US FDA approves Novartis Cosentyx for paediatric patients aged 12+ with moderate to severe hidradenitis suppurativa

Novartis announced that Cosentyx (secukinumab) received US Food and Drug Administration (FDA) approval for treating paediatric patients 12 years and older with moderate to severe hidradenitis suppurativa (HS), making it the only IL-17A inhibitor for this population, The approval of a distinct biologic option for paediatric patients living with HS allows treatment to be tailored to the individual and establishes Cosentyx as a meaningful addition to the treatment landscape.

“Hidradenitis suppurativa (HS) often begins in adolescence and can cause irreversible scarring and disabilities,” said Alexa B. Kimball, MD, MPH, lead investigator of the SUNSHINE and SUNRISE clinical trials in adult HS patients, president and CEO of Harvard Medical Faculty Physicians at Beth Israel D eaconess Medical Center, Boston, and Professor of Dermatology at Harvard Medical School. “The approval of Cosentyx represents an important advancement for younger HS patients who have had limited treatment options.”

HS is a chronic, systemic inflammatory skin disease that causes recurring boil-like lesions, which can rupture into painful wounds and lead to scarring. HS affects as many as 1 in 100 people worldwide and often begins around puberty. More than half of patients develop symptoms during adolescence, highlighting the importance of early intervention.

“Hidradenitis suppurativa (HS) affects far more than skin; it impacts confidence, emotional well-being and relationships during a formative period for many paediatric patients,” said Brindley Brooks, founder & CEO, HS Connect. “For families watching their children struggle, this FDA approval brings hope for earlier intervention.”

The distinct IL-17A mechanism provides physicians with a differentiated therapeutic option to help manage this challenging condition in younger patients, with dosing tailored to patient weight. The use of Cosentyx in patients aged 12+ with moderate to severe HS weighing 30 kg or more is supported by well-controlled adult studies and pharmacokinetic modelling extrapolated from adult HS and psoriasis clinical trials, as well as paediatric clinical trial data from other approve d indications1. The approval is also supported by dosing analysis, which predicted that weight-based dosing of Cosentyx in paediatric patients can provide similar exposure to adult HS patients.

“With more than a decade of real-world experience across multiple autoimmune diseases, Cosentyx is a well-established treatment option that many physicians trust ,” said Victor Bultó, president, Novartis US. “Yet for young people living with moderate to severe hidradenitis suppurativa (HS), treatment options have remained limited for far too long. Expanding Cosentyx to this population addresses a critical gap in care and underscores our focus on advancing solutions where we can make the greatest impact on outcomes.”

Cosentyx is a fully human biologic that directly inhibits interleukin-17A, an important cytokine involved in the inflammation underlying multiple immune-mediated inflammatory diseases. It is approved for use in adults with hidradenitis suppurativa (HS), psoriatic arthritis (PsA), moderate to severe plaque psoriasis (PsO), ankylosing spondylitis (AS), and non-radiographic axial spondyloarthritis (nr-axSpA), as well as in pediatric patients with HS, PsO, enthesitis-related arthritis (ERA), and juvenile psoriatic arthritis (JPsA). Cosentyx is supported by robust evidence and more than 10 years of real-world data demonstrating its long-term safe ty and sustained efficacy. Since its launch in 2015, it has been used to treat more than 1.8 million patients worldwide and is now approved in over 100 countries.

HS is a chronic, systemic, progressive and often painful inflammatory skin disease. It causes recurring boil-like abscesses that can burst, creating open wounds, often in the most intimate parts of the body, which may result in irreversible scarring. It can take up to 10 years on average to get a correct diagnosis, and may affect approximately 1 in 100 people globally. HS impacts patients' quality of life more than any other skin disease, and people living with H S often experience comorbidities such as obesity, diabetes, arthritis and depression.

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