Novartis confirms 5 year data for first and only fully-human IL-17A inhibitor Cosentyx® reinforcing sustained efficacy and safety profile in psoriasis

Jul 14, 2017

- - 5 year data from long-term Phase III extension study demonstrate sustained efficacy and safety of Cosentyx in patients with moderate-to-severe plaque psoriasis(1)
- - Data planned to be presented at a key medical congress in the second half of 2017. 5 year Phase III data is a milestone for assessing long-term efficacy and safety
- - Recently announced EU approval for Cosentyx label update underlined 52 week superiority versus Stelara®* in psoriasis, and efficacy in moderate-to-severe scalp psoriasis(2,3)

EAST HANOVER, N.J., July 14, 2017 /PRNewswire/ -- Novartis, a global leader in Immunology & Dermatology, confirmed today positive 5 year efficacy and safety results for Cosentyx® from a Phase III long-term extension study in patients with moderate-to-severe plaque psoriasis.[1] Data will be presented at a key medical congress in the second half of 2017. 5 year Phase III data are a milestone for assessing long-term efficacy and safety.

"Cosentyx has consistently demonstrated sustained efficacy and safety providing psoriasis patients a new standard of long-term care," said Vas Narasimhan, Global Head of Drug Development and Chief Medical Officer, Novartis. "With the first data from a trial with 5 years of follow up, Cosentyx continues to demonstrate it can provide what psoriasis patients want, clear skin."

4 year data from the same Phase III study presented at EADV 2016 already showed Cosentyx delivered almost clear or clear skin in many patients (PASI 90 - 66%, PASI 100 - 44%) from year 1 to year 4 of treatment.[13]

Recently, new label updates announced for Cosentyx in Europe demonstrated superiority of Cosentyx versus Stelara®* (ustekinumab) in moderate-to-severe plaque psoriasis on the basis of 52 week data from the CLEAR study, and expanded the use of Cosentyx for the treatment of moderate-to-severe scalp psoriasis.[2,3] Cosentyx was launched in 2015 as the first and only fully-human IL-17A inhibitor to treat psoriasis and is now approved for the treatment of psoriatic arthritis and ankylosing spondylitis as well. Novartis remains committed to investigating important scientific questions with Cosentyx that address unmet needs and could significantly enhance patients' quality of life.

About the study
The Sculpture (NCT01406938) extension study of Cosentyx for the treatment of moderate-to-severe plaque psoriasis was designed to assess long-term safety and efficacy during a double-blind period (up to 4 years) and open-label period up to year 5 (Week 260). The data analysis for Cosentyx includes all patients who reached a PASI 75 response at Week 12 and subsequently received continuous treatment with 300mg Cosentyx until the end of Year 5. The study includes analysis of the PASI 75/90/100 response rates over the extended treatment period from Year 1 (Week 52) to the end of Year 5 (Week 260), analyses of body surface area (BSA) and absolute PASI scores, proportion of patients with 1% or less BSA involvement, mean PASI

and BSA improvement, as well as the safety profile of Cosentyx.[1]

About psoriasis
Psoriasis is a common, non-contagious, auto-immune disease that affects more than 125 million people worldwide.[4] 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. Scalp psoriasis is a form of psoriasis that is reported to affect approximately half of all patients with psoriasis.[5] The disease has a significant impact on patients' quality of life, which is an aspect of the disease underestimated by most physicians.[6]

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. Up to 30% of patients with psoriasis may develop, PsA.[7] PsA is a condition in which the joints are also affected, causing debilitating symptoms including pain, stiffness and irreversible joint damage.[7,8] Psoriasis is also associated with other serious health conditions, such as diabetes, heart disease and depression.[7]

About Cosentyx and interleukin-17A (IL-17A)
Launched in January 2015, Cosentyx is a targeted treatment that specifically inhibits the IL-17A cytokine. Research suggests that IL-17A may play an important role in driving auto-inflammatory conditions in enthesitis and ultimately the body's immune response in psoriasis, psoriatic arthritis (PsA) and ankylosing spondylitis (AS).[9,10]

Cosentyx is approved in more than 75 countries for the treatment of moderate-to-severe plaque psoriasis, which includes the US, Canada, the European Union countries, Japan, Switzerland and Australia. In Europe, Cosentyx is approved for the first-line systemic treatment of moderate-to-severe plaque psoriasis in adult patients.[2] 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.[11]

Cosentyx is the first IL-17A inhibitor approved in more than 70 countries for the treatment of active PsA and AS, which includes the US and the European Union countries. Cosentyx is also approved for the treatment of PsA and pustular psoriasis in Japan.[12]

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, including "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 the investigational or approved products described in this press release, or regarding potential future revenues from such products. 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 the investigational or approved products described in this press release 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 such products will be commercially successful in the future. In particular, our expectations regarding such products 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
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 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.

Novartis is on Twitter. Sign up to follow @Novartis at http://twitter.com/novartis

For Novartis multimedia content, please visit www.novartis.com/news/media-library
For questions about the site or required registration, please contact media.relations@novartis.com

*Stelara® is a registered trademark of Janssen Biotech, Inc.

References

1. Novartis, data on file
2. Cosentyx Summary of Product Characteristics. Novartis Europharm Limited. Available at: http://www.ema.europa.eu/docs/en_GB/document_library/EPAR-Product_Information/human/003729/WC500183129.pdf. Last accessed July 2017.
3. Blauvelt A et al. Secukinumab is superior to ustekinumab in clearing skin of subjects with moderate-to-severe plaque psoriasis up to 1 year: Results from the CLEAR study. Journal of the American Academy of Dermatology. 2017;76:60-69.
4. International Federation of Psoriasis Associations (IFPA) World Psoriasis Day website. "About Psoriasis." Available at: http://www.worldpsoriasisday.com/web/page.aspx?refid=114. Last accessed June 2017.
5. Farber EM, Nall L. Natural history and treatment of scalp psoriasis. Cutis. 1992;49:396-400.
6. Wozel G. Psoriasis treatment in difficult locations: scalp, nails, and intertriginous areas. Clinics in Dermatology. 2008;26:448-459.
7. National Psoriasis Foundation. Psoriatic disease: about psoriasis. Available at: www.psoriasis.org/about-psoriasis. Last accessed June 2017.
8. Mease PJ, Armstrong AW. Managing patients with psoriatic disease: the diagnosis and pharmacologic treatment of psoriatic arthritis in patients with psoriasis. Drugs. 2014; 74:423-441.
9. Kirkham BW et al. Interleukin-17A: a unique pathway in immune-mediated diseases: psoriasis, psoriatic arthritis and rheumatoid arthritis. Immunology. 2014; 141:133-142.
10. Ivanov S, Linden A. Interleukin-17 as a drug target in human disease. Trends in Pharmacological Sciences. 2009; 30(2):95-103.
11. Cosentyx (secukinumab) [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corp, 2016.
12. Novartis, data on file
13. Bissonnette R et al. Secukinumab maintains high levels of efficacy through 4 years of treatments: results from an extension to a phase 3 study (SCULPTURE). Presented as a late breaking abstract at the European Academy of Dermatology and Venereology 2016. 1st October 2016.

Novartis Media Relations
Central media line: +41 61 324 2200

E-mail: media.relations@novartis.com

Eric Althoff	Jeannie Neufeld
Novartis Global Media Relations	Novartis Pharmaceuticals Corporation
+41 61 324 7999 (direct)	+1 862 778 2104 (direct)
+41 79 593 4202 (mobile)	+1 201 650 2728 (mobile)
eric.althoff@novartis.com	jeannie.neufeld@novartis.com

SOURCE Novartis Pharmaceuticals Corporation
