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Novartis announces publication in The Lancet showing sustained efficacy with secukinumab over one year in psoriatic arthritis patients

- *In the FUTURE 2 study, secukinumab demonstrated rapid onset of action, was significantly superior to placebo in improving signs and symptoms of psoriatic arthritis (PsA), with efficacy sustained over one year*[1]
- *Secukinumab is the first IL-17A inhibitor to significantly improve joint and skin symptoms of PsA, and provides physical functioning and quality of life benefits*[1]
- *Global regulatory submissions have been filed for secukinumab in PsA and ankylosing spondylitis, another serious long-term inflammatory disease*

Basel, June 29 2015 – Novartis announced today that new one year results from the pivotal Phase III FUTURE 2 study of secukinumab in psoriatic arthritis (PsA) were published in *The Lancet* following fast-track review. Secukinumab is the first interleukin-17A (IL-17A) inhibitor to demonstrate efficacy in a Phase III study in adult patients with active PsA.[1] PsA is a long-term, debilitating, inflammatory disease associated with joint pain and stiffness, skin and nail psoriasis, swollen toes and fingers, persistent painful tendonitis and irreversible joint damage.[2]

The new study results published in *The Lancet* show improvements observed with subcutaneous secukinumab 300 mg and 150 mg were sustained over one year of treatment in the majority of patients (64% for both doses), as measured by the American College of Rheumatology response criteria (ACR 20).[1] Moreover, ACR 50 response rates were also sustained to one year in secukinumab 300 mg and 150 mg (44% and 39% respectively). Secukinumab met the primary endpoint of the study, which was ACR 20 at Week 24 with response rates significantly higher in the secukinumab 300 mg (54%; $p<0.0001$) and 150 mg (51%; $p<0.0001$) groups versus placebo (15%), with clinical improvements observed as early as Week 3.[1] ACR 20 and 50 are standard tools used to assess improvement of PsA signs and symptoms, and represent a 20% and 50% improvement from baseline, respectively.[3]

“Secukinumab is the first IL-17A inhibitor to show consistent efficacy through one year in Psoriatic Arthritis, Psoriasis, and Ankylosing spondylitis” said Vasant Narasimhan, Global Head of Development, Novartis Pharmaceuticals. “Novartis has recently filed global regulatory submissions for secukinumab in both psoriatic arthritis and ankylosing spondylitis and will continue to work to bring this important advance to patients with these debilitating diseases.”

Secukinumab 300 mg and 150 mg also significantly improved a key secondary endpoint which was improvement in psoriasis symptoms, as measured by 90% improvements in Psoriasis Area and Severity Index score (PASI 90).[1] Achieving PASI 90 means that patients can attain clear to almost clear skin.[4] This is important as the majority of people living with PsA have a history of, or concomitant, psoriasis[5], another long-term condition which is characterized by thick and extensive skin lesions, called plaques, known to cause itching, scaling and pain.[6,7]

Although the secukinumab benefits seen in FUTURE 2 were generally higher in patients without previous treatment with standard of care anti-TNF therapy, clinical benefits were observed in both anti-TNF-naïve patients and those with an inadequate response to anti-TNFs.[1] This is important as many patients do not respond to, or tolerate these therapies and approximately 40% of people are dissatisfied with current treatments.[8,9] There is therefore, a high unmet need for patients with PsA.

Secukinumab was well tolerated in FUTURE 2, with a safety profile consistent with that observed in the psoriasis clinical trial program involving nearly 5,000 patients.[1,10] The most common adverse events (AEs) were upper respiratory tract infections and the common cold.[1]

About the FUTURE 2 study

FUTURE 2 is a Phase III, multi-center, randomized, placebo-controlled clinical trial that assessed the efficacy and safety of secukinumab, a human anti-IL-17A monoclonal antibody, in patients with PsA.[1] The study enrolled 397 patients with active PsA and compared subcutaneous loading and maintenance dosing with secukinumab 300 mg, 150 mg and 75 mg to placebo.[1]

The study met its primary endpoint of ACR 20 at Week 24. In addition, significant improvements with secukinumab were also demonstrated in psoriasis symptoms that many patients with psoriatic arthritis experience.[1] Compared to placebo at Week 24, as measured by 75% and 90% improvements in Psoriasis Area-and-Severity Index score (PASI 75 and 90) for secukinumab 300 mg (63% vs 16%, P<0.0001 and 49% vs 9%, P=0.0005 for PASI 75 and 90 respectively) and secukinumab 150 mg (48% vs 16%, P=0.0017 and 33% vs 9%, P=0.0057).[1] Secukinumab 75 mg did not significantly improve any of the pre-defined secondary endpoints.[1]

About psoriatic arthritis (PsA)

Psoriatic arthritis (PsA) is a long-term, painful inflammatory disease of the joints and skin which leads to significant disability, poor quality of life and reduced life expectancy.[2,5] PsA is closely associated with psoriasis and approximately 30% of patients with psoriasis have PsA.[5,11] Between 0.3% and 1% of the general population may be affected by PsA and as many as one in four people with psoriasis may have undiagnosed PsA.[5]

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

Secukinumab is a human monoclonal antibody that selectively neutralizes circulating IL-17A.[11] Secukinumab is the first IL-17A inhibitor with positive Phase III results for the treatment of PsA and ankylosing spondylitis (AS).[1,12] Research shows that IL-17A plays an important role in driving the body's immune response in psoriasis and spondyloarthritis conditions, including PsA and AS.[13]

In January 2015, Cosentyx (secukinumab) (at a dose of 300 mg) became the first and only IL-17A inhibitor approved in Europe as a first-line systemic treatment of moderate-to-severe plaque psoriasis in adult patients, and in the US as a treatment for moderate-to-severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy (light therapy). In addition to the EU and the US, Cosentyx has been approved in Switzerland, Chile, Australia, Canada and Singapore for the treatment of moderate-to-severe plaque psoriasis and in Japan for the treatment of moderate-to-severe plaque psoriasis and active psoriatic arthritis (PsA).

Disclaimer

The foregoing release contains forward-looking statements that can be identified by express or implied discussions regarding potential new indications or labeling for Costentyx, or regarding potential future revenues from Cosentyx. You should not place undue reliance on these statements. Such forward-looking statements are based on the current beliefs and expectations of management regarding future events, and are subject to significant known and unknown risks and uncertainties. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those set forth in the forward-

looking statements. There can be no guarantee that Cosentyx will be submitted or approved for any additional indications or labeling in any market, or at any particular time. Nor can there be any guarantee that Cosentyx will receive regulatory approval or be commercially successful in the future. In particular, management's expectations regarding Cosentyx could be affected by, among other things, the uncertainties inherent in research and development, including unexpected clinical trial results and additional analysis of existing clinical data; unexpected regulatory actions or delays or government regulation generally; the company's ability to obtain or maintain proprietary intellectual property protection; general economic and industry conditions; global trends toward health care cost containment, including ongoing pricing pressures; unexpected safety issues; unexpected manufacturing issues, and other risks and factors referred to in Novartis AG's current Form 20-F on file with the US Securities and Exchange Commission. Novartis is providing the information in this press release as of this date and does not undertake any obligation to update any forward-looking statements contained in this press release as a result of new information, future events or otherwise.

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, eye care and cost-saving generic pharmaceuticals. Novartis is the only global company with leading positions in these areas. In 2014, the Group achieved net sales of USD 58.0 billion, while R&D throughout the Group amounted to approximately USD 9.9 billion (USD 9.6 billion excluding impairment and amortization charges). Novartis Group companies employ approximately 120,000 full-time-equivalent associates. Novartis products are available in more than 180 countries around the world. For more information, please visit http://www.novartis.com.

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