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MEDIA & INVESTOR RELEASE

Novartis Cosentyx® receives EU approval for first-line systemic treatment in pediatric psoriasis

- *EU approval is based on two Phase III studies showing Cosentyx® provides fast and strong skin clearance, along with significant improvement in quality of life and a favorable safety profile*[1]

- *Moderate-to-severe psoriasis affects more than 350,000 children worldwide*[2]*, with the physical and psychological burden disrupting important formative years*[3]

- *Cosentyx is a proven brand, supported by long-term five-year sustained efficacy and safety data across psoriasis, psoriatic arthritis (PsA) and ankylosing spondylitis (AS), over 100 studies and with more than 340,000 patients treated worldwide since launch*[4,5,6,7]

- *Approval reinforces Cosentyx leadership in immuno-dermatology and rheumatology, following recent EU approval in non-radiographic axial spondyloarthritis (nr-axSpA), with plans to expand to 10 indications over the next 10 years*

Basel, August 3, 2020 — Novartis, a leader in immuno-dermatology and rheumatology, today announced the European Commission (EC) has granted the approval for Cosentyx® (secukinumab) for the treatment of moderate-to-severe plaque psoriasis in children and adolescents aged 6 to <18 years. The recommended dose for children up to 50 kg is 75 mg (without a lower weight restriction), and 150 mg for children 50 kg and over (150 mg as a starting dose, which may be increased to 300 mg, if needed).

“Psoriasis is a life-long debilitating disease that significantly impacts children’s quality of life, both physically and emotionally. There are only a few approved treatment options available for the pediatric population and so it is important to broaden the adult therapeutic options out to children when possible,” said Professor Christine Bodemer, Head of the Department of Dermatology, Necker–Enfants Malades Hospital, Paris. “This approval means Cosentyx is now available in Europe for children and adolescents, and will provide an additional option to quickly gain relief from their symptom burden and to significantly improve their quality of life.”

The approval is based on two Phase III international studies in children and adolescents aged 6 to <18 years. The studies showed that 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[1].

“The impact of psoriasis on children is much deeper than skin and can potentially lead to life course impairment,” said Todd Fox, Global Head of Medical Affairs Immunology, Hepatology

and Dermatology at Novartis. “This is the second European approval this year for Cosentyx, which also has approvals across four adult indications, reinforcing our commitment to reimagine medicine for both pediatric and adult patients.”

Children with psoriasis have a poorer quality of life than their peers due to symptoms such as itching and fatigue, in addition to feelings of stigmatization. These in turn may affect their emotional wellbeing and performance at school[8].

“Children with psoriasis are susceptible to bullying, name-calling and shaming at school, leading to higher rates of depression and anxiety than their peers,” said Jan Koren, President of the European patient group EUROPSO. “We welcome this approval, as there is a need for additional treatment options that can help give children the freedom to enjoy full and active lives by improving psoriasis symptoms and thus overall quality of life.”

Novartis is working closely with all stakeholders to ensure that eligible European pediatric patients can start benefitting from Cosentyx as quickly as possible. Novartis will also be seeking approval for Cosentyx for the treatment of moderate-to-severe plaque psoriasis in children and adolescents aged 6 to <18 years in a number of other countries including Australia, Canada, Japan and the US.

About psoriasis
Psoriasis is a life-long debilitating systemic inflammatory disease that significantly impacts patients’ quality of life, both physically and emotionally[9]. One-third of psoriasis cases begin in childhood and of these the onset is most common during adolescence[10]. 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[9,10]. There are only a few approved treatment options available and the unmet medical need remains high[3].

About the study data
The two Phase III international studies in children and adolescents aged 6 to <18 years consisted of one open-label, two-arm, parallel-group, multicentre study in children with moderate-to-severe plaque psoriasis and one randomized, double-blind, placebo and etanercept-controlled study in children with severe plaque psoriasis. Dosing regimens of Cosentyx were stratified by weight.

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 the low dose of Cosentyx reported complete relief from symptom burden of psoriasis on their quality of life 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 the 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.

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 systemic inflammation and development of moderate-to-severe plaque psoriasis, PsA, AS and nr-axSpA[11,12,13].

Cosentyx is backed by more than 12 years of clinical experience and long-term five-year data across three indications of psoriasis, PsA and AS, as well as data from real world evidence[14-19]. 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 340,000 patients treated worldwide with Cosentyx since launch[4,19].

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 109,000 people of more than 140 nationalities work at Novartis around the world. Find out more at https://www.novartis.com.

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