Novartis advances head-to-head superiority trials of Cosentyx® versus Humira®* and proposed biosimilar adalimumab**

- **SURPASS** is the first head-to-head superiority trial versus proposed biosimilar adalimumab** in ankylosing spondylitis (AS)¹
- **EXCEED** is the first head-to-head superiority trial versus Humira®* in psoriatic arthritis (PsA)²
- **Cosentyx** is a targeted biologic inhibiting IL-17A, cornerstone cytokine involved in the inflammation of entheses³

**Basel, January 9, 2018** – Novartis announced today the initiation of **SURPASS**, a head-to-head clinical trial of Cosentyx® (secukinumab) versus proposed biosimilar adalimumab** in ankylosing spondylitis (AS). SURPASS is the first head-to-head clinical trial in AS investigating superiority of Cosentyx in slowing spinal bone damage versus proposed biosimilar adalimumab**. SURPASS is currently recruiting patients, with the ‘first patient first visit’ already achieved in November 2017.¹

SURPASS and EXCEED are part of a larger rheumatology program for Cosentyx. EXCEED is a head-to-head clinical trial of Cosentyx versus Humira®* (adalimumab) in psoriatic arthritis (PsA), which is already recruiting. EXCEED is the first large double-blinded head-to-head clinical trial versus Humira®* in PsA investigating superiority of Cosentyx on ACR 20 at 52 weeks as the primary endpoint.²

“The EXCEED and SURPASS head-to-head trials are addressing important clinical questions solving residual uncertainty for patients with PsA and AS,” said Dr. Robert Landewé, Professor of Rheumatology in the Amsterdam Rheumatology and Clinical Immunology Center & the Zuyderland Medical Center, Heerlen, the Netherlands. “Head-to-head trials deliver the most robust data helping to advance clinical practice and are key to clinical decision making. In this case, these data would add to the body of evidence to underline the benefit of different biologic pathways for physicians.”

“Cosentyx is backed by strong clinical efficacy and safety data and already has supported more than 125,000 patients worldwide,” said Vas Narasimhan, Global Head, Drug Development and Chief Medical Officer, Novartis. “Many patients living with PsA and AS cannot enjoy a normal life as they are experiencing persistent pain and fatigue, and are at risk of long-term mobility loss. These patients deserve the best treatment possible and we are hopeful that the EXCEED and SURPASS trials will provide valuable answers for doctors and patients in their decision making.”

Cosentyx is the first targeted biologic that specifically inhibits IL-17A, cornerstone cytokine involved in the inflammation of entheses in spondyloarthritis, which plays a major role in PsA and AS³-⁶. Both conditions are debilitating autoimmune diseases with a high risk of mobility loss. Approximately 40 percent of PsA patients will develop irreversible joint damage and permanent physical deformity⁷. For AS patients, inflammation of the sacroiliac joints and new
bone formation of the spine is associated with increased levels of IL-17A, with severe cases progressing to irreversible spinal fusion\(^6\).

Cosentyx is the first and only fully human IL-17A inhibitor approved to treat AS, PsA and psoriasis\(^7\). It has demonstrated rapid and sustained efficacy as well as a consistently favorable safety profile, including injection site pain at rates similar to placebo\(^9\)\(^\dagger\)\(^9\). To date, Cosentyx has been used by more than 125,000 patients worldwide\(^9\).

**About Cosentyx and IL-17A**

Cosentyx (secukinumab) is the first and only fully human IL-17A inhibitor approved to treat ankylosing spondylitis (AS), psoriatic arthritis (PsA) and psoriasis\(^8\). Cosentyx is a targeted treatment that specifically inhibits IL-17A, cornerstone cytokine which plays a significant role in the pathogenesis of AS, PsA and psoriasis\(^8\)\(^\dagger\)\(^8\). Cosentyx is approved in more than 70 countries for the treatment of active AS and PsA, which includes the European Union countries and the US, as well as Japan\(^8\).

Cosentyx is also approved in more than 80 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, Cosentyx is approved for the first-line systemic treatment of moderate-to-severe plaque psoriasis in adult patients\(^6\). In the US, Cosentyx is approved as a treatment for moderate-to-severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy (light therapy)\(^17\).

**About SURPASS head-to-head clinical trial\(^1\)**

Novartis has initiated SURPASS, the first ever head-to-head superiority clinical trial of Cosentyx versus proposed biosimilar adalimumab** in slowing spinal bone damage as the primary endpoint in AS. Effect on progressive structural damage of the spine is one of the important attributes clinicians look for when assessing the performance of AS treatment options. SURPASS will allow clinicians and patients to make better treatment decisions by evaluating this important attribute of AS therapy, reducing the progression of spinal structural damage.

SURPASS will be the largest randomized, controlled study of a biologic treatment in AS and is a 1 year, parallel-group study with three treatment arms: Cosentyx 150 mg subcutaneously (sc); Cosentyx 300 mg sc and proposed biosimilar adalimumab** 40 mg sc in patients with active AS. The primary endpoint is the proportion of patients with no spinal radiographic structural progression, defined as a change from baseline of ≤0.5 in mSASSS, at 2 years. Key secondary endpoints are mean change in mSASSS, new syndesmophyte formation, and MRI measures of inflammation, at 2 years.

**About EXCEED head-to-head clinical trial\(^2\)**

Novartis has initiated EXCEED, the first ever large double-blinded head-to-head clinical trial evaluating Humira\(^6\) (adalimumab) versus Cosentyx. EXCEED is a 1 year, multi-center, randomized, double-blind, active control, Phase IIIb study evaluating the efficacy of Cosentyx monotherapy compared with Humira\(^6\) monotherapy in patients with active PsA who are naïve to biologic therapy. The study will include a large patient population involving over 800 biologic-naïve patients with PsA.

The primary endpoint will assess statistical superiority of Cosentyx monotherapy against adalimumab monotherapy for ACR 20 response rates at 1 year. Other secondary endpoints, all at 52 weeks, include PASI 90, ACR 50, disability index (HAQ-DI score) relative to baseline, and resolution of enthesitis.

**About ankylosing spondylitis and psoriatic arthritis**

AS is part of a family of life-long inflammatory diseases, which also includes PsA. AS is characterized by inflammation of the sacroiliac joints and new bone formation in the spine
caused by increased levels of IL-17A, with severe cases progressing to irreversible spinal fusion\(^7,8\). AS can cause serious impairment of movement in the spine and physical function, which impacts quality of life. People in their twenties and thirties, particularly males, are affected most often\(^16,19\).

PsA is a debilitating autoimmune disease with a high risk of mobility loss. 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 damage\(^20\). Up to 40 percent of people can suffer from joint destruction and permanent physical deformity\(^7\).

IL-17A plays a significant role in disease pathogenesis of AS, PsA and plaque psoriasis. Up to 30 percent of psoriasis patients will develop PsA during their lifetime, and as many as 1 in 4 people with psoriasis may have undiagnosed PsA\(^20,21\).

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**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 121,000 full-time-equivalent associates. Novartis products are sold in approximately 155 countries around the world. For more information, please visit [http://www.novartis.com](http://www.novartis.com).

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* Humira is a registered trademark of AbbVie Inc.

** The proposed biosimilar adalimumab used in the SURPASS trial is a development compound from Sandoz, which is currently under review by the European Medicines Agency for the treatment of several immunological diseases.
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