

## **MEDIA & INVESTOR RELEASE**

# **Novartis presents positive Phase III results from JUNIPERA study supporting Cosentyx<sup>®</sup> as a potential treatment in a JIA population at EULAR 2021**

- *Phase III JUNIPERA study met its primary endpoint, with Cosentyx<sup>®</sup> (secukinumab) showing significantly longer time to flare (longer time to worsening of symptoms<sup>1</sup>) vs. placebo ( $P < .001$ ) in pediatric patients with two subtypes of juvenile idiopathic arthritis (JIA)<sup>2</sup>*
- *JIA has limited treatment options and affects approximately 2 million children worldwide<sup>3,4</sup>. Subtypes juvenile psoriatic arthritis (JPsA) and enthesitis-related arthritis (ERA) are progressive, debilitating diseases associated with high levels of pain and functional disability, affecting children as young as two years old<sup>5</sup>*
- *Data follow recent US and EU approval of Cosentyx as a first-line systemic treatment for pediatric psoriasis, reinforcing the commitment of Novartis to the pediatric community*
- *Cosentyx has approvals across four indications, and is supported by long-term five-year sustained efficacy and safety data across psoriasis, psoriatic arthritis (PsA) and ankylosing spondylitis (AS), with more than 400,000 patients treated worldwide since launch<sup>6-9</sup>*

**Basel, June 2, 2021** — Novartis, a leader in rheumatology and immuno-dermatology, today announced 2-year positive results from the Phase III JUNIPERA study, demonstrating that Cosentyx<sup>®</sup> (secukinumab) significantly delayed time to flare vs placebo ( $P < .001$ ) in pediatric patients with juvenile psoriatic arthritis (JPsA) and enthesitis-related arthritis (ERA) – two subtypes of juvenile idiopathic arthritis (JIA)<sup>2</sup>. The data will be presented as a late-breaker at the EULAR 2021 Annual European Congress of Rheumatology (Abstract #LB0004; oral presentation: Saturday, June 5, 8:10 AM CEST)<sup>2</sup>.

“Both JPsA and ERA are progressive, chronic, debilitating diseases with limited treatment options. JIA can impact the daily lives of children and teenagers, with over 30% of children with JIA finding it difficult to attend school due to their condition, and many children still having active disease as adults,” said Dr. Hermine Brunner, Cincinnati Children’s Hospital Medical Center and lead investigator of the JUNIPERA study. “The JUNIPERA data are encouraging and pave the way for an effective treatment option that delays the worsening of symptoms leading to improvement in quality of life for these children.”

The JUNIPERA study also demonstrated sustained efficacy for Cosentyx with more patients achieving and maintaining the JIA American College of Rheumatology (ACR) 30 and JIA ACR

70 responses from Week 12 to Week 104 vs placebo. Cosentyx demonstrated a favorable safety profile with no new safety signals reported in pediatric patients (age 2 to 17 years) with two years of treatment.

“JPsA and ERA are associated with high levels of pain and functional disability, which can impact children as young as two years of age. These new data in pediatric patients are an example of our continued commitment to reimagine the future of rheumatology for those with inflammatory rheumatic diseases,” said Todd Fox, Global Head of Medical Affairs Immunology, Hepatology and Dermatology at Novartis.

Cosentyx is the first and only fully human biologic that directly inhibits interleukin-17A (IL-17A), a cornerstone cytokine involved in the inflammation and development of psoriatic arthritis (PsA), psoriasis and axial spondyloarthritis (axSpA).

Regulatory submissions in Europe and the US are anticipated in the coming weeks. In August 2020, Cosentyx received EU approval as a first-line systemic treatment for pediatric psoriasis and recently received US approval for the same indication.

Plain Language Media Summaries for JUNIPERA and other key abstracts presented at EULAR 2021 are available from the Novartis website: <https://www.novartis.com/our-focus/immunology-dermatology/abstract-summaries-eular>

#### **About the JUNIPERA study<sup>10</sup>**

JUNIPERA is a two-year, three-part, double-blind, placebo-controlled, randomized-withdrawal, Phase III study investigating the efficacy and safety of secukinumab in the juvenile idiopathic arthritis (JIA) subtypes of juvenile psoriatic arthritis (JPsA) and enthesitis-related arthritis (ERA). The JUNIPERA study 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 criteria. 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 12. In this treatment period 1, patients achieving at least JIA ACR 30 response then progressed onto treatment period 2. In treatment period 2, patients were allocated to one of two arms: secukinumab 75 mg/150 mg (depending on bodyweight) or placebo and responses observed up until Week 104.

The primary endpoint of the study was time to flare in the treatment period 2 (Week 12 to Week 104). 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 Juvenile Arthritis Disease Activity Score (JADAS), and total enthesitis and dactylitis count. Additional secondary endpoints during treatment period 2 from Week 12 to Week 104 included: effect of withdrawing secukinumab treatment with respect to JIA ACR 30/50/70/90/100 response and inactive disease; secukinumab serum concentration; safety/tolerability and immunogenicity of secukinumab.

An extension study of secukinumab to evaluate the long-term efficacy, safety and tolerability up to four years in patients with JPsA and ERA is currently ongoing.

#### **About Cosentyx® (secukinumab)**

Cosentyx is the first and only fully human biologic that directly inhibits interleukin-17A (IL-17A), a cornerstone cytokine involved in the inflammation and development of moderate-to-severe plaque psoriasis, psoriatic arthritis (PsA), ankylosing spondylitis (AS) and non-radiographic axial spondyloarthritis (nr-axSpA)<sup>8,11,12</sup>. Cosentyx is the only biologic with proven efficacy in all six key manifestations of PsA<sup>8,13,14</sup>.

Cosentyx is backed by more than 14 years of clinical experience and long-term five-year clinical data across three indications of psoriasis, PsA and AS, as well as real-world evidence<sup>6-8</sup>. These data strengthen the unique position of Cosentyx as a rapid and long-

lasting comprehensive treatment across axial spondyloarthritis, PsA and psoriatic disease, with more than 400,000 patients treated worldwide with Cosentyx since launch<sup>9</sup>.

### **Disclaimer**

This press release contains forward-looking statements within the meaning of the United States Private Securities Litigation Reform Act of 1995. Forward-looking statements can generally be identified by words such as “potential,” “can,” “will,” “plan,” “may,” “could,” “would,” “expect,” “anticipate,” “seek,” “look forward,” “believe,” “committed,” “investigational,” “pipeline,” “launch,” or similar terms, or by express or implied discussions regarding potential 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.

### **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 110,000 people of more than 140 nationalities work at Novartis around the world. Find out more at <https://www.novartis.com>.

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