Health Canada approves Cosentyx®, a biologic therapy, for the treatment of adults with moderate to severe Hidradenitis Suppurativa (HS)

May 23, 2024

- *Approval is based on the two largest Phase III trials conducted in HS – SUNSHINE and SUNRISE – demonstrating the safety and efficacy of Cosentyx® in HS*[1]
- *HS is a chronic, immunological, inflammatory skin condition estimated to affect 1 in 100 people worldwide causing painful, boil-like lumps that can lead to open wounds and irreversible scarring*[2,3,4]
- *The new treatment for HS reinforces Novartis' commitment to delivering new, innovative therapies that improve health outcomes for patients in Canada*

Montréal, Quebec, May 22, 2024 – Novartis Pharmaceuticals Canada Inc. (Novartis) is pleased to announce that Health Canada has granted Cosentyx® (secukinumab) with a Notice of Compliance (NOC) for the treatment of adult patients with moderate to severe hidradenitis suppurativa (HS) (acne inversa) who have responded inadequately to conventional systemic hidradenitis suppurativa therapy – representing a safe and efficacious new treatment option for Canadians living with the condition.[1]

While the exact cause and prevalence of HS is unknown,[2] it is estimated to affect 1-4 per cent of the Canadian population[4] which equates to between 300,000 and 1 million people.[5] HS is considered a chronic and progressive disease, meaning it can worsen over time and have a significant impact on a patient's everyday life.[4]

"People living with HS often suffer physically and mentally from the effects of the condition," said Latoya Palmer, Founder of Hidradenitis and Me Support Group. "Ensuring there are a wide range of treatment options is vital for each individual to find the right path for them."

The safety and efficacy of Cosentyx® was assessed in the two largest Phase III trials ever conducted in HS – SUNSHINE (M2301) and SUNRISE (M2302). The global, multicentre, randomized, double-blind, placebo-controlled clinical trials studied 1,084 adult patients with moderate to severe HS.[1]

"Patients who have been diagnosed with advanced HS often have limited treatment options available to them," said Dr. Susan Poelman, Dermatologist and President of the HS Foundation in Canada. "The approval of a new treatment option for HS is a welcome new addition for people living with the condition and will bring hope to patients that have achieved suboptimal control with current available therapies."

In addition to HS, Cosentyx® has been previously approved for use in Canada for a variety of conditions including plaque psoriasis, psoriatic arthritis, axial spondyloarthritis and juvenile idiopathic arthritis.[1] Given its well-known and proven safety profile, Cosentyx® will provide physicians and their patients with more treatment options to decide on the most appropriate course of action to treat their HS.

"This approval will offer a new treatment option for patients currently living with HS," added Dr. Mark Kirchhof, Division Head of Dermatology in the Faculty of Medicine at the University of Ottawa and The Ottawa Hospital. "Cosentyx® will provide dermatologists with a familiar treatment for this complex condition."

"More than 1 million patients have been treated with Cosentyx® worldwide since its launch in 2015, and we are proud that is now available in Canada as a much-needed treatment to those suffering with HS," said Mark Vineis, Country President Novartis Pharmaceuticals Canada Inc. "This approval is another example of Novartis' commitment to bringing innovative medicines to improve patient outcomes in Canada."

About Novartis
Novartis is a focused innovative medicines company. Every day, we work to reimagine medicine to improve and extend people's lives so that patients, healthcare professionals and societies are empowered in the face of serious disease. Our medicines reach more than 250 million people worldwide. Reimagine medicine with us: Visit us at https://www.novartis.com and connect with us on LinkedIn, Facebook, X/Twitter and Instagram.

In Canada, Novartis Pharmaceuticals Canada Inc. employs approximately 600 people to serve the evolving needs of patients and the healthcare system, and invests over $30 million in R&D yearly in the country. For more information visit www.novartis.ca.

About the SUNSHINE and SUNRISE trials[6,7,8]
The SUNSHINE (NCT03713619) and SUNRISE (NCT03713632) trials comprise the largest Phase III program in hidradenitis suppurativa (HS), with a combined enrollment of more than 1,000 patients in 40 countries. SUNSHINE and SUNRISE evaluated the short- (16 weeks) and long-term (up to 52 weeks) efficacy, safety and tolerability of two dose regimens of Cosentyx® (secukinumab) in adults with moderate to severe HS.

About Cosentyx® (secukinumab)
Cosentyx® is the first and only fully human biologic that directly inhibits interleukin-17A, an important cytokine involved in the inflammation of psoriatic arthritis (PsA), moderate to severe plaque psoriasis, ankylosing spondylitis (AS) and non-radiographic axial spondyloarthritis (nr-axSpA).[9,10] Cosentyx® is a proven medicine and has been studied clinically for more than 14 years. The medicine is backed by robust evidence, including 5 years of clinical data in adults supporting long-term safety and efficacy across moderate to severe plaque psoriasis, PsA and AS.[11,12,13,14,15,16,17] These data strengthen the position of Cosentyx® as a treatment across AS, nr-axSpA, PsA, moderate to severe plaque psoriasis (adult and pediatric) and two subtypes of juvenile idiopathic arthritis (JIA), enthesitis-related arthritis and juvenile psoriatic arthritis.[9] More than 1 million patients have been treated with Cosentyx® worldwide since its launch in 2015.

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