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MEDIA UPDATE

Novartis secures new approval in China for Cosentyx® (secukinumab) in pediatric psoriasis

- *China National Medical Products Administration (NMPA) approval reinforces that Cosentyx® (secukinumab) is safe and effective for children and adults with psoriasis*
- *Moderate-to-severe plaque psoriasis affects more than 350,000 children worldwide[1], with the physical and psychological burden disrupting important formative years[2]*
- *Cosentyx is a proven treatment, supported by long-term five-year sustained efficacy and safety data across several inflammatory conditions[3-5] and with more than 500,000 patients treated worldwide since launch[6]*
- *Approval in China for pediatric psoriasis combined with recent filings in the United States and Europe for juvenile psoriatic arthritis (JPsA) and enthesitis-related arthritis (ERA) further supports plans to expand Cosentyx to 10 indications over the next 10 years*

Basel, August 17, 2021 – Novartis today announced that the China National Medical Products Administration (NMPA) has further approved Cosentyx® (secukinumab) for the treatment of moderate-to-severe plaque psoriasis in pediatric patients (six years and older with a body weight ≥50 kg) who are candidates for systemic therapy or phototherapy, making it the only interleukin inhibitor approved in China for these patients. Cosentyx is already approved in China for the treatment of moderate-to-severe plaque psoriasis in adults and adult ankylosing spondylitis. The approval is based on two Phase III international studies in pediatric patients aged 6 to <18 years old, which showed that Cosentyx was as safe in children and adolescents as when used in adults[7,8].

“Psoriasis goes beyond skin symptoms. If left untreated it can become a source of embarrassment, affecting a young person’s self-esteem. The approval in China of Cosentyx means we are able to help even more children and adults around the world live their lives to the fullest, by providing them with a safe and effective therapy they can trust,” said Todd Fox, Novartis Global Medical Franchise, Head of Immunology, Hepatology and Dermatology. “With further US and European filings for childhood arthritic conditions, we have taken another step in our ambition to expand Cosentyx to 10 indications over the next 10 years as part of our commitment to immuno-dermatology and rheumatology.”

This approval in China follows recent approval of Cosentyx in the United States and Europe for the treatment of moderate-to-severe plaque psoriasis in pediatric patients six years and older who are candidates for systemic therapy or phototherapy.

Novartis is committed to making Cosentyx available to young patients who may benefit from the therapy and has recently filed for US and European regulatory approval for Cosentyx as a potential treatment in juvenile psoriatic arthritis (JPsA) and enthesitis-related arthritis (ERA), two subtypes of juvenile idiopathic arthritis (JIA). Currently, there are very limited approved treatment options for JIA, and only a minority of patients go on to achieve and maintain an inactive disease state.

Cosentyx is backed by more than 14 years of clinical experience and long-term five-year clinical data across three indications of psoriasis, psoriatic arthritis (PsA) and axial spondyloarthritis (AS), as well as real-world evidence[3-5]. These data strengthen the unique position of Cosentyx as a rapid and long-lasting comprehensive treatment across AS, PsA and psoriatic disease, with more than 500,000 patients treated worldwide with Cosentyx since launch[6].

About psoriasis
Psoriasis is a chronic, inflammatory disease that affects more than 125 million people worldwide[9], potentially impacting up to 350,000 children[1]. One-third of psoriasis cases begin in childhood, and of these, the onset is most common during adolescence[2].

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)[4,10,11]. Cosentyx is the only biologic with proven efficacy in all six key manifestations of PsA[4,12,13].

This pediatric psoriasis approval in China is for 150 mg Cosentyx given by injection every four weeks for children with a body weight of at least 50 kg. After initial counseling and proper training in the injection technique, Cosentyx can be given by a child's parent or carer at home. Cosentyx is also approved in China for treating adults with moderate-to-severe plaque psoriasis or ankylosing spondylitis.

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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 media update as of this date and does not undertake any obligation to update any forward-looking statements contained in this media update as a result of new information, future events or otherwise.

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