

NOVARTIS AG  
Form 6-K  
November 07, 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 November 07, 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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**Novartis International AG**

Novartis Global Communications

CH-4002 Basel

Switzerland

<http://www.novartis.com>

**- Investor Relations Release -**

**Novartis Phase III study shows ACZ885 helped substantially reduce steroid use in 45% of patients with serious form of childhood arthritis**

- *Chronic steroid use to treat the symptoms of systemic juvenile idiopathic arthritis (SJIA) can contribute to slowed growth and delayed puberty(1),(2)*
- *The new pivotal Phase III data also showed SJIA patients treated with ACZ885 were nearly three times less likely to suffer a new flare vs. placebo(3)*
- *ACZ885 regulatory submissions on track for 2012 in SJIA, a rare, disabling and potentially fatal auto-inflammatory disease, with spiking fever and arthritic pain(1),(4)*

**Basel, November 7, 2011** Novartis announced today new pivotal Phase III data showing 45% of children with active systemic juvenile idiopathic arthritis (SJIA) were able to substantially reduce their use of oral corticosteroids (often described as steroids) within 28 weeks of commencing treatment with ACZ885 (canakinumab) (p<0.0001)(3).

The results of the study, which met both primary endpoints, will be presented on November 9 at the American College of Rheumatology's (ACR) Annual Scientific Meeting in Chicago, US(3).

These data are very welcome because nearly half of ACZ885-treated patients were able to reduce their steroid use during the study, potentially helping decrease the impact that these drugs can have on this young population," said Dr Nico Wulffraat, one of the study investigators and pediatric immunologist at Wilhelmina Children's Hospital, University Medical Center in Utrecht, The Netherlands. "One of our main goals as physicians, and this applies to all therapies, is to provide patients with treatment options that combine effective control of their disease with a favorable safety profile, making long-term safety data monitoring important.

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In addition, patients with SJIA on ACZ885 were nearly three times (0.37 hazard ratio) less likely to suffer a new flare. Therefore, only 27% of ACZ885-treated patients experienced a new flare, vs. 75% of patients on placebo during the study ( $p=0.0043$ )(3).

Data from this trial support the safety and efficacy profile of ACZ885 in the study population. These results, along with data from a second pivotal study, are planned to form the basis for worldwide regulatory submissions in 2012. Side effects observed in this study were similar to those already seen for ACZ885's approved indication, including infections and neutropenia(3),(5). In addition, cases of macrophage activation syndrome (MAS) were reported in this study(3).

These data demonstrate the significant benefits that ACZ885 may provide this young population, both in steroid reduction and in extending the period these children can live free from SJIA flares, said David Epstein, Head of the Pharmaceuticals Division of Novartis. Novartis is committed to helping improve the health of patients with SJIA and other inflammatory diseases, which is why we are delighted to be sharing these results.

ACZ885 is an investigational fully human monoclonal antibody which neutralizes the key inflammatory mediator, interleukin-1 beta (IL-1 beta), which plays an important role in a number of diseases including SJIA(5),(6).

SJIA is the most serious form of childhood arthritis and affects less than one child per 100,000(7). It is called systemic because the inflammation affects the whole body, as well as most of the joints. The condition is characterized by potentially life-long, recurrent and painful flares, which can involve skin rash, daily spiking fevers, joint pain and limited motion(1),(4). These children can face joint destruction and growth retardation, with serious developmental and psychological consequences(1).

Therapies traditionally used to treat SJIA can only partially mitigate symptoms and do not normally prevent the long-term damage caused by the disease(7). Long-term steroid use designed to treat SJIA symptoms can also contribute to slowed growth, delayed puberty and reduced bone density(1),(2).

Novartis is also presenting a number of other studies at ACR, including a second pivotal Phase III trial of ACZ885 in SJIA, which was previously presented at the 2011 European Pediatric Rheumatology Congress in Bruges, Belgium, in September.

### About the Study

The Phase III, two-part study had an open-label, single-arm active treatment in Part I followed by a randomized, double-blind, placebo-controlled, event-driven withdrawal design in Part II(3). A total of 177 patients between the ages of 1 and 19 years with active SJIA were enrolled in the study(3). In Part I, patients received a subcutaneous (s.c.) dose of ACZ885 (4 mg/kg, up to 300 mg) every 4 weeks. After 8 weeks, patients who met the adapted ACR Pediatric 30 criteria began tapering (reducing) their steroid use until either: **a)** the dose had been decreased to  $\leq 0.5$  mg/kg(8) while maintaining the adapted ACR Pediatric 30 Criteria (successful tapering of steroids); or **b)** a maximum of 20 weeks passed without reaching this goal (unsuccessful tapering of steroids)(3). In Part II of the study, patients were randomized to either continue receiving ACZ885, or to receive placebo every 4 weeks, until a pre-specified number (37) of flare-events ( flares ) had occurred(3).

The primary endpoints were to: **a)** assess if ACZ885 allows tapering of steroids in at least 25% of SJIA patients (Part I); and **b)** demonstrate that time to flare is extended with ACZ885 vs. placebo (Part II)(3).



In Part I of the study (representing 58 patient years), 138 of 177 patients (78%) reported an adverse event (AE), with the most common being nasopharyngitis, headache and cough. Serious adverse events (SAEs) were reported in 15 patients, with the most common being infections, MAS (four cases) or flare-associated events(3). Five SAEs led to discontinuation and one patient died of MAS(3). During Part II, AEs (the most common being arthralgia, cough, nasopharyngitis and pyrexia) were reported by 40 of 50 (80%) ACZ885-treated patients (vs. 35 of 50 [70%] placebo-after-ACZ885-treated patients)(3); and six patients in each arm experienced one or more SAE, which mainly included infections, MAS and flare-associated events(3). Six patients, all in the placebo arm, discontinued the study due to AEs or SAEs during Part II(3). One patient died from MAS after study discontinuation in the placebo group.

MAS is a known, potentially fatal condition associated with SJIA that is characterized by liver abnormalities, bleeding disorders, central nervous system dysfunction and multiple organ failure(4). Approximately 10% of SJIA patients are diagnosed with MAS, some of whom suffer repeated episodes(4).

### **About ACZ885**

ACZ885 is a fully human monoclonal antibody that inhibits IL-1 beta, which is an important part of the body's immune system defenses(5). Excessive production of IL-1 beta plays a prominent role in certain inflammatory diseases, including SJIA(6). ACZ885 works by neutralizing IL-1 beta for a sustained period of time, therefore inhibiting inflammation(5).

Under the brand name Ilaris®, ACZ885 is approved in more than 50 countries, including the EU, US, Switzerland and Japan for the treatment of Cryopyrin-Associated Periodic Syndromes (CAPS), a rare, lifelong, inflammatory disorder with debilitating symptoms(5). ACZ885 is also being studied in other diseases in which IL-1 beta plays a key role in causing inflammation, such as gouty arthritis, cardiovascular disease and diabetes. Not all potential patients with these diseases would be eligible for treatment with ACZ885, if approved.

### **Disclaimer**

The foregoing release contains forward-looking statements that can be identified by terminology such as can, on track, potentially, will, plan, may, committed, potential, would, or similar expressions, or by express or implied discussions regarding potential new indications or labeling for ACZ885 or regarding potential future revenues from ACZ885. 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 ACZ885 to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that ACZ885 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 ACZ885 will achieve any particular levels of revenue in the future. In particular, management's expectations regarding ACZ885 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 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. 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>.

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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)

+41 79 593 4202 (mobile)

eric.althoff@novartis.com

**Rute Frazao Marques**

Novartis Global Pharma Communications

+41 61 696 8491 (direct)

+41 79 701 2009 (mobile)

rutefrazao.marques@novartis.com

**Tina Tuttle**

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

Novartis US Pharma Communications

+1 862 778 1625 (direct)

+1 862 222 6092 (mobile)

tina.tuttle@novartis.com

e-mail: media.relations@novartis.com

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For questions about the site or required registration, please contact: [journalisthelp@thenewsmarket.com](mailto:journalisthelp@thenewsmarket.com).

### Novartis Investor Relations

<b>Central phone:</b>	+41 61 324 7944
Susanne Schaffert	+41 61 324 7944
Pierre-Michel Bringer	+41 61 324 1065
Thomas Hungerbuehler	+41 61 324 8425
Isabella Zinck	+41 61 324 7188

<b>North America:</b>	
Richard Jarvis	+1 212 830 2433
Jill Pozarek	+1 212 830 2445
Edwin Valeriano	+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: November 07, 2011

By: /s/ MALCOLM B. CHEETHAM

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