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MEDIA & INVESTOR RELEASE

Novartis Cosentyx® gains positive CHMP opinion for pediatric psoriasis, reinforcing established efficacy and safety profile

- *EMA CHMP positive opinion paves way for Cosentyx® to become a first-line systemic treatment in pediatric psoriasis*
- *CHMP opinion based on two Phase III studies showing Cosentyx provides fast and strong skin clearance and significant improvement in quality of life[1]*
- *Moderate-to-severe psoriasis affects more than 350,000 children worldwide[2], with the physical and psychological burden disrupting important formative years[3]*
- *Potential new indication reinforces Cosentyx leadership in immuno-dermatology and rheumatology and follows recent EU approval in non-radiographic axial spondyloarthritis (nr-axSpA), with plans to expand to 10 indications over the next 10 years*

Basel, June 26, 2020 — Novartis, a leader in immuno-dermatology and rheumatology, 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) for the treatment of moderate-to-severe plaque psoriasis in children and adolescents aged 6 to <18 years.

“Psoriasis affects children much deeper than just the skin and can lead to deterioration of quality of life, potentially having a lasting impact on this vulnerable patient population,” said Todd Fox, Global Head of Medical Affairs Immunology, Hepatology and Dermatology at Novartis. “This is our second positive CHMP opinion for Cosentyx this year alone, following on from recent EC approval in nr-axSpA. The latest positive opinion is an important step forward in our commitment to reimagining care for children with psoriasis, giving them freedom to enjoy full and active lives.”

The positive CHMP opinion is based on two Phase III international studies in children and adolescents aged 6 to <18 years, one open-label, two-arm, parallel-group, multicentre study with moderate-to-severe plaque psoriasis and one randomized, double-blind, placebo and etanercept-controlled study with severe plaque psoriasis. The studies showed both low-dose (75–150 mg) and high-dose (75–300 mg) of Cosentyx were highly efficacious in rapidly improving skin symptoms and quality of life, with a favorable safety profile up to 52 weeks.

In children with moderate-to-severe plaque psoriasis, the low dose of Cosentyx provided fast and strong skin clearance, with 93% achieving Psoriasis Area Severity Index (PASI) 75 as

early as Week 12, 69% achieving PASI 90 at Week 12 and 88% at Week 24, 59.5%% achieving completely clear skin (PASI 100) by Week 12 and 67% by Week 24. In patients with severe psoriasis, the low dose of Cosentyx ensured sustained skin clearance through Week 52, with PASI 90 achieved in 75% of patients[1]. Differences in PASI 75 in patients with severe psoriasis treated with Cosentyx were seen as early as Week 4 and in patients with moderate-to-severe psoriasis as early as Week 2.

Half of children with moderate-to-severe plaque psoriasis treated with low dose of Cosentyx reported complete relief from symptom burden of psoriasis on their quality of life by as early as Week 12, as measured by Children's Dermatology Life Quality Index (CDLQI) 0/1 responses. In children with severe plaque psoriasis treated with low dose of Cosentyx, 44.7% reported complete relief by Week 12, with 60.6% by Week 52. Cosentyx safety profile of both the low dose and high dose is comparable and consistent with the established adult psoriasis indication. No new safety signals were observed in children.

Phase III data in moderate-to-severe plaque psoriasis were presented as a late breaking abstract at the 2020 American Academy of Dermatology Virtual Meeting Experience (AAD VMX) in June 2020[4]

About psoriasis
Psoriasis is a life-long debilitating systemic inflammatory disease that significantly impacts patients' quality of life, both physically and emotionally[5]. One-third of psoriasis cases begin in childhood and of these the onset is most common during adolescence[6]. Moderate-to-severe psoriasis affects more than 350,000 children worldwide and may impact children "deeper than the skin", with the physical and psychological burden of psoriasis disrupting important formative years[2]. The incidence of pediatric psoriasis has more than doubled between 1970 and 2000 in the US and an upward trend in incidence of psoriasis has been observed in several countries[5,6]. There are only a few approved treatment options available and the unmet medical need remains high[3].

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 and development of psoriatic arthritis (PsA), moderate-to-severe plaque psoriasis (PsO), ankylosing spondylitis (AS) and nr-axSpA[7,8,9].

Cosentyx is backed by robust clinical evidence, including five-year data across three indications of PsO, PsA and AS, as well as data from real world evidence[10-15]. These data strengthen the unique position of Cosentyx as a rapid and long-lasting comprehensive treatment across axSpA, PsA and psoriatic disease, with more than 340,000 patients treated worldwide with Cosentyx since launch[16-18].

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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 109,000 people of more than 145 nationalities work at Novartis around the world. Find out more at https://www.novartis.com.

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