Novartis' secukinumab shows sustained improvements in signs and symptoms for both AS and PsA in up to 80% of patients at 3 years

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- *Secukinumab is the first and only IL-17A inhibitor to show sustained improvements in signs and symptoms of ankylosing spondylitis (AS) and psoriatic arthritis (PsA)*
- *Additional data show rapid and sustained pain relief with secukinumab as early as Week 3 which is sustained up to 2 years in PsA patients*
- *Patient recruitment underway for the new EXCEED head-to-head clinical trial to show superiority of secukinumab versus adalimumab in PsA*

Basel, June 15, 2017 – Novartis announced today data showing secukinumab shows sustained improvements in the signs and symptoms for active ankylosing spondylitis (AS) at 3 years, consistent with previous findings in active psoriatic arthritis (PsA) at 3 years. New data also show secukinumab provides rapid and sustained pain relief in patients with active PsA out to 2 years. These findings were presented at the Annual European Congress of Rheumatology (EULAR 2017), in Madrid, Spain.

Secukinumab is the only fully human interleukin-17A (IL-17A) inhibitor to demonstrate 3-year efficacy and safety in Phase III studies of both AS and PsA which are life-long debilitating inflammatory diseases. Secukinumab is also used to treat moderate-to-severe psoriasis, which is significant as up to 8 in 10 patients with PsA also have psoriasis.

"These data reconfirm that secukinumab provides patients with long-lasting relief from the symptoms of ankylosing spondylitis and psoriatic arthritis, as well as now demonstrating rapid pain relief from psoriatic arthritis", said Vas Narasimhan, Global Head of Drug Development and Chief Medical Officer, Novartis. "We are pleased that secukinumab continues to provide sustained benefits for patients with psoriasis, psoriatic arthritis, and ankylosing spondylitis."

In the MEASURE 1 extension study, 80% of AS patients consistently achieved an ASAS 20 response (Assessment of Spondyloarthritis International Society response criteria) at 3 years. This was consistent with previous findings from the FUTURE 1 study in active PsA where secukinumab demonstrated sustained improvements in the signs and symptoms of disease in approximately 80% of patients at 3 years as measured by ACR 20 response (American College of Rheumatology response criteria).

A 2-year post-hoc analysis of the FUTURE 2 study evaluated secukinumab in PsA, where almost every patient (99%) reported moderate-to-extreme pain or discomfort before initiating treatment. By Week 3, half of those (50%) treated with secukinumab reported clinically meaningful improvements in pain of over 20%, as measured by Visual Analogue Scale (VAS). At Week 4, the proportion of patients reporting no pain or discomfort was greater for secukinumab (15%) than for placebo (5%) and this increased through to Week 104 (28%). Secukinumab continues to have a favorable safety profile, which was consistent with that shown in Phase III studies.

Secukinumab is the only IL-17A inhibitor approved in psoriasis, PsA and AS with more than 80,000 patients

treated in the post-marketing setting worldwide across all indications.

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

Launched in January 2015, is a targeted treatment that specifically inhibits the IL-17A cytokine. Research suggests that IL-17A may play an important role in driving autoinflammatory conditions in enthesis and ultimately the body's immune response in psoriasis, AS and PsA.

Secukinumab is the first IL-17A inhibitor approved in more than 70 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.

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. 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).

About the MEASURE 1 study

MEASURE 1 is a 2-year, multi-center, randomized, placebo-controlled Phase III study assessing the efficacy and safety of secukinumab in patients with active AS. A total of 290 of 371 patients completed the trial, after which patients were invited to enter a 3-year extension period. Of these, 274 entered the extension trial, with 260 completing 156 weeks. At the start of the 2-year study, 371 patients were enrolled and administered a secukinumab intravenous loading dose of 10 mg/kg every 2 weeks for the first 4 weeks of treatment, followed by monthly subcutaneous maintenance dosing (75 mg and 150 mg). Primary endpoints assessed superiority of secukinumab against placebo at Week 16 in the proportion of patients achieving at least a 20% improvement in the ASAS 20 response criteria. From Week 16, patients in the placebo arm of the study were re-randomized to secukinumab 75 mg or 150 mg based on ASAS 20 response, with non-responders switched at Week 16, and responders at Week 24. In total, 83/87 and 95/100 patients randomized to secukinumab 75 mg and 150 mg respectively completed 156 weeks.

About the FUTURE 1 and FUTURE 2 studies

FUTURE 1 is a randomized, doubleblind, placebo-controlled Phase III study of secukinumab in patients with active PsA. A total of 476 of 606 patients completed the trial to demonstrate the 24 week efficacy and assess the longterm safety, tolerability and efficacy up to 2 years of a 10 mg/kg intravenous loading dose followed by subcutaneous doses of secukinumab 75 mg, 150 mg. Of these 476 patients, 457 entered the FUTURE 1 extension study, with 435 completing 156 weeks.

FUTURE 2 is a randomized, double-blind, placebo-controlled Phase III study, in 397 patients with active PsA, to demonstrate the efficacy of subcutaneous secukinumab 75 mg, 150 mg, 300 mg in prefilled syringes at 24 weeks and to assess the long-term efficacy, safety and tolerability for up to 5 years.

Both studies included patients who were anti-TNF therapy naïve or inadequate responders; randomization was stratified so that approximately 70% and 65% were required to be anti-TNF therapy naïve in FUTURE 1 and FUTURE 2, respectively. In both trials, the primary endpoint was the percentage of patients achieving an ACR 20 response at Week 24. FUTURE 2 and the extension of FUTURE 1 are currently ongoing to investigate the longer-term efficacy of secukinumab.

About ankylosing spondylitis and psoriatic arthritis

AS is part of a family of life-long inflammatory diseases, which also includes PsA. It generally results in serious impairment of movement in the spine and physical function, which has an impact on quality of life. People in their teens and twenties, particularly males, are affected most often. Family members of those with AS are at higher risk.

PsA is also closely associated with psoriasis. Approximately 30% of patients with psoriasis have PsA and as many as 1 in 4 people with psoriasis may have undiagnosed PsA. Symptoms of PsA include joint pain and stiffness, skin and nail psoriasis, swollen toes and fingers, persistent painful swelling of the tendons, and irreversible joint damage6. Up to 40% of people can suffer from joint destruction and permanent physical deformity.

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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