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MEDIA UPDATE

Novartis presents latest Phase III data reinforcing Cosentyx® as a first-line systemic treatment in pediatric psoriasis

- *Latest data show Cosentyx® provides fast and strong skin clearance, significant improvement in quality of life and a favorable safety profile[1,2]*
- *Moderate-to-severe psoriasis affects more than 350,000 children worldwide[3], with the physical and psychological burden disrupting important formative years[4]*
- *FDA has accepted a submission for Cosentyx in moderate-to-severe plaque psoriasis in children and adolescents aged 6 to <18 years*
- *Cosentyx is backed by 5-year efficacy and safety data across moderate-to-severe psoriasis, psoriatic arthritis (PsA), ankylosing spondylitis (AS), with 400,000+ patients treated across four indications worldwide since launch[5-10]*

Basel, October 29, 2020 – Novartis, a leader in immuno-dermatology and rheumatology, today announced data from two pivotal international Phase III studies, which show Cosentyx® (secukinumab) provides fast and strong skin clearance and significant improvement in quality of life in children and adolescents aged 6 to <18 years with moderate-to-severe plaque psoriasis.

“Pediatric psoriasis is negatively associated with physical and emotional quality of life, with lasting impact into adulthood, yet there are limited biologic treatment options available,” said Professor Christine Bodemer, Head of the Department of Dermatology, Necker-Enfants Malades Hospital, Paris. “The results from these studies are encouraging as they show Cosentyx rapidly reduces symptom burden with a favorable safety profile in this vulnerable patient group, providing us with a much-needed treatment option.”

“These new data add to the wealth of evidence Cosentyx has across four indications,” said Todd Fox, Global Head of Medical Affairs for Immunology, Hepatology and Dermatology, Novartis. “Cosentyx is already approved as a first-line systemic treatment for children in Europe and next year we are expecting a response on our recently accepted submission to the US Food and Drug Administration.”

Plain Language Media Summaries for the two pediatric psoriasis Phase III trials and other key abstracts presented at EADV 2020 are available from the Novartis website: https://www.novartis.com/our-focus/immunology-dermatology/abstract-summaries-eadv

About psoriasis
Psoriasis is a life-long debilitating systemic inflammatory disease that significantly impacts patients' quality of life, both physically and emotionally[11]. One third of psoriasis cases begin in childhood and, of these, the onset is most common during adolescence[12]. Moderate-to-severe psoriasis affects more than 350,000 children worldwide and may impact children beyond the skin, with the physical and psychological burden of psoriasis disrupting important formative years[3]. 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[11,12]. There are only a few approved treatment options available, and the unmet medical need remains high[4].

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, multicenter 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 groups.

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[1]. 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[2]. 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[13].

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[1]. 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[2].

Cosentyx safety profile for 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[1,2].

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, psoriatic arthritis (PsA), ankylosing spondylitis (AS) and non-radiographic axial spondyloarthritis (nr-axSpA)[14-16].

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[5-10,17]. 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[18] and plans to expand to 10 indications over the next 10 years.

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About Novartis

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