

## **MEDIA & INVESTOR RELEASE**

# **Novartis Cosentyx receives FDA approval for treatment of children and adolescents with moderate to severe plaque psoriasis**

- *Approval for moderate to severe pediatric patients six years and older is based on pivotal trial data showing Cosentyx demonstrated superior improvements of skin symptoms compared to placebo<sup>1</sup>*
- *The safety profile of Cosentyx in pediatric patients with plaque psoriasis was demonstrated in two Phase III trials and is consistent with the established adult psoriasis indication<sup>1</sup>*
- *Plaque psoriasis is a chronic, inflammatory disease that may impact up to 350,000 children worldwide, with onset most common during adolescence<sup>2,3</sup>*

**Basel, June 1, 2021** — Novartis, a leader in immuno-dermatology and rheumatology, today announced the U.S. Food and Drug Administration (FDA) has approved Cosentyx® (secukinumab) for the treatment of moderate to severe plaque psoriasis in pediatric patients six years and older who are candidates for systemic therapy or phototherapy<sup>1</sup>. This is the first approval for Cosentyx in a pediatric population in the US. The Cosentyx clinical profile is supported by five years of adult data showing long-lasting efficacy and a consistent safety profile across moderate to severe plaque psoriasis, psoriatic arthritis and ankylosing spondylitis<sup>4-10</sup>.

“Treating moderate to severe plaque psoriasis in children can be complicated, as we need to balance the ability of a treatment to provide symptom relief while considering the safety profile as the top priority,” said John Browning, MD, FAAD, FAAP, MBA, clinical trial investigator, Adjunct Associate Professor of Pediatrics and Dermatology at the University of Texas Health, San Antonio. “In the pediatric pivotal study, the majority of patients treated with Cosentyx were able to achieve clear or almost clear skin with a safety profile consistent with previous clinical trials in adults. Due to the systemic nature of the disease, Cosentyx is a welcome addition as a treatment option for families dealing with this challenging condition.”

Psoriasis is a common chronic, inflammatory condition which affects approximately 8 million Americans and 1% of children and adolescents in the US<sup>2,11</sup>. Onset is most common during adolescence, with one-third of psoriasis cases beginning in the pediatric years<sup>2,12</sup>. Psoriasis can have a negative impact on the quality of life of children, especially during their formative years<sup>13</sup>.

The approved pediatric dosing for Cosentyx is 75 mg or 150 mg depending on the child’s weight at the time of dosing and is administered by subcutaneous injection every four weeks after an initial loading regimen<sup>1</sup>. After initial counseling and proper training in injection

technique, 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 impact of psoriasis on children is much deeper than skin and can potentially lead to life course impairment. Today's FDA approval further demonstrates our commitment to reimagine medicine for pediatric plaque psoriasis patients,” said Angelika Jahreis MD, PhD, Novartis Global Head Development Unit Immunology, Hepatology & Dermatology. “With more than 400,000 patients treated in over 100 countries worldwide, we continue to build on the established safety and efficacy profile of Cosentyx, with plans to expand to 10 indications over the next 10 years.”

This Cosentyx approval is based on two Phase III studies evaluating the use of Cosentyx in children aged 6 to <18 years with plaque psoriasis. The safety profile reported in these trials was consistent with the safety profile reported in adult plaque psoriasis trials. No new safety signals were observed<sup>1</sup>.

The first study, which evaluated efficacy and safety, was a 52-week (236 weeks total), randomized, double-blind, placebo- and active-controlled study which included 162 children six years of age and older with severe plaque psoriasis. The data showed Cosentyx reduced psoriasis severity at Week 12 compared with placebo as demonstrated by the following efficacy results by baseline weight strata for the approved doses (75mg for <50kg and 150mg for ≥50kg): Psoriasis Area Severity Index (PASI) 75 response (55% 75 mg vs 10% placebo (N=22 and N=20, respectively), 86% 150 mg vs 19% placebo (N=21 and N=21, respectively), 70% total Cosentyx vs 15% total placebo (N=43 and N=41, respectively) and Investigator's Global Assessment modified 2011 (IGA) “clear” or “almost clear” skin response (32% 75 mg vs 5% placebo, 81% 150 mg vs 5% placebo, 56% total Cosentyx vs 5% total placebo), co-primary endpoints of the study<sup>1</sup>.

The second Phase III study, which assessed safety, was a randomized open-label, 208-week trial of 84 subjects six years of age and older with moderate to severe plaque psoriasis<sup>1</sup>.

“Living with psoriasis is challenging, and can be highly stressful for children and adolescents,” said Randy Beranek, President and CEO, National Psoriasis Foundation. “Having expanded treatment options for this patient population is a step in the right direction to help reduce the burden of plaque psoriasis.”

### **About Psoriasis**

Psoriasis is a chronic, inflammatory disease that affects more than 125 million people worldwide<sup>2,11</sup>. One-third of psoriasis cases begin in childhood and, of these, the onset is most common during adolescence<sup>2,12</sup>. Psoriasis may impact up to 350,000 children worldwide and approximately 1% of children and adolescents in the US<sup>2,3</sup>. The incidence of pediatric psoriasis has more than doubled between 1970 and 1999 in the US<sup>12</sup>.

### **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>14,15,16</sup>. Cosentyx is the only biologic with proven efficacy in all six key manifestations of PsA<sup>15,17,18</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>8,15,19</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>20</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

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