Novartis' Cosentyx® shows almost all psoriasis patients rapidly regain skin clearance following a treatment pause

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- - 94% of patients regained their PASI 75 response and the majority re-achieved their PASI 90 or 100 response after 16 weeks of Cosentyx 300 mg retreatment(1)
- - Patients may need to pause treatment due to a number of factors, including changes in insurance coverage or the need for surgery
- - More than 20,000 U.S. patients with plaque psoriasis have been prescribed Cosentyx since launch in January 2015(2)

EAST HANOVER, N.J., March 6, 2017 /PRNewswire/ -- Novartis announced today a new analysis (post hoc) of an uncontrolled extension study which shows moderate to severe plaque psoriasis patients treated with Cosentyx® (secukinumab) rapidly regained clear or almost clear skin (Psoriasis Area Severity Index, PASI 100 or 90) following relapse during a treatment pause. The analysis also showed no anti-secukinumab antibodies were observed during retreatment.[1] PASI measures the redness, scaling and thickness of psoriatic plaques, and the extent of involvement in four regions of the body. Treatment efficacy is assessed by the reduction in the total score from baseline (i.e., a 75% reduction is known as PASI 75 and a 90% reduction is known as PASI 90). PASI 90 and 100 are higher standards of skin clearance compared to PASI 75. These findings were presented at the 2017 American Academy of Dermatology (AAD) Annual Meeting in Orlando, Fla., where Novartis presented over 35 scientific abstracts.

Previous data has shown favorable results for continuous over intermittent treatment, however sometimes patients have treatment pauses.[3] This new analysis shows that if psoriasis patients relapse during treatment pauses, the majority can achieve previous high levels of efficacy after only 16 weeks of retreatment with Cosentyx.[1]

"It is very clear that patients get the best results from continuous treatment," said Vasant Narasimhan, Global Head, Drug Development and Chief Medical Officer, Novartis. "However, if for some reason treatment has been interrupted, this analysis gives patients and clinicians the peace of mind that Cosentyx is likely to help people quickly achieve clear skin once again."

The data show the majority of patients with the highest response levels to Cosentyx (PASI 90, PASI 100) after one year of treatment on the 300 mg dose regained a high response level (PASI 75 or higher) 12-16 weeks after treatment re-initiation. For patients who previously achieved PASI 75 and relapsed after treatment discontinuation (n=136), this analysis shows that by Week 16 of retreatment with Cosentyx, 94% of patients regained a PASI 75 response, 79% of prior PASI 90 responders (n=117) regained a PASI 90 response and 67% of prior PASI 100 responders (n=67) regained a PASI 100 response. The median time to relapse was 28 weeks.[1]

In addition, the safety profile was consistent with that observed in previous studies. No patients in this analysis tested positive for anti-secukinumab antibodies. The most common adverse events (AEs) in the Cosentyx-

treatment arm were nasopharyngitis (20.7 exposure adjusted Incidence Rate [IR] per 100 patient years), arthralgia (12.6 IR) and upper respiratory tract infections (12.4 IR).[1]

"This study addresses a common issue in clinical practice that happens when plaque psoriasis patients are on biologic therapy and have to stop for any number of reasons, and then re-start the biologic," said Andrew Blauvelt, MD, MBA, President of the Oregon Medical Research Center and lead study investigator. "Importantly, we found that stopping and re-starting Cosentyx led to good re-capture of clinical responses. Low immunogenicity associated with Cosentyx may offer a partial explanation of these results and warrants further analysis."

Cosentyx is the only IL-17A inhibitor approved in plaque psoriasis, psoriatic arthritis (PsA) and ankylosing spondylitis (AS), and more than 30,000 U.S. patients have been prescribed Cosentyx in the post-marketing setting across all indications.[2]

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

Launched in January 2015, Cosentyx is a fully human monoclonal antibody (mAB) that selectively binds to the interleukin-17A (IL-17A) cytokine and inhibits its interaction with the IL-17 receptor.

Cosentyx is approved in more than 75 countries for the treatment of moderate to severe plaque psoriasis which includes the U.S., European Union countries, Japan, Switzerland, Australia 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).

In addition, Cosentyx is the first IL-17A inhibitor approved in more than 65 countries for the treatment of active AS and PsA, which includes the U.S. and European Union countries.

Novartis is committed to ensuring patients and prescribers have access to Cosentyx. Cosentyx currently is covered on over 95% of U.S. commercial formularies across its three approved indications for plaque psoriasis, PsA and AS.[4]

About the Cosentyx retreatment study

An uncontrolled, extension study of ERASURE (Efficacy of Response and Safety of Two Fixed Secukinumab Regimens in Psoriasis), which compared Cosentyx with placebo, and FIXTURE (Full Year Investigative Examination of Secukinumab vs. Etanercept Using Two Dosing Regimens to Determine Efficacy in Psoriasis), which compared Cosentyx with placebo and etanercept. A total of 181 patients treated with Cosentyx 300 mg who achieved a PASI 75 response at the end of the core studies (Week 52) were re-randomized to receive placebo every four weeks until relapse. Upon relapse, patients were retreated with Cosentyx 300 mg.[1]

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.[5] Patients reported these symptoms can negatively impact their quality of life, both psychosocially and physically, which makes daily functioning difficult.[6-8] Additionally, patients with psoriasis are at increased risk for other chronic illnesses.[9]

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
  - 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 "launch," "can," "may," "launched," "committed," 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 clinical trial results and additional analysis of existing clinical data; 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; safety, quality or 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

Located in East Hanover, NJ, Novartis Pharmaceuticals Corporation is an affiliate of Novartis 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 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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