Novartis receives FDA approval for Cosentyx® label update to include moderate to severe scalp psoriasis

Feb 08, 2018

- - US label updated to include Cosentyx® (secukinumab) data in moderate to severe scalp psoriasis - one of the difficult-to-treat types of psoriasis(1,2)
- - Approximately half of all 125 million patients with psoriasis may suffer from scalp psoriasis, which can have an impact on patients' quality of life(2-4)
- - This follows a similar European label update in June 2017(5)

EAST HANOVER, N.J., Feb. 8, 2018 /PRNewswire/ -- Novartis announced today that the US Food and Drug Administration (FDA) has approved a label update for Cosentyx® (secukinumab), the first interleukin-17A (IL-17A) antagonist approved to treat moderate to severe plaque psoriasis.[1] The updated label includes Cosentyx data in moderate to severe scalp psoriasis – one of the difficult-to-treat forms of the disease, which affects approximately half of all psoriasis patients.[1-3] The label update is effective in the US immediately, and is based on the proven efficacy and consistent safety profile of Cosentyx from a dedicated Phase III scalp psoriasis trial.[6]

The updated label for Cosentyx in scalp psoriasis addresses an important unmet need. Scalp psoriasis can be challenging to treat with topical agents or phototherapy due to the presence of hair and other factors.[2] Approximately half of all 125 million patients with psoriasis may suffer from scalp psoriasis.[2,4]

"This is an important label update for Cosentyx, the first IL-17A inhibitor approved for moderate to severe plaque psoriasis. It confirms the additional value Cosentyx offers to patients who seek a treatment effective in various areas of the body," said Eric Hughes, Global Development Unit Head, Immunology & Dermatology. "We're proud to expand treatment possibilities of Cosentyx for an even greater number of patients."

Cosentyx is currently the only fully human IL-17A antagonist to demonstrate efficacy and safety in a dedicated Phase IIIb study of scalp psoriasis.[6] The label update is based on 12-week primary endpoint results from the US study of moderate to severe scalp psoriasis patients where Cosentyx (300 mg) demonstrated superior efficacy compared to placebo.[1,6]

Cosentyx, in a separate study, has demonstrated sustained long-term efficacy, as well as a safety profile consistent with that seen in pivotal trials.[7] To date, more than 125,000 patients worldwide have been prescribed Cosentyx in the post-marketing setting across all indications since launch.[8]

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).[1] By specifically targeting IL-17A, Cosentyx addresses an important cytokine involved in the development of psoriasis.[1,9] IL-17A plays a significant role in the pathogenesis of plaque psoriasis, PsA and AS.[1,9-11]

Inhibiting IL-17A is important as up to 30% of patients with psoriasis may have PsA.[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.[7,13] 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.[6,14,15]

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.[5] 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).[1]

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 SCALP study[1,6]
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 and 3, then every four 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 switched to Cosentyx 300 mg at weeks 12, 13, 14, 15, 16 and 20 (study completion - 24 weeks). The primary endpoint was the proportion of patients who achieved PSSI 90 response at Week 12. The key secondary objective was Investigator's Global Assessment modified 2011 (IGA) 0 (clear) or 1 (almost clear) response (for the scalp only) at week 12. The proportion of patients achieving an IGA scalp only score of 0 or 1 (clear or almost clear) were 56.9% and 5.9% for Cosentyx and the placebo groups, respectively.

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 build-up of dead skin cells.[17]

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.[17] Up to 30% of patients with psoriasis may have PsA.[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.[18] Psoriasis is also associated with other serious health conditions, such as diabetes, heart disease and depression.[17]

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 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; global trends toward health care cost containment, including government, payor and general public pricing and reimbursement pressures; our ability to obtain or maintain proprietary intellectual property protection; the particular prescribing preferences of physicians and patients; general political and economic conditions; safety, quality or manufacturing issues; potential or actual data security and data privacy breaches, or disruptions of our information technology systems, 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 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.

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

References

1. Cosentyx [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; 2018.
2. Crowley JJ. Nail, Scalp, and Palmoplantar Psoriasis. Biologic and Systemic Agents in Dermatology. 2018; 160-174.
3. National Psoriasis Foundation. Scalp Psoriasis. psoriasis.org. https://www.psoriasis.org/about-psoriasis/specific-locations/scalp. Accessed January 29, 2017.
4. Profile of Psoriasis. International Federation of Psoriasis Associations. http://www.worldpsoriasisday.com/web/page.aspx?refid=114. Published March 1, 2016. Accessed January 2, 2018.
5. European Medicines Agency. Cosentyx Summary of Product Characteristics. http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medic…. Updated July 17, 2017. Accessed January 2018.
6. Bagel J, Duffin KC, Moore A, et al. The effect of secukinumab on moderate-to-severe scalp psoriasis: Results of a 24-week, randomized, double-blind, placebo-controlled phase 3b study. J Am Acad Dermatol. 2017;77:667-674.
7. Bissonnette R, Luger T, Thaçi D, et al. Secukinumab demonstrates high sustained efficacy and a favorable safety profile through 5 years of treatment in moderate to severe psoriasis. EPoster presented at 26th EADV Congress; September 13-17, 2017, Geneva, Switzerland. Poster #P2223.

8. Data on File. Number of Patients Prescribed Cosentyx. Novartis Pharmaceuticals Corp; Nov. 2017.
9. Zeichner J, Armstrong A. The Role of IL-17 in the Pathogenesis and Treatment of Psoriasis. J Clin Aesthetic Dermatol. 2016 9(6 Suppl 1):S3–S6 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5395242/. Accessed January 2, 2018.
10. Barker J, Kaplan DH, Nestle FO, Psoriasis. N Engl J Med. 2009;361:496-509. http://www.nejm.org/doi/full/10.1056/NEJMra0804595#t=article. Accessed January 2, 2018.
11. Girolomoni G, Mrowietz U, Paul C. Psoriasis: rationale for targeting interleukin-17. Br J Dermatol. 2012;167:717-24.
12. Mease PJ, Gladman DD, Papp KA, et al. Prevalence of rheumatologist-diagnosed psoriatic arthritis in patients with psoriasis in European/North American dermatology clinics. J Am Acad Dermatol. 2013;69(5): 729-735.
13. Lacour JP, Paul C, Jazayeri S, et al. Secukinumab administration by autoinjector maintains reduction of plaque psoriasis severity over 52 weeks: results of the randomized controlled JUNCTURE trial. J Eur Acad Dermatol Venereol. 2017;31(5):847-856.
14. Study of Safety, Tolerability, and Efficacy of Secukinumab in Subjects With Moderate to Severe Palmoplantar Psoriasis. ClinicalTrials.gov.https://clinicaltrials.gov/ct2/show/NCT01806597?term=secukinumab&cond=palmoplantar%2Bpsoriasis&cntry1=NA%3AUS&rank=1. Published March 7, 2013. Accessed January 2, 2018.
15. Study of Safety, Tolerability, and Efficacy of Secukinumab in Subjects With Moderate to Severe Nail Psoriasis.ClinicalTrials.gov. https://clinicaltrials.gov/ct2/show/NCT01807520?term=secukinumab&draw=4&rank=13. Published March 8, 2013. Accessed January 2, 2018.
16. Pharmaceuticals and Medical Devices Agency. Review Report. Pharmaceuticals and Medical Devices Agency http://www.pmda.go.jp/files/000216877.pdf. Published November 12, 2015. Accessed January 2, 2018.
17. Global Report on Psoriasis. World Health Organization. http://apps.who.int/iris/bitstream/10665/204417/1/9789241565189_eng.pdf. Published 2016. Accessed January 2, 2018.
18. 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.

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

Novartis Investor Relations

Central investor relations line: +41 61 324 7944
E-mail: investor.relations@novartis.com

Central		North America	
Samir Shah	+41 61 324 7944	Richard Pulik	+1 212 830 2448
Pierre-Michel Bringer	+41 61 324 1065	Cory Twining	+1 212 830 2417
Thomas Hungerbuehler	+41 61 324 8425		
Isabella Zinck	+41 61 324 7188		

SOURCE Novartis
