NICE recommends Novartis Cosentyx® (secukinumab) as the first biologic treatment for hidradenitis suppurativa (HS) since 2016

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- Hidradenitis suppurativa (HS) is a painful, chronic and progressive inflammatory skin disease with over 50% of people reporting a mental health impact[1,2]
- The National Institute for Health and Care Excellence (NICE) has released final draft guidance recommending Cosentyx® (secukinumab) as a cost-effective treatment option for adults in England and Wales with active moderate to severe HS, where there has been an inadequate response to conventional systemic HS therapy and where adalimumab is not suitable, did not work or has stopped working[3,4]
- The interim Innovative Medicines Fund (IMF) in England and New Treatment Fund in Wales will allow eligible patients in England and Wales to obtain early access to secukinumab[5,6]
- Secukinumab, an interleukin-17A inhibitor, has a generally well tolerated safety profile, with 8 years of real-world use in more than 1 million patients globally[4,7]

London, 27 October 2023 — Today, Novartis announced that the National Institute for Health and Care Excellence (NICE) has issued final draft guidance, recommending the use of Cosentyx® (secukinumab) as a treatment option for adults in England and Wales with active moderate to severe hidradenitis suppurativa (HS). It will be recommended for people who have had an inadequate response to conventional systemic HS therapy and where adalimumab is not suitable, did not work or has stopped working[3,4].

Novartis has an agreement with NHS England allowing eligible people living with HS to obtain immediate access to secukinumab through the interim Innovative Medicines Fund (IMF), which provides funding to accelerate NICE-recommended non-cancer medicines into the NHS[5]. The New Treatment Fund in Wales, which ensures faster patient access to medicines recommended by NICE, will enable early access to secukinumab for eligible patients in Wales[6].

The final draft guidance from NICE recommends secukinumab as a new treatment option – the second recommended biologic treatment option in England and Wales – to help reduce HS symptoms[8]. HS is a long-term, painful, chronic and progressive inflammatory skin disease that causes recurring boil-like lumps that can burst into open wounds causing irreversible scarring, often in the most intimate parts of the body[1,9]. HS affects at least 200,000 people in the UK and on average, it takes 10 years for people living with HS to get a correct diagnosis, which can result in disease progression and significantly impact their quality of life[2,9,10].

“HS is an undertreated disease that causes substantial physical and emotional distress to those who live with it”, said Dr John Ingram, Clinical Reader and Consultant Dermatologist, Cardiff. “Until now, there has only been one approved biologic treatment for HS, and many patients can lose response. Today’s NICE decision provides physicians with a second treatment option that has shown significant clinical benefits in the domains that matter most to patients, including swift improvement in quality of life and skin pain.”

“People living with HS often experience debilitating pain, which can make everyday tasks such as dressing,

bathing and sitting at a desk chair really challenging", said Phil Brady, Chief Operating Officer at British Skin Foundation. "HS can also have a substantial impact on many other aspects of a person's life, such as their mental health and relationships. New treatment options are needed to help the HS community find relief from the burden of this disease, and we welcome today's decision from NICE."

The draft NICE decision is based on robust results from two trials in the largest Phase III programme in HS to date, SUNSHINE and SUNRISE[8,11,12]. The data showed that treatment response rates in patients randomised to secukinumab continued to improve beyond the primary endpoint analysis at Week 16 to more than 55% of patients achieving a Hidradenitis Suppurativa Clinical Response at Week 52[8,11,12]. Additionally, approximately 50% of patients randomised to secukinumab had a reduction in HS-related pain at Week 52[8,11,12]. Safety findings were consistent with the generally well tolerated safety profile of secukinumab in its approved dermatological and rheumatological licensed indications and are further supported by data from 8 years of real-world use[7,8]. The full results were recently published in *The Lancet*[8].

"Today's NICE recommendation is an example of how we are reimagining medicine to improve the lives of people with hard-to-treat inflammatory conditions and has been made possible through effective collaboration with NICE and NHS England", said Marie-Andrée Gamache, Country President, Novartis Innovative Medicines UK and Ireland. "Since its first approval in the UK in 2015, secukinumab has been used to treat over 1 million patients worldwide and could now provide another option for eligible patients in England and Wales who continue to struggle with the painful and debilitating symptoms of 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), non-radiographic axial spondyloarthritis (nr-axSpA) and hidradenitis suppurativa (HS)[4,13,14]. Cosentyx is a medicine that 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 its long-term safety and efficacy profile across moderate to severe plaque psoriasis, PsA and AS[13,15-20]. These data strengthen the position of Cosentyx as a treatment option across AS, nr-axSpA, PsA, HS, moderate to severe plaque psoriasis (adult and pediatric) and two subtypes of juvenile idiopathic arthritis; enthesitis-related arthritis and juvenile psoriatic arthritis[4]. More than 1 million patients have been treated with Cosentyx worldwide since its launch in 2015[4,7]. Cosentyx is approved in more than 100 countries, most recently gaining approval for HS in Europe[21,22]. Novartis is continuing to explore the potential of Cosentyx in other indications in areas of high unmet need.

About Novartis

Novartis is reimagining medicine to improve and extend people's lives. As a leading global medicines company, we strive to use innovative science and digital technologies to create 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 https://www.novartis.com/uk-en/.

In the UK, we employ approximately 1,300 people to serve healthcare needs across the whole of the UK, as well as supporting the global operations of Novartis. Since 2014, Novartis has invested over £200 million in R&D and is a leading sponsor of clinical trials, in the UK. For more information, please visit www.novartis.com/uk-en/. Novartis UK is on Twitter. Sign up to follow @NovartisUK.

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