

NOVARTIS AG  
Form 6-K  
October 24, 2011

# 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 24 2011**

**(Commission File No. 1-15024)**

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**Novartis AG**

(Name of Registrant)

**Lichtstrasse 35**

**4056 Basel**

**Switzerland**

(Address of Principal Executive Offices)

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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: o **No: x**

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**Novartis International AG**

Novartis Global Communications

CH-4002 Basel

Switzerland

<http://www.novartis.com>

**- Investor Relations Release -**

**MEDIA RELEASE • COMMUNIQUE AUX MEDIAS • MEDIENMITTEILUNG**

**Novartis Phase II data show AIN457 provided rapid and significant relief of symptoms in up to 81% of patients with psoriasis**

- *In three Phase II trials, AIN457 provided a substantial increase in skin clearance in patients with moderate-to-severe plaque psoriasis(1)-(3)*
- *AIN457, a fully human anti-IL17A monoclonal antibody, offers a novel mechanism of action that suppresses the underlying inflammation in psoriasis(1)-(3)*
- *Approximately 2% of the world's population are affected by plaque psoriasis, a chronic disease characterized by thick, extensive skin lesions, called plaques(4),(5)*

**Basel, October 24 2011** Novartis has announced positive results from three Phase II trials showing that AIN457 (secukinumab) produced a quick and significant improvement of symptoms in patients with moderate-to-severe plaque psoriasis. The results were presented at the annual European Academy of Dermatology and Venereology (EADV) Congress, in Lisbon, Portugal.

In one study, 81% of patients receiving AIN457 150mg subcutaneously once a month experienced at least a 75% improvement of psoriasis signs and symptoms as measured by PASI (Psoriasis Area and Severity Index) vs 9% for placebo at week 12 ( $p < 0.001$ )(1). In another study, results also showed that 83% of patients who were given an intravenous starting dose of AIN457 experienced at least a 75% improvement of symptoms vs 10% for placebo(3). A third study showed that receiving AIN457 in the first month was beneficial to 55% of patients vs 2% for placebo at week 12 ( $p < 0.001$ )(2).

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These data suggest that AIN457 could potentially bring about a considerable improvement in the lives of patients with moderate-to-severe plaque psoriasis by producing a rapid response and substantial relief of symptoms, said Dr. Kim Papp, Dermatologist and Director of Research at Probity Medical Research, Waterloo, Ontario, Canada, and one of the investigators of the studies. Plaque psoriasis is a disruptive and often painful chronic immune disease and there is a critical need for new treatment options that combine long-term efficacy with a favorable safety profile.

AIN457 is a fully human, targeted monoclonal antibody that specifically and rapidly binds to and neutralizes interleukin-17A (IL-17A), an inflammatory cytokine implicated in a number of immune-mediated diseases, including psoriasis(6),(7).

We are encouraged by these positive Phase II results and look forward to receiving the results of larger-scale and longer-term Phase III studies with AIN457 which began this year, said John Hohneker, Global Head of Development for Integrated Hospital Care at Novartis. Novartis is committed to providing new treatment options for patients with moderate-to-severe plaque psoriasis, who face significant daily physical discomfort as well as the serious psychological impact of living with this disease.

Plaque psoriasis is a common hereditary, immune-mediated systemic disorder characterized by skin lesions, called plaques. Approximately 2% of the population has plaque psoriasis and 30% of these patients suffer from its moderate-to-severe form(4),(5),(8),(9). Chronic plaque psoriasis can have a profound impact on a patient's life. The skin lesions associated with plaque psoriasis are associated with significant symptoms, such as itching, scaling and pain, which ultimately impact a patient's emotional, social, occupational and physical functioning. The effects of chronic plaque psoriasis on patient's reduced health related quality of life are similar to those seen with arthritis, hypertension, heart disease, diabetes and depression(10),(11).

### **About the Studies**

The three double-blind, parallel group, placebo-controlled Phase II studies presented at EADV were designed to evaluate the safety and efficacy of AIN457 in different doses and administration regimens. The primary endpoints of the studies were PASI 75 responses at Week 12, with PASI 90 responses at Week 12 among the secondary endpoints. The primary endpoint was met for one or more of the doses (25, 75 and 150 mg, subcutaneously; 3 mg/kg, 10mg/kg and 3x10mg/kg, intravenously) and regimens (Early, Monthly and Single) studied in each trial. In all three studies, 60% of patients experienced adverse events with AIN457 in the first twelve weeks compared to 61% with placebo. Serious adverse events were reported in 3% of AIN457 patients vs 1% with placebo(1)-(3).

### **About AIN457**

AIN457 is a fully human monoclonal antibody neutralizing interleukin-17A, a key pro-inflammatory cytokine. Phase II studies in moderate-to-severe plaque psoriasis and arthritides (rheumatoid arthritis, ankylosing spondylitis and psoriatic arthritis) have suggested that AIN457 may provide a new mechanism of action for the treatment of immune-mediated diseases(1)-(3). The Phase III program for these potential indications has already commenced.

### **Disclaimer**

The foregoing release contains forward-looking statements that can be identified by terminology such as could, potentially, look forward to, committed, or similar expressions, or by express or implied discussions regarding potential future marketing approvals for AIN457, or the timing of any such approvals, or regarding potential future revenues from AIN457. 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 with AIN457 to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that AIN457 will be submitted or approved for sale in any market, or at any particular time. Nor can there be any guarantee that AIN457 will achieve any particular levels of revenue in the future. In particular, management's expectations regarding AIN457 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 healthcare solutions that address the evolving needs of patients and societies. Focused solely on healthcare, Novartis offers a diversified portfolio to best meet these needs: innovative medicines, eye care, cost-saving generic pharmaceuticals, consumer health products, preventive vaccines and diagnostic tools. Novartis is the only company with leading positions in these areas. In 2010, the Group's continuing operations achieved net sales of USD 50.6 billion, while approximately USD 9.1 billion (USD 8.1 billion excluding impairment and amortization charges) was invested in R&D throughout the Group. Headquartered in Basel, Switzerland, Novartis Group companies employ approximately 121,000 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>.

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## References

- (1) Papp K.A. et al. *Secukinumab efficacy and safety preliminary results from a phase II subcutaneous dose-ranging study in the treatment of moderate-to-severe plaque psoriasis*. Presented at: 20th Congress of the European Academy of Dermatology and Venereology; 20-24 October, 2011; Lisbon, Portugal. Oral presentation FC01.5.
- (2) Rich P.A. et al. *Secukinumab, a new fully human monoclonal anti-Interleukin-17A antibody, in the treatment of moderate-to-severe plaque psoriasis: Interim efficacy and safety data from a phase II regimen-finding trial*. Presented at: 20th Congress of the European Academy of Dermatology and Venereology; 20-24 October, 2011; Lisbon, Portugal. Oral presentation FC01.6.
- (3) Papp K.A. et al. *Secukinumab, a novel fully human antibody to interleukin-17A, in the treatment of moderate-to-severe plaque psoriasis: Efficacy and safety interim results from a phase II intravenous induction dose-ranging study*. Presented at: 20th Congress of the European Academy of Dermatology and Venereology; 20-24 October, 2011; Lisbon, Portugal. Oral presentation FC01.7.
- (4) Huerta C, Rivero E, Garcia Rodriguez LA. *Incidence and risk factors for psoriasis in the general population*. *Arch Dermatol*. 2007;143:1559-1565
- (5) National Psoriasis Foundation. About Psoriasis: Statistics. Available at: [http://www.psoriasis.org/learn\\_statistics](http://www.psoriasis.org/learn_statistics).
- (6) Leipe J, Grunke M, Dechant C, et al. *Arthritis Rheum*. 2010;62:2876-2885.
- (7) Moseley TA, Haudenschild DR, Rose L, Reddi AH. *Cytokine Growth Factor Rev*. 2003;14:155-174.
- (8) Reich K, Mrowietz U. *Treatment goals in psoriasis*. *JDDG*. 2007;5:566-574
- (9) Pandey S. *Psoriasis a chronic, non-contagious autoimmune disease: a conventional treatment*. *Int J Pharmaceutical Sciences Review and Research*. 2010;1:61-67.
- (10) Sampogna F, Chren MM, Melchi CF, Pasquini P, Tabolli S, Abeni D (February 2006). *Age, gender, quality of life and psychological distress in patients hospitalized with psoriasis*. *Br. J. Dermatol*. 154 (2): 325-331.
- (11) Rapp SR, Feldman SR, Exum ML, et al (1999). *Psoriasis causes as much disability as other major medical diseases*. *J Am Acad Dermatol*; 41:401-7.

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## Novartis Media Relations

**Central media line :** +41 61 324 2200  
**Eric Althoff**

Novartis Global Media Relations

+41 61 324 7999 (direct)

**Rute Frazao Marques**

Novartis Global Pharma Communications

+41 61 696 8491 (direct)

## Edgar Filing: NOVARTIS AG - Form 6-K

+41 79 593 4202 (mobile)

+41 79 701 2009 (mobile)

eric.althoff@novartis.com

rutefrazao.marques@novartis.com

e-mail: media.relations@novartis.com

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### Novartis Investor Relations

**Central phone:**

Susanne Schaffert

Pierre-Michel Bringer

Thomas Hungerbuehler

Isabella Zinck

+41 61 324 7944

+41 61 324 7944

+41 61 324 1065

+41 61 324 8425

+41 61 324 7188

**North America:**

Richard Jarvis

Jill Pozarek

Edwin Valeriano

+1 212 830 2433

+1 212 830 2445

+1 212 830 2456

e-mail: [investor.relations@novartis.com](mailto:investor.relations@novartis.com)

e-mail: [investor.relations@novartis.com](mailto: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: October 24, 2011

By: /s/ MALCOLM B. CHEETHAM

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