

NOVARTIS AG
Form 6-K
January 19, 2016

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 6-K

REPORT OF FOREIGN PRIVATE ISSUER

PURSUANT TO RULE 13a-16 or 15d-16 OF

THE SECURITIES EXCHANGE ACT OF 1934

Report on Form 6-K dated January 15, 2016

(Commission File No. 1-15024)

Novartis AG

(Name of Registrant)

Lichtstrasse 35

4056 Basel

Switzerland

(Address of Principal Executive Offices)

Edgar Filing: NOVARTIS AG - Form 6-K

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F:

Form 20-F: **Form 40-F:**

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):

Yes: **No:**

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7):

Yes: **No:**

Indicate by check mark whether the registrant by furnishing the information contained in this form is also thereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934.

Yes: **No:**

Novartis receives two new FDA approvals for Cosentyx to treat patients with ankylosing spondylitis and psoriatic arthritis in the US

- *Cosentyx is the first and only interleukin-17A (IL-17A) inhibitor approved for adult patients with ankylosing spondylitis (AS) and psoriatic arthritis (PsA)*
- *FDA approval for Cosentyx is based on efficacy and safety outcomes shown across four Phase III studies, including over 1,500 patients with either AS or PsA[1]*
- *In studies, Cosentyx met the primary endpoints showing statistically significant improvements versus placebo in the signs and symptoms of AS and PsA[1]*

The digital press release with multimedia content can be accessed here:

Basel, January 15, 2016 - Novartis announced today that the US Food and Drug Administration (FDA) has approved Cosentyx® (secukinumab) for the treatment of two new indications - adults with active ankylosing spondylitis (AS) and active psoriatic arthritis (PsA). AS and PsA are both life-long, painful and debilitating inflammatory diseases that affect the joints and/or spine. If not treated effectively, both conditions can lead to irreversible joint and/or spinal bone damage caused by years of inflammation[2],[3].

Cosentyx is the first in a new class of medicines called interleukin-17A (IL-17A) inhibitors to treat both AS and PsA. The two new indications follow the earlier FDA approval for Cosentyx in January 2015 to treat adult patients with moderate-to-severe plaque psoriasis, and European approval for AS and PsA in November 2015.

"These new approvals are a potential turning point for people living with ankylosing spondylitis and psoriatic arthritis in the US, as Cosentyx provides a novel and targeted way of inhibiting the inflammatory process of these two conditions," said David Epstein, Division Head, Novartis Pharmaceuticals. "The results from our studies have shown that the majority of patients treated with Cosentyx have a significant reduction in their signs and symptoms of ankylosing spondylitis and psoriatic arthritis, and show major improvements in their ability to undertake everyday activities."

In the US, it is estimated that up to 0.5% of the population have AS, and up to 1% live with PsA[4],[5]. If not treated effectively, these conditions can lead to irreversible damage to the spine and joints, causing life-long pain and disability that can have a negative impact on even simple tasks in life[2],[3]. There is an urgent unmet need for new medicines for these conditions. Currently many patients are dissatisfied with their treatments, and up to 40% do not respond sufficiently to anti-tumor necrosis factor-alpha (anti-TNFs) therapy[6].

The approvals are based on the efficacy and safety outcomes from four placebo-controlled Phase III studies, which included over 1,500 adult patients with AS or PsA that were biologic treatment naïve or had an inadequate response / were intolerant to anti-TNFs[1]. In the studies, Cosentyx met the primary endpoints achieving statistically significant improvements versus placebo in the signs and symptoms of AS and PsA, as measured by at least a 20% improvement in the Assessment of Spondyloarthritis International Society criteria (ASAS 20*) at Week 16, and a 20% reduction in the American College of Rheumatology (ACR 20) response criteria at Week 24, respectively[1]. ASAS 20 and ACR 20 are standard tools used to assess clinical improvement in AS and PsA.

More than 9,600 patients have been treated with Cosentyx in clinical trials across multiple indications, and over 15,000 patients with psoriasis have already been treated in the post-marketing setting[7]. The safety profile of Cosentyx was shown to be consistent with that seen in clinical trials across multiple indications[7],[8-10].

About ankylosing spondylitis (AS)

- Ankylosing spondylitis (AS) is painful and often progressively debilitating, caused by spine inflammation that can result in irreversible damage[11].
- Up to 70% of patients who go on to develop severe AS will form spinal fusions (where the bones grow together) over 10 to 15 years, which significantly reduces mobility[12].
- People aged 25 or older, particularly males, are affected most often[13].
- Family members of those with AS are at higher risk[13].
- Approximately 20-40% of patients do not respond well to standard of care biologic medicines, and there are few therapeutic options available to those people[6].

About psoriatic arthritis (PsA)

- Psoriatic arthritis (PsA) is an inflammatory condition of the joints and is often associated with a scaly skin condition called psoriasis[3].
- Symptoms include joint pain and stiffness, skin and nail psoriasis, swollen toes and fingers and persistent painful enthesitis (inflammation of the sites where tendons or ligaments insert into the bone)[3].
- Up to 40% of people can suffer from joint destruction and permanent physical deformity[3],[14].
- Up to 15% of people with psoriasis may have undiagnosed PsA[15].
- As many as 30% of patients with psoriasis will have PsA[16].
- New medicines are needed as many patients do not respond to, or tolerate, current therapies and approximately 45% of PsA patients are dissatisfied with treatments[17].

About Cosentyx AS and PsA clinical trial programs

Pivotal Phase III studies in the Cosentyx clinical trial program, that provided key data for the submission, were MEASURE 1 and MEASURE 2 involving 590 patients with AS, and FUTURE 1 and FUTURE 2 including 1,003 patients with PsA. Data from these pivotal trials were published in the *New England Journal of Medicine* and *The Lancet*. These are multi-center, randomized, placebo-controlled studies designed to evaluate the efficacy and safety of Cosentyx in AS and PsA. Additional follow-up of patients from these trials is still ongoing[8],[9],[18]. Novartis

continues to investigate Cosentyx for its potential role in preventing radiographic progression of spinal and joint structural damage in AS and PsA patients respectively, as shown by x-ray.

About Cosentyx and interleukin-17A (IL-17A)

Cosentyx is a fully human monoclonal antibody that selectively neutralizes circulating IL-17A[19]. Research suggests that IL-17A may play an important role in driving the body's immune response in psoriasis, PsA and AS[20].

Cosentyx is the first IL-17A inhibitor with positive Phase III results for the treatment of PsA and AS[8],[9],[18], and is now approved in Europe and the US for these conditions. Cosentyx is approved for the treatment of AS and PsA in Ecuador and Bangladesh, and for the treatment of PsA in Japan.

In addition, over 50 countries have also approved Cosentyx 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 the only first-line biologic approved for the systemic treatment of moderate-to-severe plaque psoriasis in adult patients. In the US, Cosentyx is also approved as a treatment for moderate-to-severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy (light therapy).

Disclaimer

The foregoing release contains forward-looking statements that can be identified by words such as "potential," "can," "may," "will," "suggests," 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 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 issues; unexpected manufacturing or quality 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 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 2014, the Group achieved net sales of USD 58.0 billion, while R&D throughout the Group amounted to approximately USD 9.9 billion (USD 9.6 billion excluding impairment and amortization charges). Novartis Group companies employ approximately 120,000 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>.

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

References

[1] Cosentyx (secukinumab) [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corp, 2015.

- [2] Schett et al. Structural damage in rheumatoid arthritis, psoriatic arthritis, and ankylosing spondylitis: traditional views, novel insights gained from TNF blockade, and concepts for the future. *Arthritis Res Ther.* 2011; 13: S4.
- [3] 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.
- [4] Reveille JD. Epidemiology of spondyloarthritis in North America. *Am. J. Med.Sci.* 2011; 341(4):284-286.
- [5] Husni, ME. Psoriatic arthritis. Cleveland Clinic. August 2010. Available at <http://www.clevelandclinicmeded.com/medicalpubs/diseasemanagement/rheumatology/psoriatic-arthritis/>. Last accessed December 10, 2015.
- [6] Dougados M, Baeten D. Spondyloarthritis. *The Lancet.* 2011; 377:2127-37.
- [7] Novartis data on file, November 2015.
- [8] Baeten D, Sieper J, Braun J, et al. Secukinumab, interleukin-17A inhibition in ankylosing spondylitis. *N Engl J Med.* 2015; 373:2534-48.
- [9] Mease, PJ, McInnes, IB, Kirkham, B, et al. Secukinumab, a human anti-interleukin-17A monoclonal antibody, in patients with psoriatic arthritis (FUTURE 2): a randomised, double-blind, placebo-controlled, phase 3 trial. *The Lancet.* 2015; 386(9999):1137-1146.

[10] Mease P, McInnes IB, Kirkham B, et al. Secukinumab provides sustained improvements in psoriatic arthritis: 2-year efficacy and safety results from a phase 3 randomized, double-blind, placebo-controlled trial. Presented at the 2015 ACR/ARHP Annual Meeting, San Francisco, USA, November 9. Oral presentation number 2148.

[11] Spondylitis Association of America website. Ankylosing spondylitis. Available at <https://www.spondylitis.org/Learn-About-Spondyloarthritis/Ankylosing-Spondylitis>. Last accessed December 9, 2015.

[12] Barkham N, Kong K O, Tennant A, et al. The unmet need for anti-tumour necrosis factor (anti-TNF) therapy in ankylosing spondylitis. *Rheumatology*. 2005; 44:1277-1281.

[13] Dean LE, Jones GT, MacDonald AG, et al. Global prevalence of ankylosing spondylitis. *Rheumatology*. 2014; 53(4):650-7.

[14] Hammadi A. Psoriatic arthritis: prognosis. *Medscape*, December 11, 2014. Available at <http://emedicine.medscape.com/article/2196539-overview#a6>. Last accessed October 26, 2015.

[15] Villani AP, Rouzaud M, Sevrain M, et al. Prevalence of undiagnosed psoriatic arthritis among psoriasis patients: systematic review and meta-analysis. *J Am Acad Dermatol*. 2015; 73(2):242-8.

[16] Gladman DD, Antoni C, Mease P, et al. Psoriatic arthritis: epidemiology, clinical features, course, and outcome. *Ann Rheum Dis*. 2005; 64:14-17.

[17] Armstrong AW, et al. Undertreatment, treatment trends, and treatment dissatisfaction among patients with psoriasis and psoriatic arthritis in the United States: findings from the National Psoriasis Foundation surveys, 2003-2011. *October 2013*;149(10):1180-5.

[18] Mease PJ, McInnes IB, Kirkham B, et al. Secukinumab inhibition of interleukin-17A in patients with psoriatic arthritis. *N Engl J Med*. 2015; 373(14):1329-39.

[19] Kirkham BW, Kavanaugh A, Reich K. Interleukin-17A: a unique pathway in immune-mediated diseases: psoriasis, psoriatic arthritis and rheumatoid arthritis. *Immunology*. 2014; 141:133-142.

[20] Ivanov S, Linden A. Interleukin-17 as a drug target in human disease. *Trends Pharmacol Sci*. 2009; 30(2):95-103.

* ASAS 20 is improvement of $\geq 20\%$ and ≥ 1 unit on a 10-unit scale in at least three of the four core ASAS domains, with no worsening of $\geq 20\%$ and ≥ 1 unit in the fourth.

###

Novartis Media Relations

Central media line: +41 61 324 2200

Eric Althoff

Novartis Global Media Relations
+41 61 324 7999 (direct)
+41 79 593 4202 (mobile)
eric.althoff@novartis.com

Bhavin Vaid

Novartis Global Pharma Communications
+41 61 324 8175 (direct)
+41 79 792 7510 (mobile)
bhavin.vaid@novartis.com

e-mail: media.relations@novartis.com

For Novartis multimedia content, please visit www.thenewsmarket.com/Novartis

For questions about the site or required registration, please contact: journalisthelp@thenewsmarket.com.

Novartis Investor Relations

Central phone: +41 61 324 7944

Samir Shah +41 61 324 7944 **North America:**

Pierre-Michel Bringer +41 61 324 1065 Richard Pulik +1 212 830 2448

Thomas Hungerbuehler +41 61 324 8425 Sloan Pavsner +1 212 830 2417

Isabella Zinck +41 61 324 7188

e-mail: investor.relations@novartis.com e-mail:
investor.relations@novartis.com

Media release (PDF): <http://hugin.info/134323/R/1979259/725048.pdf>

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Novartis AG

Date: January 15, 2016 By: /s/ PAUL PENEPEPENT
Name: Paul Penepent
Head Group Financial
Title: Reporting and
Accounting