Novartis new data reinforces superiority of Cosentyx® versus Stelara® in achieving skin clearance for psoriasis patients

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- -- Results from CLARITY study show Cosentyx® (secukinumab) was significantly more effective than Stelara® (ustekinumab) in delivering clear and almost clear skin at 12 weeks and at 16 weeks(1)
- -- Data support findings from the CLEAR study, which found Cosentyx was superior to Stelara® in achieving sustained skin clearance (PASI 90) at 52 weeks(2)
- -- Cosentyx is the first and only fully human interleukin-17A (IL-17A) antagonist that showed sustained skin clearance rates at 5 years in patients from a psoriasis Phase III study(3)

EAST HANOVER, N.J., Jan. 16, 2018 /PRNewswire/ -- Novartis announced today results from the head-to-head CLARITY study demonstrating the superiority of Cosentyx® (secukinumab) compared to Stelara® (ustekinumab) in delivering clear and almost clear skin in adults with moderate to severe plaque psoriasis at 12 weeks. The study results show 66.5% and 72.3% of patients treated with Cosentyx ($p < 0.0001$) achieved both co-primary endpoints PASI 90 and IGA mod 2011 0/1, respectively, compared to 47.9% and 55.4% of patients, respectively, treated with Stelara® ($p < 0.0001$).[1] At Week 12, patients receiving Cosentyx had significantly greater PASI 100 responses (key secondary objective) compared to those taking Stelara® (38.1% vs. 20.1%, respectively; $p < 0.0001$). The study findings, which support previously presented data from the CLEAR study demonstrating the superiority of Cosentyx to Stelara® in achieving sustained skin clearance (PASI 90 response rates) at 52 weeks, were presented as a poster on January 16th at the Winter Clinical Dermatology Conference in Hawaii.[2]

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.[4-7] All key secondary endpoints in the CLARITY study were met. At Week 4, PASI 75 response rates were significantly superior with Cosentyx compared to Stelara® (40.2% vs. 16.3%; $p < 0.0001$). At Week 16, Cosentyx demonstrated significantly superior response rates compared to Stelara® for PASI 75 (91.7% vs. 79.8%; $p < 0.0001$), PASI 90 (76.6% vs. 54.2%; $p < 0.0001$), PASI 100 (45.3% vs. 26.7%; $p < 0.0001$), and IGA mod 2011 0/1 (78.6% vs. 59.1%; $p < 0.0001$).[1]

"These data add to the robust body of evidence supporting the use of Cosentyx to treat moderate to severe plaque psoriasis," said Mark Lebwohl, MD and Chairman of the Waldman Department of Dermatology at the Icahn School of Medicine at Mount Sinai Hospital in New York City. "With these findings, clinicians can have even greater confidence including Cosentyx in their treatment plans."

The safety profile of Cosentyx was in line with the known safety profile.[1]

To date, more than 125,000 patients worldwide have been prescribed Cosentyx in the post-marketing setting across all indications.[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).[9] By specifically targeting IL-17A, Cosentyx addresses an important cytokine involved in the development of psoriasis.[9,10] IL-17A plays a significant role in the pathogenesis of plaque psoriasis, PsA and AS.[9-12] Inhibiting IL-17A is important as up to 30% of patients with psoriasis may have PsA.[13]

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.[3,14] 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).[9]

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 CLARITY study[1,20]
CLARITY (NCT02826603) is a 52-week, multicenter, randomized, double-blind study to demonstrate the superiority of Cosentyx (secukinumab) 300 mg vs. Stelara® (ustekinumab) in moderate to severe plaque psoriasis patients. Co-primary endpoints were 90% or more improvement from Baseline Psoriasis Area and Severity Index (PASI 90) and Investigator's Global Assessment (IGA) mod 2011 0/1 (clear or almost clear) response rates at Week 12. Key secondary objectives included demonstrating superiority of secukinumab vs. ustekinumab with respect to PASI 75 at Week 4; PASI 75 and 100 at Week 12; PASI 75, 90, 100 and IGA mod 2011 0/1 at Week 16. Missing values were handled by multiple imputation.

Patients were randomized 1:1 to receive subcutaneous secukinumab 300 mg (n = 550) at Baseline, Weeks 1, 2 and 3, then every 4 weeks from Week 4 to 48, or ustekinumab (n = 552) 45 mg or 90 mg subcutaneously (depending upon body weight at randomization), according to approved label.

About psoriasis
Psoriasis is a common, non-contagious, auto-immune disease that affects more than 125 million people worldwide.[21] 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.[22]

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.[22] Up to 30% of patients with psoriasis may have PsA.[13] PsA is a condition in which the joints are also affected, causing debilitating symptoms including pain, stiffness and for some people, irreversible joint damage.[23] Psoriasis is also associated with other serious health conditions, such as diabetes, heart disease and depression.[22]

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; 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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Novartis Media Relations
Central media line: +41 61 324 2200
E-mail: media.relations@novartis.com

Eric Althoff

Novartis Global Media Relations

+41 61 324 7999 (direct)

+41 79 593 4202 (mobile)

eric.althoff@novartis.com

Jeannie Neufeld

Novartis Pharmaceuticals Corporation

+1 862 778 2104 (direct)

+1 201 650 2728 (mobile)

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		

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23. mailto:jeannie.neufeld@novartis.com
24. mailto:investor.relations@novartis.com