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)

Novartis AG

(Name of Registrant)

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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:

Form 20-F: x Form 40-F: o

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- 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).

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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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