

NOVARTIS AG  
Form 6-K  
September 27, 2012

# 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 September 27, 2012**

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

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(Name of Registrant)

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(Address of Principal Executive Offices)

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

**Novartis data show AIN457 significantly reduced signs and symptoms in patients with hard-to-treat moderate-to-severe plaque psoriasis**

- *Phase II data show AIN457 given weekly during the first month of treatment improved hand/foot psoriasis at Week 12 (54% of patients vs 19% on placebo)(1)*
- *AIN457 selectively binds to and inhibits interleukin-17A, a key driver of immune-mediated diseases and a promising target for the next generation of therapy(2)-(4)*
- *AIN457 pivotal Phase III trials with more than 3,000 psoriasis patients on track with regulatory submissions expected in 2013*
- *Psoriasis on the hands, feet and nails is traditionally difficult-to-treat, causes functional and social disability and can affect up to 55% of psoriasis patients(5),(6)*

**Basel, September 27, 2012** Novartis announced today new Phase II data showing AIN457 (secukinumab) may significantly improve moderate-to-severe plaque psoriasis on the hands, feet and nails when used every week for the first month of treatment, compared to placebo(1),(7). Additional analysis on patients with moderate-to-severe plaque psoriasis also showed that AIN457 may successfully improve quality of life by Week 12 in the study(8).

These new AIN457 data are particularly welcome since they demonstrate significant improvement in the signs and symptoms of patients, even when difficult-to-treat areas are involved, said Prof. Kristian Reich, one of the study investigators and Professor of Dermatology, Venereology, and Allergology in Hamburg, Germany. Many patients with hand, foot or nail psoriasis are restricted in their daily life and work because they may not be able to walk or use their hands, negatively impacting their quality of life.

The results will be presented today at the European Academy of Dermatology and Venereology (EADV) 21st Congress, in Prague, Czech Republic. They provide additional insight into the safety and efficacy of AIN457, following the presentation of the study's primary endpoint at EADV in 2011.

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The new data from the sub-analyses undertaken on the Phase II study show AIN457 was nearly three times more effective than placebo at reducing moderate-to-severe plaque psoriasis on the hands and/or feet when given every week during the first month of treatment (54.3% of patients vs. 19.2% respectively,  $p=0.005$ ), as measured by the Investigator's Global Assessment (IGA)(1). Patients also benefited if they received AIN457 once every four weeks, with 39.0% experiencing either clear or minimal psoriasis after 12 weeks of treatment(1). Another analysis found that these AIN457 treatment schedules also notably reduced the signs and symptoms of finger nail psoriasis compared to placebo(7).

The study safety analysis of these data showed a comparable safety profile between treatment and placebo, with the most common adverse events (AEs) observed being infections(1),(7).

Other new data presented at EADV in the total moderate-to-severe plaque psoriasis study population show that AIN457 improved skin-related quality of life in 25 times more patients after 12 weeks of treatment when given every week for the first month, compared to placebo (40.8% vs. 1.6%,  $p < 0.001$ ), as measured by the Dermatology Life Quality Index (DLQI)(8). In this same treatment group, significantly more patients experienced improvements in pain and discomfort compared to placebo (36.2% vs. -1.5%) from baseline; and in anxiety and depression versus placebo (16.3% vs. 6.2%), as measured by EuroQol (EQ-5D)(8). The effect of psoriasis on patients' health-related quality of life has been shown to be similar to diseases such as cancer, heart attack, arthritis, type 2 diabetes and depression(9).

These encouraging results show that through its novel mode of action, AIN457 may significantly increase treatment success and improve the quality of life of patients suffering from moderate-to-severe plaque psoriasis, said John Hohneker, Head of Development for Integrated Hospital Care for the Pharmaceuticals Division of Novartis. We look forward to receiving the results of the larger-scale and longer-term Phase III studies, which are expected in 2013.

All core pivotal trials for AIN457 in moderate-to-severe plaque psoriasis are on track, involving more than 3,000 patients worldwide, and indicating a high interest from both medical and patient communities. Phase III data in moderate-to-severe plaque psoriasis is expected in 2013, with regulatory submissions to follow shortly thereafter.

#### **About the study**

Data are based on a double-blind, parallel group, placebo-controlled Phase II study involving 404 patients, which met its primary endpoint of PASI 75 (Psoriasis Area and Severity Index) responses at Week 12(10). It was designed to evaluate the safety and efficacy of AIN457 in different regimens (weekly for the first month; once every four weeks; or single dose) of 150 mg given subcutaneously(10).

The undertaken sub-analyses included assessment of AIN457 treatment efficacy in 131 patients with hand and/or foot psoriasis, often described as palmoplantar psoriasis(1). All 404 patients were involved in assessing health-related quality of life, and data from 304 patients were used to assess AIN457 treatment efficacy in nail psoriasis(7),(8).

#### **About AIN457**

AIN457 is a fully human monoclonal antibody inhibiting interleukin-17A (IL-17A), a key pro-inflammatory cytokine. 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 AIN457 may provide a new mechanism of action for the treatment of immune-mediated diseases(10)-(13). The Phase III programs for these potential indications are ongoing, and first interpretable results are expected in 2013 for moderate-to-severe plaque psoriasis and in 2014 for arthritic conditions. Phase II studies are also ongoing in other areas, including multiple sclerosis.

#### **About psoriasis**

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Approximately 2% of the world's population, or around 125 million patients, are affected by plaque psoriasis, a chronic disease characterized by thick and extensive skin lesions, called plaques, known to cause itching, scaling and pain(14),(15). More than one third of patients with plaque psoriasis suffer from its moderate-to-severe form(16).

Patients with hand, foot and nail psoriasis endure significantly greater physical disabilities than those whose psoriasis is limited to other parts of the body(5),(6). This includes functional disability, burning sensations, skin soreness, prolonged duration of psoriasis and the risk of joint involvement and secondary infections(5),(6). Estimated to affect between 10% and 55% of all psoriasis patients, nail, hand and foot psoriasis is notoriously difficult to treat

and often requires systemic treatment such as biologics to maintain an adequate clinical response(5),(6),(17).

## Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as promising, on track, expected, encouraging, may, look forward to, to follow, or similar expressions, or by express or implied discussions regarding potential marketing submissions or approvals for AIN457, or the timing of any such submissions or 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 approval 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; the company's ability to obtain or maintain patent or other proprietary intellectual property protection; unexpected manufacturing issues; 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 2011, the Group achieved net sales of USD 58.6 billion, while approximately USD 9.6 billion (USD 9.2 billion excluding impairment and amortization charges) was invested in R&D throughout the Group. Novartis Group companies employ approximately 126,000 full-time-equivalent associates and operate in more than 140 countries around the world. For more information, please visit <http://www.novartis.com>.

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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: September 27, 2012

By: /s/ MALCOLM B. CHEETHAM

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