

NOVARTIS AG
Form 6-K
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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 October 23, 2015

(Commission File No. 1-15024)

Novartis AG

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

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Yes: **No:**

Novartis receives positive CHMP opinion for the first IL-17A inhibitor Cosentyx(TM) to treat ankylosing spondylitis and psoriatic arthritis

Cosentyx (secukinumab) is recommended for approval in Europe for the treatment of ankylosing spondylitis (AS) and psoriatic arthritis (PsA) patients

Cosentyx demonstrated rapid onset of action and long-term sustainability in patients with and without prior treatment using anti-tumor-necrosis-factor (anti-TNF) therapy[1],[2]

Urgent need for new medicines exists, as significant numbers of AS and PsA patients are dissatisfied with current treatments[3]-[6]

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

<http://multimediacapsule.thomsonone.com/novartis/novartis-receives-positive-chmp-opinion-for-the-first-il-17a-inhibitor-to-tr>

Basel, October 23, 2015 - Novartis announced today that the Committee for Medicinal Products for Human Use (CHMP) has recommended the approval of Cosentyx^(TM) (secukinumab) in Europe to treat ankylosing spondylitis (AS) and psoriatic arthritis (PsA) patients. Following two separate regulatory submissions, Cosentyx is now recommended for the treatment of active AS in adults who have responded inadequately to conventional therapy, such as non-steroidal anti-inflammatory drugs (NSAIDs), and for the treatment of active PsA in adult patients alone or in combination with methotrexate (MTX) when the response to previous disease modifying anti-rheumatic drug (DMARD) therapy has been inadequate.

Cosentyx is the first of a new class of medicines called interleukin-17A (IL-17A) inhibitors to be recommended for AS and PsA - conditions that affect around five million people in Europe[7],[8],[9]. Both are 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 damage caused by years of inflammation[3]-[5].

"Novartis is pleased to be so close to bringing this life-changing medicine to people living with ankylosing spondylitis and psoriatic arthritis who are struggling to find the right treatment to control their symptoms," said David Epstein, Division Head, Novartis Pharmaceuticals. "With Cosentyx, we have seen major and rapid reductions in the signs and symptoms of disease, including pain, disease progression and joint damage, paving the way for a potential new standard of care."

New treatment options with an alternative way of working are needed for both conditions as many patients do not achieve an adequate response from standard treatments, such as DMARDs, NSAIDs or anti-TNF therapies. For example, with the current biologic standard of care - anti-TNFs - up to 45% of PsA patients and up to 40% of AS patients are dissatisfied with, do not respond to or do not tolerate their treatment[3]-[6].

Cosentyx Phase III studies have consistently demonstrated significant improvements in the signs and symptoms of AS and PsA. Clinical improvements were seen as early as Week 3 and through to Week 52, with benefits reported across the spectrum of patients who have either never taken or who have had prior treatment with anti-TNF therapies[1],[2].

The safety profile of Cosentyx was shown to be consistent to that reported in clinical trials across multiple indications involving more than 9,600 patients[10].

The European Commission reviews the recommendations of the CHMP who then provide their final decision on approval, usually two months or earlier, following CHMP opinion. This is applicable to all European Union and European Economic Area countries. Cosentyx has been approved for the treatment of PsA in Japan since December 2014 and has received approval in 49 countries worldwide for the treatment of moderate-to-severe plaque psoriasis.

About the CHMP recommendation

For patients with AS and PsA, the recommended dose is Cosentyx 150 mg by subcutaneous injection with initial dosing at Weeks 0, 1, 2 and 3, followed by monthly maintenance dosing starting at Week 4. For PsA patients with concomitant moderate-to-severe plaque psoriasis, or who are anti-TNF inadequate responders, the recommended dose is Cosentyx 300 mg.

Pivotal Phase III studies in the Cosentyx clinical trial program, that provided key data for the CHMP submission, were MEASURE 1 and MEASURE 2 in AS, and FUTURE 1 and FUTURE 2 in PsA. These are all ongoing multi-center, randomized, placebo-controlled studies that have been designed to evaluate the efficacy and safety of Cosentyx in AS and PsA[1],[2],[11],[12].

About ankylosing spondylitis (AS)

AS is a painful, progressively debilitating condition caused by inflammation of the spine. Up to 70% of patients with severe AS develop spinal fusion (where the bones grow together) over 10 to 15 years, which significantly reduces mobility and quality of life[13]. AS occurs in approximately 1.78 million people in Europe[6],[7] and typically affects young men and women aged 25 or older[14].

About psoriatic arthritis (PsA)

PsA, closely associated with psoriasis, is part of a family of long-term diseases impacting joints. PsA occurs in approximately 3.1 million people in Europe[8],[9]. As many as one in four people with psoriasis may have

undiagnosed PsA[15].

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

Cosentyx is a human monoclonal antibody that selectively neutralizes circulating IL-17A[16]. Cosentyx is the first IL-17A inhibitor with positive Phase III results for the treatment of PsA and AS. Research shows that IL-17A plays an important role in driving the body's immune response in psoriasis and spondyloarthritis conditions, including PsA and AS[17]-[22].

In total, 49 countries have approved Cosentyx for the treatment of moderate-to-severe plaque psoriasis which includes the European Union and European Economic Area countries. In January 2015, Cosentyx (at a recommended dose of 300 mg in the US and EU) became the first IL-17A inhibitor approved in the EU and US for the treatment of moderate-to-severe plaque psoriasis. 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 approved as a treatment for moderate-to-severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy (light therapy). In addition, Cosentyx has been approved in Switzerland, Australia, Canada and a number of other countries for the treatment of moderate-to-severe plaque psoriasis. In Japan, Cosentyx is approved for the treatment of moderate-to-severe plaque psoriasis and also for the treatment of PsA.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by words such as "positive CHMP opinion," "recommended," "so close," "potential," "recommendations," "recommendation," 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. Sieper J, Braun J, Baraliakos X, et al. Secukinumab, a monoclonal antibody to interleukin-17A, significantly improves signs and symptoms of active ankylosing spondylitis: results of a phase 3, randomized, placebo-controlled trial with subcutaneous loading and maintenance dosing. ACR/ARHP Annual Meeting, Boston, MA, USA, 2014. Poster presentation (presentation number 536).
2. 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, No. 9999; p1137-1146.
3. Dougados M, Baeten D. Spondyloarthritis. *The Lancet*. 2011;377-2127-37.
4. Gossec L, Smolen JS, Gaujoux-Viala C, et al. European League Against Rheumatism recommendations for the management of psoriatic arthritis with pharmacological therapies. *Ann Rheum Dis*. 2012;71:4-12.
5. Menter A, Korman NJ, Elmets CA, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Section 6: guidelines of care for the treatment of psoriasis and psoriatic arthritis: case-based presentations and

- evidence-based conclusions. *J Am Acad Dermatol*. 2011;65:137-74.
6. Dean LE, Jones GT, MacDonald AG, et al. Global prevalence of ankylosing spondylitis. *Rheumatology (Oxford)*. 2014;53(4):650-7.
 7. 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. *JAMA Dermatol*. 2013 Oct;149(10):1180-5.
 8. United Nations. World Population Prospects - The 2012 Revision. Last accessed October 2015 at http://esa.un.org/unpd/wpp/Publications/Files/WPP2012_Volume-I_Comprehensive-Tables.pdf.

9. Lai-Shan Tam, Ying-Ying Leung and Edmund K. Li. Psoriatic arthritis in Asia. Last accessed October 2015 at <http://rheumatology.oxfordjournals.org/content/early/2009/08/27/rheumatology.kep230.full.pdf>.
10. Novartis data on file, September 2015.
11. Baeten D, Braun J, Baraliakos X, et al. Secukinumab, a monoclonal antibody to interleukin-17A, significantly improves signs and symptoms of active ankylosing spondylitis: results of a 52-week phase 3 randomized placebo-controlled trial with intravenous loading and subcutaneous maintenance dosing. ACR /ARHP Annual Meeting, Boston, MA, USA, 2014. Oral presentation (Abstract number 819).
- 12.. 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.
13. 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.
14. Feldtkeller E, Khan M, Van Der Heijde D, et al. Age at disease onset and diagnosis delay in HLA-B27 negative vs. Positive patients with ankylosing spondylitis. *Rheum Int*. 2003;23(2):61-66.
15. National Psoriasis Foundation. Press release: Nearly one in four people with psoriasis may have undiagnosed psoriatic arthritis according to a recent study from the National Psoriasis Foundation. Last accessed October 2015 at <https://www.psoriasis.org/page.aspx?pid=2197>.
16. Kirkham BW, Kavanaugh A, Reich K. Interleukin-17A: a unique pathway in immune-mediated diseases: psoriasis, psoriatic arthritis and rheumatoid arthritis. *Immunology*. 2014; 141:133-42.
17. Gaffen SL. Structure and signaling in the IL-17 receptor family. *Nat Rev Immunol*. 2009;9(8):556-67.
18. Ivanov S, Linden A. Interleukin-17 as a drug target in human disease. *Trends Pharmacol Sci*. 2009;30(2):95-103.
19. Kopf M, Bachmann MF, Marsland BJ. Averting inflammation by targeting the cytokine environment. *Nat Rev Drug Discov*. 2010; 9(9):703-18.
20. Onishi RM, Gaffen SL. Interleukin-17 and its target genes: mechanisms of interleukin-17 function in disease. *Immunology*. 2010;129(3):311-21.
21. Krueger J, Fretzin S, Suárez-Fariñas M, et al. IL-17A is essential for cell activation and inflammatory gene circuits in subjects with psoriasis. *J Allergy Clin Immunol*. 2012;130(1):145-154.
22. Johansen C, Usher PA, Kjellerup RB, et al. Characterization of the interleukin-17 isoforms and receptors in lesional psoriatic skin. *Brit J Dermatol*. 2009;160(2):319-24.

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Media release (PDF): <http://hugin.info/134323/R/1961015/714985.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: October 23, 2015 By: /s/ PAUL PENEPEPENT
Name: Paul Penepent
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Title: Reporting and
Accounting