Novartis data show psoriasis patients treated with Cosentyx® reported improvements in quality of life measures as early as Week 4

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- - Psoriasis patients receiving Cosentyx (secukinumab) reported improvements beyond the skin in mobility, self-care, and usual activities versus patients receiving placebo(1)
- - Skin lesions are only one of the multiple manifestations of psoriatic disease, which can affect nails and joints and have an overall impact on patients' quality of life(2-4)
- - The data from a pooled analysis highlight the importance of considering quality of life, in addition to skin clearance, as part of a psoriasis management plan(1)

EAST HANOVER, N.J., Jan. 28, 2019 /PRNewswire/ -- Novartis announced today results from a pooled analysis of four Phase 3 clinical trials demonstrating patients with moderate-to-severe plaque psoriasis (PsO) treated with Cosentyx® (secukinumab) 300 mg reported improvements in mobility, self-care, and usual activities components of the EQ-5D-3L questionnaire as early as Week 4 when compared to placebo in patients who reported problems at baseline.[1] The results were presented at the 15th Annual Maui Derm for Dermatologists 2019.

"Moderate-to-severe plaque psoriasis can impact every aspect of a person's life," stated Steven R. Feldman, M.D., Ph.D, Wake Forest School of Medicine*. "These findings suggest that helping patients feel better through improved quality of life and ability to function should be a goal as important as skin clearance in psoriasis management."

Plaque psoriasis is characterized by painful red, raised, dry patches of skin usually covered by silvery or white scales.[2] The disease typically involves the extensor areas of the forearms and shins, along with hard-to-treat areas like the scalp, palms of the hand, soles of the feet and finger nails.[2,3] Many patients with psoriasis also live with concurrent psoriatic arthritis (PsA), an inflammatory form of arthritis causing stiffness, pain, and swelling in the joints. When left untreated, PsA can cause irreversible joint damage and lead to physical limitations.[4] For patients experiencing symptoms of PsO and PsA the physical limitations can lead to psychological problems that can affect every day social activities and work causing embarrassment, lack of self-esteem, anxiety and depression.[2,4-5]

The pooled analysis of the ERASURE, FIXTURE, FEATURE, and JUNCTURE trials included patients with moderate-to-severe plaque psoriasis who were randomized to receive placebo or Cosentyx 300 mg and who reported problems with mobility, self-care, or usual activities (e.g. work, study, housework, family or leisure activities) at baseline, as recorded by the EQ-5D questionnaire. The percentages of patients reporting problems in the EQ-5D-3L mobility, self-care, or usual activities domains were compared at weeks 4, 8, and 12 between patients receiving placebo (n=282) and Cosentyx 300 mg (n=309).[1]

- Change in Mobility: The percentage of patients reporting no problems in mobility at Week 4 was higher with Cosentyx 300 mg compared with placebo (60.7% vs 38.5%); similar trends were observed at Weeks 8 (73.6% vs 48.1%) and 12 (71.4% vs 46.6%).[1]
- Change in Self Care: The percentage of patients reporting no problems in self-care at Week 4 was higher with Cosentyx 300 mg compared with placebo (71.4% vs 40.9%); similar trends were observed at Weeks 8 (79.2% vs 42.3%) and 12 (87.1% vs 43.0%).[1]
- Change in Usual Activities: The percentage of patients reporting no problems in usual activities at Week 4 was twice higher with Cosentyx 300 mg compared with placebo (63.8% vs 31.1%); similar trends were observed at Weeks 8 (74.4% vs 35.7%) and 12 (82.7% vs 42.6%).[1]

Cosentyx is the first and only fully human IL-17A antagonist approved to treat moderate to severe plaque psoriasis, psoriatic arthritis (PsA), and ankylosing spondylitis (AS).[6] To date, over 14,630 unique prescribers have experience with Cosentyx,

and have prescribed Cosentyx to more than 105,000 US patients to date 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 an important role in the pathogenesis of plaque psoriasis, PsA and AS.[8-10] Up to 30% of patients with psoriasis may have PsA.[11-12]

In psoriasis, Cosentyx delivers long-lasting skin clearance with a sustained response and favorable safety profile out to 5 years, as demonstrated in a clinical study, along with convenient dosing in a patient-friendly auto injector.[13,14] 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.[15-17]

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.[18] 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.[19]

About the Pooled Analysis[1]

This pooled analysis of four phase 3 clinical trials (ERASURE, FIXTURE, FEATURE, and JUNCTURE) included patients with moderate-to-severe psoriasis who were randomized to receive placebo or Cosentyx (Secukinumab) 300 mg and who reported problems with mobility, self-care, or usual activities at baseline. Demographic characteristics (age, sex, race, and body weight), treatment history, and clinical characteristics (body surface area [BSA]; Dermatology Life Quality Index [DLQI]; mobility, self-care, and usual activities domains of the EQ-5D-3L; Psoriasis Area and Severity Index [PASI]; and concurrent PsA [30.1% of patients in placebo arm and 25.9% of patients in Cosentyx 300 mg arm]) were examined at baseline. The EQ-5D-3L is a general health instrument with 5 domains (mobility, self-care, usual activities [eg, work, study, housework, family or leisure activities], pain/discomfort, and anxiety/depression), each scored at 3 levels. For the purpose of this study, "some problems" and "extreme problems" were grouped as "any problems," resulting in scoring at 2 levels. The percentages of patients reporting problems in the EQ-5D-3L mobility, self-care, or usual activities domains were compared at Weeks 4, 8, and 12 between patients receiving placebo and those receiving Cosentyx 300 mg.

About psoriasis

Psoriasis is a common, non-contagious, auto-immune disease that affects more than 125 million people worldwide.[2,20] 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.[2]

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.[2] Up to 30% of patients with psoriasis may have PsA.[11-12] PsA is a condition in which the joints are also affected, causing debilitating symptoms including pain, stiffness and for some people, irreversible joint damage.[4] Psoriasis is also associated with other serious health conditions, such as diabetes, heart disease and depression.[2]

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.

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About Novartis
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List of links present in page

1. https://qa1.novartis.us/news/media-releases/novartis-data-show-psoriasis-patients-treated-cosentyx-reported-improvements-quality-life-measures-early-week-4
2. https://c212.net/c/link/?t=0&l=en&o=2358123-1&h=1150990800&u=http%3A//www.fda.gov/medwatch&a=www.fda.gov/medwatch
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13. https://clinicaltrials.gov/ct2/show/NCT02267135?term=Scalp&cond=secukinumab&rank=1
14. https://clinicaltrials.gov/ct2/show/NCT01807520?term=secukinumab&draw=4&rank=13
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