

NOVARTIS AG
Form 6-K
July 08, 2013

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 July 8, 2013

(Commission File No. 1-15024)

Novartis AG

(Name of Registrant)

Lichtstrasse 35

4056 Basel

Switzerland

(Address of Principal Executive Offices)

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

Edgar Filing: NOVARTIS AG - Form 6-K

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 International AG
Novartis Global Communications
CH-4002 Basel
Switzerland

<http://www.novartis.com>

MEDIA RELEASE • COMMUNIQUE AUX MEDIAS • MEDIENMITTEILUNG

Novartis announces secukinumab (AIN457) demonstrated superiority to Enbrel® in head-to-head Phase III psoriasis study

- *FIXTURE trial of more than 1,300 moderate-to-severe plaque psoriasis patients showed superiority of secukinumab (AIN457) to Enbrel® (etanercept)*
- *All primary and secondary endpoints were met*
- *FIXTURE is a pivotal trial for registration; Regulatory submissions for secukinumab (AIN457), a therapy targeting IL-17A, are on track for the second half of 2013*

Basel, July 8, 2013 Novartis announced today top-line results from the head-to-head Phase III psoriasis study which showed the superiority of secukinumab (AIN457) in clearing skin to Enbrel®* (etanercept), an anti-tumor necrosis factor (anti-TNF) therapy. In addition, secukinumab (AIN457) met all primary and secondary endpoints.

The FIXTURE trial (the **F**ull year **I**nvestigative **eX**amination of secukinumab vs. **e**Tanercept Using 2 dosing **R**egimens to determine **E**fficacy in psoriasis) was a randomized, double-blind, double-dummy, placebo-controlled, multicenter global study of subcutaneous secukinumab (AIN457) in moderate-to-severe plaque psoriasis involving 1,307 patients. It was designed to demonstrate efficacy after 12 weeks of treatment, compared to placebo and etanercept, and to assess the safety, tolerability and long-term efficacy up to 52 weeks. Established treatment measures were used to assess the efficacy of secukinumab (AIN457) including PASI 75 (Psoriasis Area and Severity Index 75) and the Investigator's Global Assessment (IGA mod 2011), a standard tool to assess the clearing of skin after treatment.

These results showing that secukinumab (AIN457) is superior to Enbrel, a current standard-of-care therapy, are great news for people living with moderate-to-severe plaque psoriasis, said Tim Wright, Global Head of Development, Novartis Pharmaceuticals. With 40-50% of people living with moderate-to-severe plaque psoriasis dissatisfied with their current therapies, there is clearly an unmet medical need for new therapies that act faster and longer to relieve pain, itching and other symptoms.

Edgar Filing: NOVARTIS AG - Form 6-K

Full results from the secukinumab (AIN457) Phase III study program, the largest undertaken in moderate-to-severe plaque psoriasis to date, are expected to be presented at major medical congresses later this year.

Secukinumab (AIN457) is the first medicine selectively targeting IL-17A to present Phase III results. IL-17A is a central cytokine (messenger protein) in the development of psoriasis, and is found in high concentration in skin affected by the disease(1)-(3). Research shows that IL-17A plays a role in driving the body's autoimmune response in disorders such as moderate-to-severe plaque psoriasis and is a preferred target for investigational therapies(1)-(5).

In the FIXTURE study, the observed safety profile of secukinumab (AIN457) was consistent with previously reported results from Phase II studies in moderate-to-severe plaque psoriasis and no new safety concerns were identified(6),(7).

About plaque psoriasis

Approximately 2% of the world's population, or around 125 million people, are affected by plaque psoriasis(8),(9), with more than one third of these suffering from its moderate-to-severe form(10). Psoriasis is a chronic disease characterized by thick and extensive skin lesions, called plaques, known to cause itching, scaling and pain(8). This common and distressing disease is not simply a cosmetic problem – even those with very mild symptoms find their condition affects their everyday lives(11). Psoriasis is also associated with psychosocial effects and those with more severe disease are at a greater risk of death from comorbid diseases such as heart disease and diabetes(12),(13).

About the secukinumab (AIN457) clinical trial program in psoriasis

The robust secukinumab (AIN457) Phase III clinical trial program involved more than 3,300 patients in over 35 countries on five continents. Primary endpoints for four studies related to PASI 75 and IGA (IGA mod 2011) and the fifth study evaluated the proportion of patients who maintained PASI 75 after having achieved PASI 75 after 12 weeks of active treatment. The studies evaluated 150 mg and 300 mg doses of secukinumab (AIN457).

About secukinumab (AIN457)

Secukinumab (AIN457) is a fully human monoclonal antibody that selectively binds to and neutralizes IL-17A, a key pro-inflammatory cytokine(1)-(3). Proof-of-concept and Phase II studies in moderate-to-severe plaque psoriasis and arthritic conditions (psoriatic arthritis, ankylosing spondylitis and rheumatoid arthritis) have suggested that secukinumab (AIN457) may potentially provide a new mechanism of action for the successful treatment of immune-mediated diseases(6),(7),(14)-(16). The Phase III programs for these potential indications are ongoing. Results are being released this year for moderate-to-severe plaque psoriasis, and in 2014 and beyond for arthritic conditions. Phase II studies are also ongoing in other areas, including multiple sclerosis.

About Novartis in specialty dermatology

Novartis is committed to developing innovative, life-changing specialty dermatology therapies redefining treatment paradigms and transforming patient care in severe skin diseases where there are remaining high unmet medical needs. The Novartis specialty dermatology portfolio includes two unique targeted products in Phase III development, secukinumab (AIN457) for moderate-to-severe plaque psoriasis and omalizumab (Xolair®) for chronic spontaneous urticaria (CSU). There are also more than 10 compounds in early stage development for a wide range of severe skin diseases in the Novartis specialty dermatology portfolio.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as on track, expected, investigational, potentially, potential, ongoing, committed, goal, or similar expressions, or by express or implied discussions regarding potential marketing submissions or approvals for secukinumab (AIN457), potential submissions or approvals for new indications or labeling for Xolair, or regarding potential future revenues from such products. You should not place undue reliance on these statements. Such forward-looking statements reflect the current views of management regarding future events, and involve known and unknown risks, uncertainties and other factors that may cause actual results to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that secukinumab (AIN457) will be submitted or approved for sale in any market, or at any particular time. Nor can there be any guarantee that Xolair will be submitted or approved for any additional indications or labeling in any market. Neither can there be any guarantee that such products will

achieve any particular levels of revenue in the future. In particular, management's expectations regarding these products could be affected by, among other things, unexpected clinical trial results, including unexpected new clinical data and unexpected additional analysis of existing clinical data; unexpected regulatory actions or delays or government regulation generally; competition in general; government, industry and general public pricing pressures; unexpected manufacturing issues; the company's ability to obtain or maintain patent or other proprietary intellectual property protection; the impact that the foregoing factors could have on the values attributed to the Novartis Group's assets and liabilities as recorded in the Group's consolidated balance sheet, and other risks and factors referred to in Novartis AG's current Form 20-F on file with the US Securities and Exchange Commission. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those anticipated, believed, estimated or expected. 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, cost-saving generic pharmaceuticals, preventive vaccines and diagnostic tools, over-the-counter and animal health products. Novartis is the only global company with leading positions in these areas. In 2012, the Group achieved net sales of USD 56.7 billion, while R&D throughout the Group amounted to approximately USD 9.3 billion (USD 9.1 billion excluding impairment and amortization charges). Novartis Group companies employ approximately 129,000 full-time-equivalent associates and operate in more than 140 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>.

*Enbrel® is a registered trademark of Amgen Inc.

References

- (1) Gaffen SL. Structure and signaling in the IL-17 receptor family. *Nat Rev Immunol*. 2009; 9(8):556-67.
- (2) Ivanov S, Linden A. Interleukin-17 as a drug target in human disease. *Trends Pharmacol Sci*. 2009; 30(2):95-103.
- (3) Kopf M, Bachmann MF, Marsland BJ. Averting inflammation by targeting the cytokine environment. *Nat Rev Drug Discov*. 2010; 9(9):703-18.
- (4) Onishi RM, Gaffen SL. Interleukin-17 and its target genes: mechanisms of interleukin-17 function in disease. *Immunology*. 2010; 129(3):311-21.
- (5) 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.
- (6) Papp KA, Langley RG, Sigurgeirsson B, et al. Efficacy and safety of secukinumab in the treatment of moderate-to-severe plaque psoriasis: a randomized, double-blind, placebo-controlled phase II dose-ranging study. *BJD* 2013; 168, pp412-421.

Edgar Filing: NOVARTIS AG - Form 6-K

- (7) Rich PA, Sigurgeirsson B, Thaci D, et al. Secukinumab induction and maintenance therapy in moderate-to-severe plaque psoriasis: a randomized, double-blind, placebo-controlled, phase II regimen-finding study. *BJD* 2013;168: 402-411.
- (8) Nestle FO, Kaplan DH, Barker J. Psoriasis. *N Engl J Med* 2009; 361(5):496-509.
- (9) Brezinski EA, Armstrong AW. Off-Label Biologic Regimens in Psoriasis: A Systematic Review of Efficacy and Safety of Dose Escalation, Reduction, and Interrupted Biologic Therapy. *PLoS ONE*; 7(4):e33486.
- (10) Krueger JG, Koo J, Lebwohl M, et al. The impact of psoriasis on quality of life: Results for a 1998 National Psoriasis Foundation patient membership survey. *Arch Derm.* 2001; 137:280-284.
- (11) Mason AR, Mason J, Cork M et al. Topical treatments for chronic plaque psoriasis. *Cochrane Database Syst Rev.* 2009;15;(2):CD005028.
- (12) Abuabara K, Azfar RS, Shin DB, Neimann AL, Troxel AB, Gelfand JM. Cause-specific mortality in patients with severe psoriasis: a population-based cohort study in the U.K. *Br J Dermatol.* 2010 Sep;163(3):586-92
- (13) Gelfand JM, Troxel AB, Lewis JD, Kurd SK, Shin DB, Wang X, Margolis DJ, Strom BL. The risk of mortality in patients with psoriasis: results from a population-based study. *Arch Dermatol.* 2007 Dec;143(12):1493-9.

(14) Genovese MC, Durez P, Richards HB, et al. Efficacy and safety of secukinumab in patients with rheumatoid arthritis: a phase II, dose-finding, double-blind, randomised, placebo controlled study. *Ann Rheum Dis* 2013;72:863-869.

(15) Baeten D, Sieper J, Emery P, et al. The anti-il17a monoclonal antibody secukinumab (AIN457) showed good safety and efficacy in the treatment of active ankylosing spondylitis. At: EULAR 2011, The Annual European Congress of Rheumatology, 25-28 May 2011, London, UK. Abstract 0174.

(16) McInnes IB, Sieper J, Braun J, et al. Efficacy and safety of secukinumab, a fully human anti-interleukin-17A monoclonal antibody, in patients with moderate-to-severe psoriatic arthritis: a 24-week, randomised, double-blind, placebo-controlled, phase II proof-of-concept trial. *Ann Rheum Dis* 2013 Jan 29; doi:10.1136/annrheumdis-2012-202646.

###

Novartis Media Relations

Central media line: +41 61 324 2200
Eric Althoff

Miranda Duncan

Novartis Global Media Relations

Novartis Global Pharma Communications

+41 61 324 7999 (direct)

+41 61 324 2012 (direct)

+41 79 593 4202 (mobile)

+41 79 826 0599 (mobile)

eric.althoff@novartis.com

miranda.duncan@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
Pierre-Michel Bringer +41 61 324 1065
Thomas Hungerbuehler +41 61 324 8425
Isabella Zinck +41 61 324 7188

North America:
Stephen Rubino +1 862 778 8301
Jill Pozarek +1 212 830 2445
Edwin Valeriano +1 212 830 2456

e-mail: investor.relations@novartis.com

e-mail: investor.relations@novartis.com

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: July 8, 2013

By: /s/ MALCOLM B. CHEETHAM

Name: Malcolm B. Cheetham
Title: Head Group Financial
Reporting and Accounting