Novartis late-breaking data show Cosentyx® continues to deliver high skin clearance for majority of psoriasis patients at four years

Oct 01, 2016

- -- New data at EADV show Cosentyx delivers almost clear or completely clear skin in majority of patients (PASI 90 - 66%, PASI 100 - 44%) after four years of treatment1
- -- Data show that with Cosentyx, 97% of PASI 90 and 99% of PASI 100 response rates were maintained from Year 1 to Year 41*
- -- Additional data show Cosentyx, the first fully human IL-17A inhibitor approved for psoriasis, psoriatic arthritis and ankylosing spondylitis, provided benefit to patients with difficult-to-treat psoriasis of the palms and soles up to 1.5 years2

EAST HANOVER, N.J., Oct. 1, 2016 /PRNewswire/ -- Novartis announced today new data showing Cosentyx® (secukinumab) delivers efficacy in patients with moderate to severe plaque psoriasis out to four years of treatment. These late-breaking data come from the extension study of the Phase III SCULPTURE trial.[1] Results were presented for the first time at the 25th European Academy of Dermatology and Venereology (EADV) Congress in Vienna, Austria.

"These impressive results show that Cosentyx keeps working year-on-year, maintaining high levels of skin clearance with a favorable safety profile," said Vasant Narasimhan, Global Head, Drug Development and Chief Medical Officer, Novartis. "Psoriasis patients need therapies they can use over long periods of time without loss of efficacy and we are pleased that Cosentyx is proving a sustainable choice for patients."

The ultimate aim of psoriasis treatment is clear skin, and the Psoriasis Area Severity Index (PASI) 90 response is considered an important measure of treatment success.[3] SCULPTURE extension patients received the same blinded maintenance treatment regimen and dose up to the end of Year 3. In the fourth year, the study became open label. All results presented are for the Cosentyx 300 mg every 4 weeks group. Almost clear skin (PASI 90) was achieved by 68.5% of patients at Year 1 (Week 52) and 61.9% of patients at Year 3 (Week 156), and was maintained at Year 4 (Week 208) in 66.4% of patients.[1]

In addition, completely clear skin (PASI 100) was achieved by 43.8% of patients at Year 1 and 41.7% of patients at Year 3, and was maintained at Year 4 in 43.5% of patients. The historic standard goal of treatment, PASI 75 skin clearance, was achieved by 88.9% of patients at Year 1 and 78.4% of patients at Year 3, and was maintained by 88.5% of patients at Year 4. The most common adverse events (AEs) at Year 4 were nasopharyngitis (12.1%) and upper respiratory tract infection (3.5%) and were similar to those observed at Year 1.[1]

Also presented at EADV were results from the GESTURE study demonstrating the strength of Cosentyx versus placebo in patients with moderate to severe palmoplantar plaque psoriasis, which are considered difficult areas to treat on the body. At Week 16, about 40% of patients achieved clear or almost clear palms and soles with Cosentyx 300 mg every 4 weeks, which continued to improve with approximately 60% of patients achieving clear or almost clear palms and soles at Week 80 (Year 1.5). AEs were reported in 47 of the

69 patients receiving Cosentyx 300 mg and 27 of the 68 patients receiving placebo at Week 80.[2] Patients with palmoplantar psoriasis are known to suffer greater disability and discomfort than those with psoriasis on other areas.[4]

"The four-year study adds to a growing body of evidence that Cosentyx is an important longer-term treatment option for patients with moderate to severe plaque psoriasis," said Craig Leonardi, MD, study author and adjunct professor of dermatology at St. Louis University Medical School. "Furthermore, the palms and soles of the feet are generally very difficult to treat. This new data is significant as there is still high unmet need for effective treatments for those living with palmoplantar psoriasis."

Additional data presented at EADV from a study in moderate to severe scalp psoriasis showed Cosentyx demonstrated superior efficacy compared to placebo. In the study, Psoriasis Scalp Severity Index (PSSI) 90 responses were achieved by a significantly greater percentage of patients receiving Cosentyx 300 mg (52.9%) than placebo (2.0%) at Week 12 ($P<0.001$). AEs were reported in 52.9% of patients receiving Cosentyx 300 mg and 49.0% of patients receiving placebo at Week 12. No serious AEs were reported with Cosentyx.[5]

About the four-year Cosentyx safety and efficacy study (A2304E1)
A2304E1 is a multicenter, double-blind and open-label extension study to evaluate the long-term safety and efficacy of Cosentyx in patients with moderate to severe plaque psoriasis. Patients who completed 52 weeks of the core SCULPTURE and STATURE studies and re-consented to treatment were eligible for the extension, and continued the same Cosentyx dose and regimen that they were receiving in their core study. Patients did not have to achieve a PASI 75 response at the end of their core study to enroll. A total of 642 patients entered the extension study: 168 continued on Cosentyx 300 mg every 4 weeks, 152 continued on Cosentyx 150 mg every 4 weeks, 172 continued on Cosentyx 300 mg retreatment-as-needed, and 150 continued on Cosentyx 150 mg retreatment-as-needed. At the end of Week 156, the study was open-label and patients could continue their assigned dose and regimen or switch to 300 mg every 4 weeks based on the investigator's judgment. Results presented at EADV focus on those patients from the SCULPTURE core study who enrolled in the extension study. The primary endpoint of this extension study was overall safety and tolerability. Secondary efficacy measures included the proportion of patients achieving PASI 75, PASI 90 and PASI 100.[1]

About the palmoplantar psoriasis Cosentyx study (GESTURE extension)
The GESTURE study is a randomized, double-blind, placebo-controlled study to evaluate the efficacy and safety of Cosentyx in 205 patients with moderate to severe palmoplantar plaque psoriasis (pustular psoriasis was not included). Eligible patients were equally randomized to one of three groups: 1) Cosentyx 300 mg; 2) Cosentyx 150 mg, or 3) Placebo administered at Weeks 0, 1, 2, 4, and then every 4 weeks thereafter. At Week 16, patients in the placebo group who did not achieve a score of 0 (clear) or 1 (almost clear) on the palmoplantar Investigator's Global Assessment (ppIGA) and at least a 2-point reduction from baseline were re-randomized to receive either Cosentyx 300 mg or 150 mg. The primary endpoint was the proportion of patients who achieved a ppIGA 0/1 response at Week 16. Secondary objectives included the evaluation of ppIGA response over time and overall safety and tolerability.[2]

About the scalp psoriasis Cosentyx study
This study is a randomized, double-blind, placebo-controlled study to evaluate the efficacy and safety of Cosentyx in 102 patients with moderate to severe scalp psoriasis. Eligible patients were equally randomized to either subcutaneous Cosentyx 300 mg or placebo at Weeks 0, 1, 2, 3, and 4 and then every 4 weeks for 12 weeks. At Week 12, patients in the placebo group who did not achieve at least a 90% improvement from baseline in the Psoriasis Scalp Severity Index (PSSI) score were re-randomized to Cosentyx 300 mg until study completion. The primary endpoint was the proportion of patients who achieved PSSI 90 response rate at Week 12.[5]

About Cosentyx (secukinumab) and interleukin-17A (IL-17A)
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.[6]

Cosentyx is approved in more than 65 countries for the treatment of moderate to severe plaque psoriasis which includes the European Union countries, Japan, Switzerland, Australia, the U.S. and Canada.[7] 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.[6]

More than 10,000 patients have been treated with Cosentyx in clinical trial settings across multiple indications, and over 50,000 patients have been treated in the post-marketing setting.[7]

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, psoriatic arthritis, and ankylosing spondylitis.[8]

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.[9] Patients reported these symptoms can negatively impact their quality of life, both psychosocially and physically, which makes daily functioning difficult.[10-12] Additionally, patients with psoriasis are at increased risk for other chronic illnesses.[13]

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 "continues," "aim," "growing," "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 receive additional regulatory approvals or 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, 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
Novartis Pharmaceuticals Corporation offers a broad range of medicines for cancer, cardiovascular disease, endocrine disease, inflammatory disease, infectious disease, neurological disease, organ transplantation, psychiatric disease, respiratory disease and skin conditions.

Located in East Hanover, NJ 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 118,000 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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* As observed analyses.

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