 kg or more)[1]. It is administered as a subcutaneous injection by a pre-filled syringe or Sensoready® pen every 4 weeks after initial loading doses[1]. With appropriate guidance/instruction from a healthcare professional, Cosentyx can be administered by an adult caregiver outside of a healthcare provider’s office via a single-dose prefilled syringe or Sensoready® pen.

The approval is based on data from the Phase III JUNIPERA study, a two-year, three-part, double-blind, placebo-controlled, randomized-withdrawal trial that enrolled 86 children and adolescents aged 2 to 18 years old with a confirmed diagnosis of ERA or JPsA according to a modified International League of Associations for Rheumatology classification criteria[7]. The primary endpoint of the study was time to flare in the treatment period 2 (Week 12 to Week 104)[7]. In children and adolescents aged 2 to 18 years old, the study demonstrated that patients with active JPsA (n = 34; mean age: 12.2) treated with Cosentyx had a longer time to flare, showing an 85% reduction in the risk of flare ($P<0.001$) versus placebo[1,8]. The study also demonstrated that patients with active ERA (n = 52; mean age: 13.7) treated with Cosentyx had a significantly longer time to flare, showing a 53% reduction in the risk of flare versus placebo[1,8]. Safety in this pediatric population was consistent with the known safety profile of Cosentyx for the treatment of plaque psoriasis, PsA, non-radiographic axial spondyloarthritis and ankylosing spondylitis[2].

“The symptoms of PsA and ERA can be debilitating for children and adolescents living with these chronic conditions, impacting their daily lives,” said Tiffany Westrich-Robertson, CEO, International Foundation for Autoimmune & Autoinflammatory Arthritis (AiArthritis). “It is encouraging to see an additional treatment option for these underserved patient populations.”

In July 2020, Cosentyx received EU approval as a first-line systemic treatment for pediatric psoriasis in patients aged 6 to 18 years old and recently received approval in the US and China[1,9,10]. 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[11].

Novartis has filed a regulatory submission for Cosentyx in ERA and JPsA in Europe with a decision anticipated in the coming months.

**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, 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 5 years of clinical data in adults supporting long-term safety and efficacy across moderate to severe plaque psoriasis, PsA and AS[14-20]. 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 500,000 patients treated worldwide since launch in 2015[1,21,22].

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marketing approvals, new indications or labeling for the investigational or approved products described in this press release, or regarding potential future revenues from such products. You should not place undue reliance on these statements. Such forward-looking statements are based on our current beliefs and expectations regarding future events, and are subject to significant known and unknown risks and uncertainties. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those set forth in the forward-looking statements. There can be no guarantee that the investigational or approved products described in this press release will be submitted or approved for sale or for any additional indications or labeling in any market, or at any particular time. Nor can there be any guarantee that such products will be commercially successful in the future. In particular, our expectations regarding such products could be affected by, among other things, the uncertainties inherent in research and development, including clinical trial results and additional analysis of existing clinical data; regulatory actions or delays or government regulation generally; global trends toward health care cost containment, including government, payor and general public pricing and reimbursement pressures and requirements for increased pricing transparency; our ability to obtain or maintain proprietary intellectual property protection; the particular prescribing preferences of physicians and patients; general political, economic and business conditions, including the effects of and efforts to mitigate pandemic diseases such as COVID-19; safety, quality, data integrity or manufacturing issues; potential or actual data security and data privacy breaches, or disruptions of our information technology systems, and other risks and factors referred to in Novartis AG's current Form 20-F on file with the US Securities and Exchange Commission. Novartis is providing the information in this press release as of this date and does not undertake any obligation to update any forward-looking statements contained in this press release as a result of new information, future events or otherwise.

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