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MEDIA & INVESTOR RELEASE

Patients with hidradenitis suppurativa experienced sustained efficacy and symptom improvement at one year when treated with Novartis Cosentyx®

- *In two of the largest Phase III trials conducted in hidradenitis suppurativa (HS), Cosentyx® (secukinumab) treatment response rates continued to improve beyond the primary endpoint analysis at Week 16 to more than 55% at Week 52, as evaluated by the HS Clinical Response (HiSCR) measure*[1]

- *Safety findings were consistent with the well-established safety profile of Cosentyx in its approved indications*[1]

- *HS is a recurrent skin disease affecting one in 100 people worldwide, causing painful, boil-like abscesses that can lead to open wounds and irreversible scarring in the most intimate parts of the body*[2,3]

- *There is only one approved therapy for HS and many patients, even those on treatment, still experience uncontrolled symptoms*[4]

Basel, February 4, 2023 – Novartis announced today that *The Lancet* has published long-term data from the pivotal SUNSHINE and SUNRISE trials evaluating Cosentyx® (secukinumab) in moderate-to-severe hidradenitis suppurativa (HS)[1]. In two of the largest Phase III trials conducted in HS, Cosentyx treatment response rates continued to improve beyond the primary endpoint analysis at Week 16 to more than 55% of patients achieving a HS Clinical Response (HiSCR) measure at Week 52[1].

Overall, at Week 52, more than 60% of patients were free of flares[1]. Additionally, more than 50% experienced a meaningful reduction in pain, which has been identified by patients as the most burdensome symptom of HS[1,5].

“HS is complex, painful, hard to treat and impacts patients’ quality of life at very high levels,” said Alexa B. Kimball, MD, MPH, lead investigator of the trials, investigator at Beth Israel Deaconess Medical Center, Massachusetts, US, and Professor of Dermatology at Harvard Medical School. “These results build on the positive findings shared last year, providing additional promising data about the long-term efficacy and safety of Cosentyx in HS. As a physician who frequently treats people living with HS, I see patients with tremendous need for new options that reduce symptoms, disability, pain and flares.”

Safety results were consistent with the well-established profile of Cosentyx, with no new signals[1]. Long-term efficacy and safety results were also seen among patients who previously did not respond to biologic therapies[1]. Further details are available here:

https://www.novartis.com/news/media-library/52-week-results-cosentyx-hidradenitis-suppurativa-summary.

“People living with HS currently only have one approved treatment option for this disfiguring disease,” said Angelika Jahreis, M.D., Ph.D., FAAD, Global Head Development Unit Immunology and Clinical Development Excellence, Novartis. “These data show that Cosentyx could provide meaningful and long-lasting improvement of HS symptoms. Based on these encouraging data, we hope to soon deliver a new treatment to healthcare professionals and people living with HS.”

These results have been submitted to regulatory authorities in Europe and the United States, and decisions are expected in 2023. If approved, Cosentyx will be the first and only interleukin-17 inhibitor for the treatment of moderate-to-severe HS.

About the SUNSHINE and SUNRISE trials[1]
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 are identical, global Phase III multicenter, randomized, double-blind, placebo-controlled, parallel-group studies that evaluated the short-term (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. Results at Week 16 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 in both the SUNSHINE and SUNRISE trials (45.0% vs 33.7% [P=.0070] and 42.3% vs 31.2% [P=0.0149], respectively). HiSCR is defined as at least a 50% decrease in abscess and inflammatory nodule (AN) count with no increase in the number of abscesses and/or draining tunnels. At Week 16, the study arm receiving Cosentyx 300 mg 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 this arm did not meet statistical significance in the SUNSHINE study (41.8% vs 33.7% [P=0.0418]). Secondary endpoints included the percentage change from baseline in abscess and AN count, proportion of patients experiencing a flare, and proportion of patients with Numeric Rating Scale 30 (skin pain) response after 16 weeks of treatment.

An exploratory analysis assessed the long-term effects of Cosentyx for each of the primary and secondary endpoints up to 52 weeks. HiSCR values observed at Week 16 following either dose regimen of Cosentyx were improved over time to Week 52 (SUNSHINE: SECQ2W [56.4%]; SECQ4W [56.3%]; SUNRISE: SECQ2W [65.0%]; SECQ4W [62.2%]), with rapid improvements seen in patients who switched from placebo at Week 16. The safety profile was consistent with that of Cosentyx in its existing indications.

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)[6,7]. 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[8-14]. 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. More than 875,000 patients have been treated with Cosentyx worldwide since its launch in 2015. Cosentyx is approved in more than 100 countries, most recently gaining approval for JIA in the US and Europe[16,17].

About hidradenitis suppurativa (HS)
HS is a painful and recurrent inflammatory skin disease[2]. It causes boil-like abscesses that can burst, creating open wounds, often in the most intimate parts of the body, resulting in irreversible scarring[2]. It can take 10 years to get a diagnosis, even though HS affects approximately one in 100 people globally[2,18]. There is currently only one approved biologic treatment and around 50% of patients treated can lose response[4]. In advanced cases, healthcare professionals often consider surgery to remove abscesses and prevent the disease from spreading further, an invasive procedure that frequently results in additional scarring[19]. HS impacts a patient's quality of life more than any other skin disease, and people living with HS often experience comorbidities such as obesity, diabetes, arthritis and depression[3,20,21].

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