Novartis new data show Cosentyx® improved quality of life over 5 years in two thirds of patients with moderate to severe plaque psoriasis

Feb 16, 2018

- - Two thirds of patients on Cosentyx® (secukinumab) reported no impact of skin disease on their quality of life over 5 years, SCULPTURE study shows(1)
- - Study findings show absolute PASI ≤1/≤2/≤3 responses were sustained in those treated with Cosentyx from Year 1 to Year 5(1)
- - Cosentyx is the first and only fully human interleukin-17A (IL-17A) antagonist that showed sustained skin clearance rates at 5 years in patients from a psoriasis Phase III study(2)

EAST HANOVER, N.J., Feb. 16, 2018 /PRNewswire/ -- Novartis announced today additional results from the SCULPTURE study showing that two thirds of moderate to severe plaque psoriasis patients treated with Cosentyx® (secukinumab) reported no impact of skin disease on their quality of life through 5 years, as described by the Dermatology Life Quality Index (DLQI) 0/1 response (72.7% at Year 1 and 65.5% at Year 5) – a questionnaire used to evaluate the impact of skin disease on a patient's quality of life.[1,3] These data were presented at the 2018 American Academy of Dermatology (AAD) Annual Meeting in San Diego, California.

Study findings also show absolute PASI ≤1/≤2/≤3 responses at Year 1 (58.6%, 67.9% and 74.1%, respectively) were sustained to Year 5 (53.3%, 66.4% and 75.4%, respectively); as observed analysis.[1] Absolute PASI scores can provide an indication of disease severity after treatment.[4] Achievement of an absolute PASI score lower than 2 or 3 has been proposed as an indication of treatment success.[4]

Psoriasis is not simply a cosmetic problem, but a persistent, chronic (long-lasting), and sometimes distressing disease, which can affect even the smallest aspects of people's lives on a daily basis.[5]

"There is a link between achieving skin clearance and improved quality of life, and proper management of psoriasis should address both the physical symptoms of the disease and its impact on patients' daily lives," said Craig Leonardi, MD, Adjunct Professor of Dermatology at St. Louis University School of Medicine. "Results from the SCULPTURE study show treatment with Cosentyx can deliver both over the long-term. It's encouraging to see such improvements in DLQI responses and absolute PASI scores below 3 through 5 years."

"It is encouraging to see such positive responses reported by psoriasis patients themselves, who are experiencing an improved quality of life over an extended period of time," said Randy Beranek, President and CEO of the National Psoriasis Foundation. "We know first-hand from patients how debilitating psoriasis can be and this data provides hope that patients on an effective treatment can have the opportunity to experience clear skin that can last."

The most common adverse events included nasopharyngitis, upper respiratory tract infection and headache, consistent with those reported in the core study and previous Phase III studies.[1]

Cosentyx is the first and only fully human IL-17A antagonist approved to treat ankylosing spondylitis (AS), psoriatic arthritis (PsA) and moderate to severe plaque psoriasis.[6] To date, more than 140,000 patients worldwide have been prescribed Cosentyx in the post-marketing setting across all indications.[7]

About Cosentyx (secukinumab) and IL-17A
Cosentyx, launched in 2015, is the first and only fully-human interleukin-17A (IL-17A) antagonist approved to treat moderate to severe plaque psoriasis, psoriatic arthritis (PsA) and ankylosing spondylitis (AS).[6] By specifically targeting IL-17A, Cosentyx addresses an important cytokine involved in the development of psoriasis.[6,8] IL-17A plays a significant role in the pathogenesis of plaque psoriasis, PsA and AS.[6, 8-10] Inhibiting IL-17A is important as up to 30% of patients with psoriasis may have PsA.[11]

In psoriasis, Cosentyx delivers long-lasting skin clearance with a sustained response rates and favorable safety profile out to 5 years, as demonstrated in a clinical study, along with convenient dosing in a patient-friendly auto injector.[2, 12] Cosentyx has been studied in dedicated trials for the most difficult-to-treat types of plaque psoriasis – palmoplantar psoriasis (psoriasis of the hands and feet), scalp psoriasis, and nail psoriasis.[13-15]

Cosentyx is 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 treatment of moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy.[16] 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).[6]

In addition, Cosentyx is the first IL-17A antagonist approved in more than 65 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.[17]

About the Cosentyx SCULPTURE study (NCT01406938)[1,2]
NCT01406938 is a multicenter, double-blind and open-label, 4-year extension to the core Phase III SCULPTURE study. In SCULPTURE, PASI 75 responders at Week 12 were randomized to double-blind maintenance treatment of Cosentyx 300 mg or 150 mg, given either at a 4-week fixed-interval regimen or in a retreatment-as-needed regimen. Patients who completed 52 weeks of the core SCULPTURE study were eligible to continue the same dose and regimen in the extension study (N=642). Patients subsequently entered the extension phase and continued the same double-blinded treatment regimen to Year 3, and thereafter un-blinded to the end of the study at Year 5 (n=126 at Week 260). The primary objective of this extension study was to assess the long-term safety and tolerability of Cosentyx in patients with moderate to severe plaque psoriasis. Efficacy measures included proportion of patients achieving PASI 75, PASI 90 and PASI 100. The current as observed analysis describes PASI 75/90/100 at Year 1 (88.9%, 68.5% and 43.8%, respectively) and Year 5 (88.5%, 66.4% and 41%); absolute PASI ≤1/≤2/≤3 responses at Year 1 (58.6%, 67.9% and 74.1%, respectively) and Year 5 (53.3%, 66.4% and 75.4%, respectively), Dermatology Life Quality Index (DLQI) 0/1 at Year 1 (72.7%) and Year 5 (65.5%), and long-term safety and tolerability.

About psoriasis
Psoriasis is a common, non-contagious, auto-immune disease that affects more than 125 million people worldwide.[18] Plaque psoriasis is the most common form of the disease and appears as raised, red patches covered with a silvery white build-up of dead skin cells.[5]

Psoriasis is not simply a cosmetic problem, but a persistent, chronic (long-lasting), and sometimes distressing

disease, which can affect even the smallest aspects of people's lives on a daily basis.[5] Up to 30% of patients with psoriasis may have PsA.[11] PsA is a condition in which the joints are also affected, causing debilitating symptoms including pain, stiffness and for some people, irreversible joint damage.[19] Psoriasis is also associated with other serious health conditions, such as diabetes, heart disease and depression.[5]

INDICATIONS
Cosentyx is a human interleukin-17A antagonist indicated for the treatment of:

- moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy
- adults with active psoriatic arthritis (PsA)
- adults with active ankylosing spondylitis (AS)

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
This press release contains forward-looking statements within the meaning of the United States Private Securities Litigation Reform Act of 1995. Forward-looking statements can generally be identified by words such as "potential," "can," "will," "plan," "expect," "anticipate," "look forward," "believe," "committed," "investigational," "pipeline," "launch," or similar terms, or by express or implied discussions regarding potential

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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, cost-saving generic and biosimilar pharmaceuticals and eye care. Novartis has leading positions globally in each of these areas. In 2017, the Group achieved net sales of USD 49.1 billion, while R&D throughout the Group amounted to approximately USD 9.0 billion. Novartis Group companies employ approximately 122,000 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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