# New Novartis data show Cosentyx demonstrated sustained superiority in skin clearance (PASI 90) versus Stelara at Week 52

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- - Late-breaking data at AAD show Cosentyx® remains superior to Stelara® in achieving almost clear skin (PASI 90) at Week 16 and at one year in 76.2% versus 60.6% of moderate to severe psoriasis patients(1)
- - Exploratory analysis showed a higher percentage of Cosentyx patients achieved completely clear skin (PASI 100) compared to Stelara patients at Week 52(1)
- - Cosentyx is the first and only human IL-17A antagonist approved by the FDA for adult patients with moderate to severe plaque psoriasis, active ankylosing spondylitis (AS) and active psoriatic arthritis (PsA)

EAST HANOVER, N.J., March 5, 2016 /PRNewswire/ -- Novartis today announced new late-breaking data from the head-to-head CLEAR study, showing that Cosentyx® (secukinumab) was superior in achieving a key secondary efficacy endpoint of near clear skin on the Psoriasis Area Severity Index (PASI 90) in significantly more moderate to severe psoriasis patients compared to Stelara®* (ustekinumab) at Week 52.[1] These findings were presented for the first time at the American Academy of Dermatology (AAD) 74th Annual Meeting in Washington, D.C.

Cosentyx is the first and only fully human interleukin-17A (IL-17A) antagonist approved to treat adult patients with moderate to severe plaque psoriasis, with almost 15,000 U.S. patients prescribed to date.[2] Cosentyx also was recently approved for the treatment of psoriatic arthritis and ankylosing spondylitis in the U.S.[3]

"The new CLEAR data reinforce that a majority of patients can achieve clear or almost clear skin with Cosentyx and that those results continue over time and compared favorably to Stelara," said Andrew Blauvelt, MD, MBA, President of the Oregon Medical Research Center and lead study investigator. "This is an important consideration for patients as psoriasis is a chronic disease that requires ongoing treatment."

The ultimate aim of psoriasis treatment is clear skin, and the PASI 90 response is considered an important measure of treatment success.[4] Meeting the primary and all secondary endpoints at both Week 16 (PASI 90 response for the Cosentyx treatment group was 80.1% vs. 59.0% for the Stelara treatment group; P<0.0001) and Week 52, Cosentyx demonstrated it remained superior to Stelara in achieving PASI 90 (76.2% vs. 60.6%; P<0.0001) at Week 52.[1] As previously presented, this study also demonstrated 50.0% of Cosentyx patients achieved PASI 75 at Week 4 compared to 20.6% of Stelara patients (P<0.0001).[5]

In an exploratory analysis, a higher percentage of Cosentyx patients achieved completely clear skin (PASI 100) compared to Stelara patients at Week 52 (45.9% vs. 35.8%; P=0.0103). Cosentyx also showed significantly greater Dermatology Life Quality Index (DLQI) 0/1 responses versus Stelara (71.6% vs. 59.2%; P=0.0008).[1]

"We've heard that for many psoriasis patients, their worries don't always end after successful treatment to clear or almost clear their skin. They may still wonder if their medicine will become less effective over time," said Christi Shaw, US Country Head, President of Novartis Corporation and Novartis Pharmaceuticals

Corporation. "We understand this concern. At Novartis, our commitment to patients includes pursuing studies like CLEAR one-year data comparing Cosentyx to Stelara to provide helpful information for physicians and patients to use in deciding the best course of treatment for them."

The safety profile of Cosentyx was consistent with previously reported Phase III trials and similar to Stelara. In the study, the most common adverse events (AEs) in the Cosentyx-treatment arm during the 52 week study were nasopharyngitis (27.1 exposure adjusted Incidence Rate [IR] per 100 patient years), headache (13.5 IR) and upper respiratory tract infection (10.1 IR). The most common AEs in the Stelara-treatment arm during the 52 week study were nasopharyngitis (31.0 IR), headache (14.2 IR) and upper respiratory tract infection (9.9 IR). Non-fatal serious adverse events were comparable between Cosentyx and Stelara treatment groups (9.6 IR and 8.5 IR, respectively). One death was reported in the Stelara treatment group, to date.[1]

About the CLEAR study

CLEAR (Comparison to assess Long-term Efficacy, sAfety and toleRability of secukinumab vs. ustekinumab) is a multi-center, double-blind, parallel-group study evaluating Cosentyx (n=334) versus Stelara (n=335) to compare the efficacy, safety and tolerability in adults with moderate to severe plaque psoriasis. Patients were randomized to receive either Cosentyx (300 mg) by subcutaneous injection at Baseline, Weeks one, two and three, then every four weeks from Week four to 48, or Stelara (dosing per label). Cosentyx achieved the primary objective of superior PASI 90 response at Week 16 and this data was presented at AAD 2015. The 52-week PASI 90 response is a secondary objective in this study.[5]

Efficacy data presented at the AAD Annual Meeting included both non-response and multiple imputation data sets.[1]

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

Cosentyx is a human monoclonal antibody (mAB) that selectively binds to the interleukin-17A (IL-17A) cytokine and inhibits its interaction with the IL-17 receptor.[3]

Cosentyx is approved in over 50 countries for the treatment of moderate to severe plaque psoriasis which includes the European Union countries, Japan, Switzerland, Australia, the U.S. and Canada. In the U.S., Cosentyx is approved for the treatment of moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy (light therapy). Cosentyx is also approved for adult patients with active ankylosing spondylitis and active psoriatic arthritis.[3]

About psoriasis

Affecting about 7.5 million Americans, psoriasis is a chronic immune-mediated disease characterized by thick and extensive skin lesions (plaques), which can cause itching, scaling, and pain.[6] Patients reported these symptoms can negatively impact their quality of life, both psychosocially and physically, which makes daily functioning difficult.[7,8,9] Additionally, patients with psoriasis are at increased risk for other chronic illnesses.[10]

INDICATIONS

COSENTYX® (secukinumab) is a prescription medicine used to treat adults:

- with moderate to severe plaque psoriasis that involves large areas or many areas of the body, and who may benefit from taking injections or pills (systemic therapy) or phototherapy (treatment using ultraviolet or UV light, alone or with systemic therapy)
- with active psoriatic arthritis

- with active ankylosing spondylitis

IMPORTANT SAFETY INFORMATION

Do not use COSENTYX if you have had a severe allergic reaction to secukinumab or any of the other ingredients in COSENTYX. See the Medication Guide for a complete list of ingredients.

COSENTYX is a medicine that affects your immune system. COSENTYX may increase your risk of having serious side effects such as:

Infections

COSENTYX may lower the ability of your immune system to fight infections and may increase your risk of infections.

- Your doctor should check you for tuberculosis (TB) before starting treatment with COSENTYX.
- If your doctor feels that you are at risk for TB, you may be treated with medicine for TB before you begin treatment with COSENTYX and during treatment with COSENTYX.
- Your doctor should watch you closely for signs and symptoms of TB during treatment with COSENTYX. Do not take COSENTYX if you have an active TB infection.

Before starting COSENTYX, tell your doctor if you:

- are being treated for an infection
- have an infection that does not go away or that keeps coming back
- have TB or have been in close contact with someone with TB
- think you have an infection or have symptoms of an infection such as:

- fevers, sweats, or chills
- muscle aches
- cough
- shortness of breath
- blood in your phlegm
- weight loss
- warm, red, or painful skin or sores on your body
- diarrhea or stomach pain
- burning when you urinate or urinate more often than normal

After starting COSENTYX, call your doctor right away if you have any signs of infection listed above. Do not use COSENTYX if you have any signs of infection unless you are instructed to by your doctor.

Inflammatory Bowel Disease

New cases of inflammatory bowel disease or "flare-ups" can happen with COSENTYX, and can sometimes be serious. If you have inflammatory bowel disease (ulcerative colitis or Crohn's disease), tell your doctor if you have worsening disease symptoms during treatment with COSENTYX or develop new symptoms of stomach

pain or diarrhea.

Serious Allergic Reactions

Serious allergic reactions can occur. Get emergency medical help right away if you get any of the following symptoms: feeling faint; swelling of your face, eyelids, lips, mouth, tongue, or throat; trouble breathing or throat tightness; chest tightness; or skin rash. If you have a severe allergic reaction, do not give another injection of COSENTYX.

Before starting COSENTYX, tell your doctor if you:

- have any of the conditions or symptoms listed above for infections
- have inflammatory bowel disease (Crohn's disease or ulcerative colitis)
- are allergic to latex. The needle caps contain latex.
- have recently received or are scheduled to receive an immunization (vaccine). People who take COSENTYX should not receive live vaccines.
- have any other medical conditions
- are pregnant or plan to become pregnant. It is not known if COSENTYX can harm your unborn baby. You and your doctor should decide if you will use COSENTYX.
- are breastfeeding or plan to breastfeed. It is not known if COSENTYX passes into your breast milk.

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Know the medicines you take. Keep a list of your medicines to show your doctor and pharmacist when you get a new medicine.

How should I use COSENTYX?

See the detailed Instructions for Use that comes with your COSENTYX for information on how to prepare and inject a dose of COSENTYX, and how to properly throw away (dispose of) used COSENTYX Sensoready® pens and prefilled syringes.

- Use COSENTYX exactly as prescribed by your doctor.
- If your doctor decides that you or a caregiver may give your injections of COSENTYX at home, you should receive training on the right way to prepare and inject COSENTYX. Do not try to inject COSENTYX yourself, until you or your caregiver has been shown how to inject COSENTYX by your doctor or nurse.

The most common side effects of COSENTYX include: cold symptoms, diarrhea, and upper respiratory infections. These are not all of the possible side effects of COSENTYX. Call your doctor for medical advice about side effects.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

Please see accompanying full Prescribing Information, including Medication Guide.

Disclaimer
The foregoing release contains forward-looking statements that can be identified by words such as "can," "continue," "consideration," "aim," "may," "will," "commitment," or similar terms, or by express or implied discussions regarding potential new indications or labeling for Cosentyx, 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 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 or quality 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

Located in East Hanover, New Jersey, Novartis Pharmaceuticals Corporation is an affiliate of Novartis AG, which 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 2015, the Group achieved net sales of USD 49.4 billion, while R&D throughout the Group amounted to approximately USD 8.9 billion (USD 8.7 billion excluding impairment and amortization charges). Novartis Group companies employ approximately 119,000 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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*Stelara® is a registered trademark of Janssen Biotech, Inc.

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