Novartis Cosentyx® sets the new benchmark in psoriasis with robust 5-year sustained efficacy and safety Phase III data

Sep 13, 2017

- - Cosentyx® (secukinumab) is the first and only fully human IL-17A antagonist to show sustained skin clearance rates at 5 years in Phase III in psoriasis(1)
- - Landmark data show that PASI 90 and PASI 100 response rates were nearly 100% maintained with Cosentyx from Year 1 to Year 5 in patients with moderate to severe plaque psoriasis(1)
- - 5-year data from a Phase III study reinforce Cosentyx long term skin clearance and safety(1)

EAST HANOVER, N.J., Sept. 13, 2017 /PRNewswire/ -- Novartis announced today first of its kind Phase III data showing Cosentyx® (secukinumab) delivered high and long-lasting skin clearance in patients with moderate to severe plaque psoriasis at 5 years.[1] These data were presented for the first time at the 26th European Academy of Dermatology and Venereology (EADV) Congress in Geneva, Switzerland.

By specifically targeting interleukin-17A (IL-17A), Cosentyx addresses an important cytokine involved in the development of psoriasis.[2,3] IL-17A plays a significant role in the pathogenesis of plaque psoriasis, psoriatic arthritis (PsA) and ankylosing spondylitis (AS).[2-5] Inhibiting IL-17A is important as up to 30% of patients with psoriasis may have PsA.[6]

"5-year Phase III data are a respected scientific milestone to demonstrate the long-term efficacy and safety of many treatments," said Craig Leonardi, MD, Adjunct Professor of Dermatology at St. Louis University School of Medicine. "These long-term data for Cosentyx provide further confirmation for both patients and doctors that Cosentyx is a safe and effective treatment option for psoriasis."

"The 5-year data reinforce Cosentyx as an important treatment option for those people living with psoriasis who aspire for skin clearance that can last," said Vas Narasimhan, Global Head, Drug Development and Chief Medical Officer, Novartis. "Cosentyx is the first and only IL-17A antagonist approved for psoriasis, psoriatic arthritis and ankylosing spondylitis and has been prescribed to more than 100,000 patients since launch."

Clear skin is the aim of psoriasis treatment, and a Psoriasis Area and Severity Index (PASI) 75, 90 or 100 response is considered an important measure of treatment success.[7-10] Over the extended treatment period from Year 1 (Week 52) to the end of Year 5 (Week 260), PASI 75/90/100 response rates remained consistent.[1] In the 168 psoriasis patients at Year 1, PASI 75 and PASI 90 were achieved by 89% and 69% respectively. This high rate was maintained at Year 5 with 126 patients observed (89% and 66%, respectively). In addition, 44% of psoriasis patients achieved completely clear skin (PASI 100) at Year 1 and this rate was maintained to Year 5 (41%). Cosentyx continued to have a favorable and consistent safety profile.[1,2]

To date, more than 100,000 patients worldwide have been prescribed Cosentyx in the post-marketing setting across all indications.[11] In addition, 2017 marks 10 years since the first patient, first visit in a clinical trial with Cosentyx.[11]

About Cosentyx and IL-17A

Cosentyx, launched in 2015, is the first and only fully-human IL-17A antagonist approved to treat moderate to severe plaque psoriasis, PsA and ankylosing spondylitis (AS).[2] By specifically targeting interleukin-17A (IL-17A), Cosentyx addresses an important cytokine involved in the development of psoriasis.[2,3] IL-17A plays a significant role in the pathogenesis of plaque psoriasis, psoriatic arthritis (PsA) and ankylosing spondylitis (AS).[2-5] Inhibiting IL-17A is important as up to 30% of patients with psoriasis may have PsA.[6]

In psoriasis, Cosentyx delivers long-lasting skin clearance, with proven sustainability, safety out to 5 years and convenient once-monthly dosing (every four weeks) in a patient-friendly auto injector.[1,12] Cosentyx is also being 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.[13,14]

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 first-line systemic treatment of moderate to severe plaque psoriasis in adult patients.[15] 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).[2]

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.[16]

About the Cosentyx 5-year extension study (NCT01406938)[1]

NCT01406938 is a multicenter, double-blind and open-label, 5-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 SCULPTURE study were eligible to continue the same dose and regimen in the extension study (N=642).

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.

About psoriasis

Psoriasis is a common, non-contagious, auto-immune disease that affects more than 125 million people worldwide.[17] Plaque psoriasis is the most common form of the disease and appears as raised, red patches covered with a silvery white buildup of dead skin cells.[18]

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.[18] Up to 30% of patients with psoriasis may have PsA.[6] 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.[18]

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 marketing approvals, 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 our current beliefs and expectations 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 sale or 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, our 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; our ability to obtain or maintain proprietary intellectual property protection; the particular prescribing preferences of physicians and patients; global trends toward health care cost containment, including government, payor and general public pricing and reimbursement pressures; general economic and industry conditions, including the effects of the persistently weak economic and financial environment in many countries; 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
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