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Novartis seeks leadership with Cosentyx® showing no radiographic progression in ankylosing spondylitis at 4 years

- *For the first time for any biologic, data show almost 80 percent of ankylosing spondylitis (AS) patients on Cosentyx® have no radiographic progression of the spine at 4 years*[1]
- *These new data also confirm sustained improvement in signs and symptoms in almost 80 percent of patients, with a favorable and consistent safety profile*[1]
- *Cosentyx, the only IL-17A inhibitor approved for AS, is a fully human, highly targeted biologic for first-line use in this chronic inflammatory disease that can lead to mobility loss*[2]

Basel, November 6, 2017 – Novartis announced today new long-term Cosentyx® (secukinumab) data for patients with ankylosing spondylitis (AS)[1]. This study is unique as these data show, for the first time with any biologic, that almost 80 percent of AS patients treated with Cosentyx have no radiographic progression (mSASSS <2) of the spine at 4 years[1]. The new data also confirm sustained improvement in signs and symptoms in almost 80 percent of patients, while Cosentyx delivers a favorable and consistent safety profile[1]. The new data will be presented as a late-breaker during the 2017 American College of Rheumatology/Association of Rheumatology Health Professionals (ACR/ARHP) Annual Meeting in San Diego, United States.

“The key finding of these data is that patients treated with Cosentyx may now have the opportunity to maintain their mobility for a longer time. This is very important as ankylosing spondylitis is a crippling condition that can impact people in their twenties when they still have many decades of their life ahead of them,” said Vas Narasimhan, Global Head, Drug Development and Chief Medical Officer, Novartis. “For the first time for any biologic, Cosentyx shows that almost 80 percent of patients had no radiographic progression for as long as 4 years. These data demonstrate the potential of Cosentyx to help patients live with less pain and retain their mobility for longer”.

These new long-term data add to a growing body of evidence demonstrating the unique position of Cosentyx with lasting efficacy and proven safety across AS, psoriatic arthritis (PsA) and moderate-to-severe psoriasis[1,3–6]. Cosentyx is the first and only IL-17A inhibitor approved for AS. Cosentyx is a highly targeted biologic for first-line use in AS, a chronic inflammatory disease that can lead to prolonged pain and mobility loss[2].

About Cosentyx and IL-17A
Cosentyx is the first and only fully human IL-17A inhibitor approved to treat AS, PsA and psoriasis[7]. Cosentyx is a targeted treatment that specifically inhibits the IL-17A cytokine, which plays a significant role in the pathogenesis of AS, PsA and plaque psoriasis[7,8,9]. Cosentyx 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. Cosentyx is also approved for the treatment of PsA and pustular psoriasis in Japan[10].

Cosentyx is also 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, Cosentyx is approved for the first-line systemic treatment of moderate-to-severe plaque psoriasis in adult patients[7]. 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)[11].

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 Cosentyx in patients with active AS. A total of 290 of 371 patients completed the trial, after which 274 patients were invited to enter a 3-year extension period[1,12]. Primary endpoints assessed superiority of Cosentyx against placebo at Week 16 in the proportion of patients achieving at least a 20% improvement in the ASAS 20 response (Assessment of Spondyloarthritis International Society response criteria)[4,13]. From Week 16, patients in the placebo arm of the study were re-randomized to Cosentyx 75 mg or 150 mg based on ASAS 20 response, with non-responders switched at Week 16, and responders at Week 24[1,13].

Of the patients participating in the study, almost 80 percent demonstrated no radiographic progression over 208 weeks of treatment, as indicated by the modified Stoke Ankylosing Spondylitis Spinal Score (mSASSS) X-ray assessment measure[1]. Importantly, no structural progression of AS in the spine was paired with sustained results on patient-reported pain measures, with over 75 percent preserving an ASAS 20 response at 4 years[1]. The safety profile of Cosentyx was shown to be consistent with that seen in clinical trials across multiple indications[1,3–6].

About ankylosing spondylitis (AS)
AS is part of a family of lifelong inflammatory diseases that 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[14,15]. Family members of those with AS are at higher risk[15].

AS is a chronic, inflammatory disease that causes pain and stiffness in the spine and joints and can lead to a significant loss of mobility if not properly managed[15,16]. Many patients with AS respond inadequately to current standard of care anti-TNF therapies[2]. In severe cases, the spine and joints above the tailbone can fuse together[16]. Radiography, computed tomography (CT), or magnetic resonance imaging (MRI) of the spine or sacroiliac joints is needed to track the progression of AS and the effectiveness of treatment[16].

Improvements in the symptoms of AS are measured by the ASAS response criteria (ASAS 20). This is defined as an improvement of at least 20 percent, and absolute improvement of at least 10 units on a 0–100 mm scale in at least three of the following criteria: improvement in flexibility, night time pain, ability to perform specific tasks, morning stiffness, and no further deterioration in the condition. The percentage of patients reaching an ASAS 20 response is an accepted way of measuring the efficacy of treatments in AS[17].

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