MEDIA & INVESTOR RELEASE

Novartis Cosentyx® shows clinically meaningful symptom improvements in patients with hidradenitis suppurativa in pivotal Phase III trials

- Results from two parallel trials show Cosentyx® (secukinumab) demonstrated superior efficacy vs placebo with statistically significant improvement in hidradenitis suppurativa (HS) signs and symptoms1

- Safety results were consistent with the well-established Cosentyx safety profile

- HS is a chronic, inflammatory skin condition affecting up to one in 100 people worldwide2, resulting in painful, potentially disfiguring lesions, which leaves feelings of stigmatization and can severely impact quality of life3,4

- Data from SUNSHINE and SUNRISE trials were submitted as part of regulatory applications to health authorities in Europe; plan to submit in the US by year end

Basel, September 10, 2022 — Novartis announced the results from two pivotal, Phase III studies (SUNSHINE and SUNRISE), in which Cosentyx® (secukinumab) demonstrated rapid and sustained relief from the common clinical signs and symptoms of moderate-to-severe hidradenitis suppurativa (HS) with a favorable safety profile5,6. The data were presented as a late-breaking abstract at the 31st European Academy of Dermatology and Venereology (EADV) Congress1.

“Hidradenitis suppurativa can cause intense pain, disability and anxiety, impacting many aspects of daily living. However, there are only limited treatment options available that can make a difference to people living with this debilitating disease,” said Dr. Alexa B. Kimball, lead investigator of the trials, investigator at Beth Israel Deaconess Medical Center, and Professor of Dermatology, Harvard Medical School. “These efficacy and safety findings are promising for people living with HS, who are in urgent need of new treatment options.”

These Phase III data have been submitted to regulatory authorities in Europe and will be submitted to regulatory authorities in the United States this year, with the goal of bringing Cosentyx as a new treatment option to patients living with HS as soon as possible. Novartis also plans to share the long-term results from the trials in 2023. Available data support the sustained efficacy over continuous treatment up to 52 weeks in patients with HS7.

“We are excited to share these promising results showing the benefit of Cosentyx as a treatment that provides relief from common signs and symptoms, pain and flares for people living with HS, with a favorable safety profile. We hope to offer Cosentyx as a potential new treatment option as soon as possible to support this underserved patient community, as part
of our ambition to expand Cosentyx to 10 indications," said Todd Fox, Global Head of Medical Affairs Immunology, Novartis. "Beyond Cosentyx, we are also committed to advancing research in HS and are currently exploring a number of treatments with various mechanisms of action with hopes to further address the ongoing unmet needs of people living with this disease."

The trials assessed two Cosentyx dose regimens across 16-week (vs placebo) and 52-week treatment periods. Results showed a significantly higher proportion of patients achieved a Hidradenitis Suppurativa Clinical Response (HiSCR) when treated with Cosentyx 300 mg, dosed every two weeks (after standard weekly loading doses), compared with placebo at Week 16 in both the SUNSHINE and SUNRISE trials (45.0% vs 33.7% [P=0.0070] and 42.3% vs 31.2% [P=0.0149], respectively)\(^1\). Cosentyx 300 mg dosed every four weeks (after standard weekly loading doses) was superior to placebo for achieving HiSCR in the SUNRISE study (46.1% vs 31.2% [P=0.0022]), though did not meet statistical significance in the SUNSHINE study (41.8% vs 33.7% [P=0.0418])\(^5,6\). HiSCR is defined as at least a 50% decrease in abscess and inflammatory nodule count with no increase in the number of abscesses and/or draining tunnels\(^5,6\). The safety profile was consistent with that of Cosentyx in existing indications, and no new safety signals were observed in either dosing group\(^1\).

A key secondary endpoint was skin pain, as measured by the patient’s global assessment of skin pain Numeric Rating Scale (NRS30). In data pooled from the two studies, the 300 mg dose of Cosentyx given every two weeks proved statistically superior to placebo in reducing skin pain, the most bothersome symptom of HS\(^1,8\). Further details on the primary and secondary endpoints are available on the Novartis website: [https://www.novartis.com/healthcare-professionals/medical-congresses-and-events/abstractsummaries-eadv](https://www.novartis.com/healthcare-professionals/medical-congresses-and-events/abstractsummaries-eadv).

Since its initial approval in 2015, Cosentyx has helped more than 700,000 patients worldwide across five approved immune-mediated diseases, with the goal of preventing disease progression across even more immunological conditions in the future while demonstrating sustained treatment efficacy and safety\(^9-20\).

**About the SUNSHINE and SUNRISE trials**

The SUNSHINE and SUNRISE trials comprise the largest Phase III program in hidradenitis suppurativa (HS), having enrolled more than 1,000 patients in 33 countries\(^5,6\). SUNSHINE (NCT03713619) and SUNRISE (NCT03713632) are identical, global Phase III multicenter, randomized, double-blind, placebo-controlled, parallel group studies that evaluated the short (16 weeks) and long-term (up to 52 weeks) efficacy, safety and tolerability of two dose regimens of Cosentyx in adults with moderate-to-severe HS. SUNSHINE included 541 patients, and SUNRISE included 543 patients. Patients in each study were randomized to one of three experimental arms: Cosentyx 300 mg every two weeks after five weekly placebo doses; Cosentyx 300 mg every four weeks after five weekly placebo doses; placebo dose every two weeks after five weekly placebo doses. The primary endpoint of both trials assessed achievement of HS Clinical Response (HiSCR) after 16 weeks of treatment. Key secondary endpoints included the percentage change from baseline in abscess and inflammatory nodule (AN) count at Week 16, proportion of patients experiencing a flare over 16 weeks, and proportion of patients with Numeric Rating Scale 30 (skin pain) response (reported as pooled data from both trials) at Week 16.

**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, anklyosing spondylitis (AS) and non-radiographic axial spondyloarthritis (nr-axSpA)\(^16,21\). Cosentyx is a proven medicine and has been studied clinically for more than 14 years. The medicine is backed by robust evidence, including five years of clinical data in adults supporting long-term safety and efficacy across moderate to severe plaque psoriasis, PsA and AS\(^9,15,22\). 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 (ERA) and juvenile psoriatic arthritis (JPsA). More than 700,000 patients have been treated with Cosentyx worldwide since launch in 2015\textsuperscript{16,19,20}. Cosentyx is approved in more than 100 countries, most recently gaining approval for JIA in the United States and Europe.

About hidradenitis suppurativa (HS)
HS is a chronic, inflammatory, debilitating skin condition with systemic comorbidities that has a profoundly negative effect on a patient’s quality of life and mental health\textsuperscript{2-4}. It is characterized by recurrent lumps or nodules under the skin that become inflamed and painful, breaking open to cause abscesses and sores\textsuperscript{2,23}. The chronic debilitating nature of HS makes it one of the most distressing dermatological conditions, with a considerable psychological burden on sufferers\textsuperscript{3}. Once considered a rare condition, it is now thought that as many as one in 100 people are affected by HS\textsuperscript{2}. There is no cure for HS and current HS treatment regimens are limited, often inadequate and can require a surgical approach\textsuperscript{24,25}. Often, they cannot be taken for an extended time, or only provide temporary and moderate relief\textsuperscript{24,25}. It takes on average seven years to get an HS diagnosis after the first onset of symptoms\textsuperscript{26}.

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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 108,000 people of more than 140 nationalities work at Novartis around the world. Find out more at
References


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