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MEDIA & INVESTOR RELEASE

Novartis Cosentyx® gains positive CHMP opinion for hidradenitis suppurativa

- *Positive opinion paves way for first new treatment option in hidradenitis suppurativa (HS) in nearly a decade*

- *Committee for Medicinal Products for Human Use (CHMP) opinion based on robust Phase III data showing Cosentyx® (secukinumab) provided rapid symptom relief from as early as Week 4, with response rates continuing to improve up to 1 year*[1–4]

- *Safety findings were consistent with the known safety profile of Cosentyx across its five approved indications*[1]

- *Regulatory decision from the US Food and Drug Administration (FDA) expected later this year*

Basel, April 26, 2023 — Novartis announced today that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency has adopted a positive opinion and recommended granting a marketing authorization for Cosentyx® (secukinumab) in adults with active moderate to severe hidradenitis suppurativa (HS).

“HS is an under-treated inflammatory skin disease, and I regularly see its devastating impact in my practice. We need more options that can address its multiple signs and symptoms, especially boil-like abscesses, pain and scarring, and bring fast, long-lasting results,” said Professor Christos C. Zouboulis, President of the European Hidradenitis Suppurativa Foundation, Director of the Departments of Dermatology, Venereology, Allergology and Immunology, Staedtisches Klinikum Dessau and Founding Professor of Dermatology and Venereology at the Brandenburg Medical School, Germany. “Today’s news gives me hope that we may soon have a new option to offer our patients in Europe.”

“HS pain can be excruciating at times, limiting my ability to do everyday tasks such as dressing, bathing, walking, exercise, cooking and cleaning. It’s humbling to have to ask others to help tie my shoelaces. Beyond the pain, the drainage, fatigue and other HS symptoms impact my relationships, intimacy, mental health, work and finances. New treatment options are needed to help improve the lives for people with HS,” said Dr. Barry McGrath, PhD, Acting CEO, HS Ireland.

HS affects 1 in 100 people worldwide[5], and in Europe, there are around 200,000 people currently living with moderate to severe stages of the condition[6]. The impact of disease is

substantial, even for those on treatment, as there is currently only one approved biologic treatment for HS, and around 50% of patients can lose response[7]. HS causes boil-like abscesses that can burst and become open wounds that can result in irreversible scarring, often in the most intimate parts of the body[5,8]. Patients describe their HS-related pain as the most debilitating symptom, which worsens as disease severity increases[5,8].

The positive CHMP opinion is based on robust results from two trials in the largest Phase III program in HS, SUNSHINE and SUNRISE[9,10]. The data showed that treatment response rates in patients randomized to Cosentyx continued to improve beyond the primary endpoint analysis at Week 16 to more than 55% of patients achieving a Hidradenitis Suppurativa Clinical Response (HiSCR) at Week 52[1]. Additionally, approximately 50% of patients randomized to Cosentyx had a meaningful reduction in HS-related pain at Week 52[1]. Safety findings were consistent with the known safety profile of Cosentyx in its approved dermatologic and rheumatologic diseases and are further supported by data from 8 years of real-world use[1]. The full results were recently published in *The Lancet*[1].

“This positive CHMP opinion brings us one step closer to offering the first new HS treatment in nearly a decade,” said Marie-France Tschudin, President of Novartis Innovative Medicines International and Chief Commercial Officer. “If approved, Cosentyx will provide a much-needed alternative to support the underserved community of approximately 200,000 people with moderate to severe HS in Europe, many of whom are living with painful, uncontrolled symptoms.”

The recommendation for Cosentyx in HS will be referred to the European Commission, which is expected to deliver a final decision within 2 months. The Phase III results from SUNSHINE and SUNRISE have also been submitted to the US Food and Drug Administration with a decision expected later this year.

About the SUNSHINE and SUNRISE trials[1,9,10]
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- (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. A Hidradenitis Suppurativa Clinical Response (HiSCR), the primary endpoint in the two pivotal trials, 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. Results at Week 16 showed that a significantly higher proportion of patients achieved a HiSCR when treated with Cosentyx 300 mg dosed every 2 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* = .0149], respectively). A greater proportion of patients randomized to Cosentyx 300 mg dosed every 4 weeks (after standard weekly loading doses) achieved a HiSCR compared with placebo in both SUNSHINE (41.8% vs 33.7% [*P* = .0418]) and SUNRISE (46.1% vs 31.2% [*P* = .0022]) trials; however, this improvement was only statistically significant in SUNRISE. Secondary endpoints included the percentage change from baseline in AN count, proportion of patients experiencing a flare, and proportion of patients with a skin pain numeric rating scale 30 response after 16 weeks of treatment.

An exploratory analysis assessed the long-term effects of Cosentyx for each of the primary and secondary endpoints for 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)[11,12]. 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[13–19]. 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[12]. More than 1 million patients have been treated with Cosentyx worldwide since its launch in 2015[20]. Cosentyx is approved in more than 100 countries[21], most recently gaining approval for JIA in the US and Europe[22,23].

About hidradenitis suppurativa (HS)
HS is a painful and recurrent inflammatory skin disease[5]. It causes boil-like abscesses that can burst, creating open wounds, often in the most intimate parts of the body, resulting in irreversible scarring[5,8]. It can take 10 years to get a diagnosis, even though HS affects approximately 1 in 100 people globally[5,24]. There is currently only one approved biologic treatment and around 50% of patients treated can lose response[7]. In advanced cases, healthcare professionals often consider surgery to remove abscesses, an invasive procedure that frequently results in additional scarring[8]. 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[8,25,26].

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