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Novartis' secukinumab is first and only IL-17A inhibitor to potentially modify the course of psoriasis

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- *New data suggests that disease modification with secukinumab may be achievable for around 20% of patients following one year of treatment*[1]
- *Patients with longer disease duration before treatment with secukinumab were more likely to relapse, highlighting the potential importance of early treatment with secukinumab*[1]
- *To further investigate disease modification, Novartis has initiated the STEPIn trial, evaluating secukinumab in patients with early onset of moderate-to-severe psoriasis*[2]

Basel, March 21, 2017 – Novartis today announced new data suggesting, for the first time, that secukinumab may modify the course of moderate-to-severe psoriasis leading to long-term, treatment-free skin clearance[1]. Secukinumab is the first and only IL-17A inhibitor to have reported this potential of disease modification. These data were presented at the 13th Annual Maui Derm for Dermatologists 2017, Maui, Hawaii at which Novartis presented 14 abstracts.

Following one year of treatment with secukinumab, patients were randomized to either continuous treatment or treatment cessation until relapse. Patients with continuous treatment maintained their high level of response. Among the patients that discontinued treatment, 21% of psoriasis patients maintained skin clearance (PASI 75) for up to one year without treatment and 10% maintained skin clearance for up to two years without treatment[1]. Patients with longer disease duration were more likely to relapse, suggesting that early intervention increases the chance of remaining relapse free[1].

Previous data has shown that secukinumab, a fully human, specific inhibitor of the IL-17A cytokine, delivers long-lasting clear or almost clear skin (PASI 90 to PASI 100) in up to 80% of patients out to four years[3,4].

"These results suggest that secukinumab may go beyond simply treating symptoms and could actually modify the course of psoriasis, and highlights the need for further investigation into early intervention," said Vas Narasimhan, Global Head, Drug Development and Chief Medical Officer, Novartis. "Being able to change the course of disease is the ultimate goal of treatment, which is why we are investing in the STEPIn trial to further understand the disease modifying ability of secukinumab in psoriasis."

This is the first robust long-term data on psoriasis following treatment discontinuation. These data (from extension study A2302E1) show low scores on the Psoriasis Area Severity Index (PASI) were maintained after treatment discontinuation following one year on secukinumab (PASI score of 2.9 after one year and 1.7 after two years off-drug, vs. 20.5 and 19.2 at Baseline)[1]. Additionally, of the 120 patients who were PASI 75 responders and switched to placebo at one year, 21% remained relapse-free after one year and 10% were relapse-free after two years off-treatment[1]. Patients who had a longer disease duration before secukinumab treatment were more likely to relapse, highlighting the potential importance of early treatment[1]. To further investigate the disease modification potential of secukinumab, Novartis has initiated the STEPIn trial to assess early intervention in new-onset disease. The ambition is to identify a novel strategy of treating patients with

new-onset moderate-to-severe psoriasis, by providing evidence to inform the use of early treatment[2].

Secukinumab is the only IL-17A inhibitor approved in psoriasis, psoriatic arthritis (PsA) and ankylosing spondylitis (AS). 80,000 patients have been treated with secukinumab worldwide in the post-marketing setting[5].

About secukinumab and interleukin-17A (IL-17A)

Launched in January 2015, secukinumab is a targeted treatment that specifically inhibits the IL-17A cytokine. Secukinumab delivers long-lasting clear skin, with proven sustainability, safety out to four years and convenient once-monthly dosing in a patient-friendly auto injector[6].

Secukinumab is approved in more than 75 countries for the treatment of moderate-to-severe plaque psoriasis, which includes the European Union countries, Japan, Switzerland, Australia, the US and Canada. In Europe, secukinumab is approved for the first-line systemic treatment of moderate-to-severe plaque psoriasis in adult patients[7]. In the US, secukinumab is approved as a treatment for moderate-to-severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy (light therapy)[8].

In addition, secukinumab is the first IL-17A inhibitor approved in more than 65 countries for the treatment of active AS and PsA, which includes the European Union countries and the US. secukinumab is also approved for the treatment of PsA and pustular psoriasis in Japan[5].

About A2302E1[1]

A2302E1 is a double-blind, placebo-controlled study of 120 psoriasis patients and an extension of pivotal phase 3 studies ERASURE and FIXTURE. After one year of secukinumab treatment, patients who achieved a PASI 75 response were randomized to receive either Cosentyx 300mg or placebo. During the treatment withdrawal concomitant psoriasis medication was prohibited; upon relapse placebo patients were retreated with secukinumab.

About STEPIn[2]

A randomized, multicenter study to evaluate the effect of secukinumab 300mg by subcutaneous injection. administered during 52 weeks to patients suffering from new-onset moderate-to-severe plaque psoriasis as early intervention compared to standard of care treatment with narrow-band UVB. STEPIn aims to demonstrate the benefit of early secukinumab treatment with the ultimate goal of altering the natural course of psoriasis with a reduced disease burden and need for treatment.

About Psoriasis

Psoriasis is a common, non-contagious, autoimmune disease that affects more than 125 million people worldwide[9]. Plaque psoriasis is the most common form of the disease and appears as raised, red patches covered with a silvery white buildup of dead skin cells.

Psoriasis is not simply a cosmetic problem, but a persistent, chronic (long-lasting), and sometimes distressing disease, which can affect even the smallest aspects of people's lives on a daily basis. Up to 30% of patients with psoriasis have, or will develop, PsA[10]. PsA is a condition in which the joints are also affected, causing debilitating symptoms including pain, stiffness and irreversible joint damage[10,11]. Psoriasis is also associated with other serious health conditions, such as diabetes, heart disease and depression[8].

About Novartis

Novartis provides innovative healthcare solutions that address the evolving needs of patients and societies. Headquartered in Basel, Switzerland, Novartis offers a diversified portfolio to best meet these needs: innovative medicines, cost-saving generic and biosimilar pharmaceuticals and eye care. Novartis has leading positions globally in each of these areas. In 2016, the Group achieved net sales of USD 48.5 billion, while R&D throughout the Group amounted to approximately USD 9.0 billion. Novartis Group companies employ approximately 118,000 full-time-equivalent associates. Novartis products are sold in approximately 155 countries around the world. For more information, please visit http://www.novartis.com.

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