# Novartis presents new Cosentyx® data demonstrating long-term response and safety in ankylosing spondylitis

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- New data show that 73% of ankylosing spondylitis (AS) patients taking Cosentyx® (secukinumab) achieved improvement in AS signs and symptoms at four years, with sustained ASAS response rates[1]
- AS is a painful and often progressively debilitating arthritic disease that causes inflammation of the spinal joints that can result in irreversible damage[2,3,4]
- Cosentyx is the first and only IL-17A antagonist to show sustained response in terms of improvements in signs and symptoms of AS[1,5]

EAST HANOVER, N.J., Oct. 22, 2018 /PRNewswire/ --Novartis announced today new data showing Cosentyx® (secukinumab) delivered sustained ASAS response rates, a measure to evaluate improvements in the signs and symptoms of ankylosing spondylitis (AS), out to four years.[1] The data, from the MEASURE 2 study, show that ASAS20 response was achieved in a high proportion (73.3%) of AS patients treated with Cosentyx 150 mg at Year 4.[1] The long-term four year data were presented during the 2018 American College of Rheumatology/Association of Rheumatology Health Professionals (ACR/ARHP) Annual Meeting in Chicago.

AS is a form of arthritis that causes inflammation of the spinal joints that can lead to severe, chronic pain and discomfort.[2] AS is a progressive disease which can cause permanent damage over time.[3,4] In the U.S., it is estimated up to 1.5 million people are living with the disease.[6]

"Long-term four year data are an important milestone for showing long-term safety and efficacy in patients with AS," said Marcia Kayath, Head U.S. Clinical Development and Medical Affairs, Novartis. "The data presented at ACR/ARHP add to the robust body of evidence for Cosentyx as a consistent, and now long-term, treatment option for patients suffering with AS."

Data presented from 106 patients treated with Cosentyx 150 mg or those initially treated with placebo who switched to Cosentyx 150 mg for four years, showed 73.3% achieved at least a 20% improvement in AS symptoms at four years, as measured by the Assessment of Spondyloarthritis International Society response criteria (ASAS20), a standard tool used to assess clinical improvement in AS.[1] Additionally, more than half (60.5%) achieved an ASAS40 response at Week 208.[1]

These data add to the body of evidence for Cosentyx, the first interleukin-17A antagonist, to demonstrate efficacy in controlled Phase III AS studies.[1,5]

The safety profile was consistent with that observed in previous studies and similar across arms, with no new adverse events (AEs) identified.[1] Upper respiratory tract infection and nasopharyngitis were the most frequently reported AEs with any secukinumab dose, with exposure-adjusted incidence rates (EAIR; per 100 patient-years) of 23.7 and 10.2, respectively.[1]

Cosentyx is the first and only IL-17A antagonist to show sustained ASAS response rates, a measure of improvements in signs and symptoms of AS.[1,5] More than 160,000 patients have been prescribed Cosentyx across all indications worldwide since launch.[7]

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.[5]

Cosentyx is approved in more than 75 countries, which includes the European Union countries and the U.S., across all indications – ankylosing spondylitis (AS), psoriatic arthritis and psoriasis. Cosentyx is approved for the treatment of AS in 85 countries, including the U.S., Canada, the EU and Australia.

About ankylosing spondylitis (AS)
AS is a debilitating auto-inflammatory disease often overlooked due to the difficulty in diagnosis in the early stages.[2,4] It's a form of arthritis that typically begins in young adulthood and primarily affects the spine by creating inflammation in the spinal joints (or vertebrae), but can also affect other areas, such as the sacroiliac joints.[2,3,4] It can lead to severe, chronic pain and discomfort and in the more advanced cases, this inflammation can cause new bone formation where sections of the spine or sacroiliac joints fuse together.[2,3,4]

About the MEASURE 2 data[1]
The efficacy results presented at ACR/ARHP 2018 were analyzed using the as observed methodology.

In the study, participants (N = 219) were randomized to receive subcutaneous secukinumab 150 mg, 75 mg or placebo at baseline, Weeks (Wks) 1, 2 and 3 and every 4 wks from Wk 4. At Wk 16, placebo-treated patients were re-randomized to receive secukinumab 150 or 75 mg every 4 weeks. Efficacy results are reported for patients initially randomized to secukinumab 150 mg and those who switched from placebo to secukinumab 150 mg at Wk 16 (N = 106). A total of 39 patients increased their dose from 75 mg to 150 mg starting at Wk 140; these patients were analyzed in the group they were originally assigned to.

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.

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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
Novartis is reimagining medicine to improve and extend people's lives. As a leading global medicines company, we use innovative science and digital technologies to create transformative treatments in areas of great medical need. In our quest to find new medicines, we consistently rank among the world's top companies investing in research and development. Novartis products reach nearly 1 billion people globally and we are finding innovative ways to expand access to our latest treatments. About 125 000 people of more than 140 nationalities work at Novartis around the world. Novartis Pharmaceuticals Corporation, a US affiliate of Novartis, is located in East Hanover, NJ.

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