

NOVARTIS AG  
Form 6-K  
September 21, 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 September 16, 2011

(Commission File No. 1-15024)

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**Novartis AG**

(Name of Registrant)

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(Address of Principal Executive Offices)

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**- Investor Relations Release -**

**Novartis study showed ACZ885 provided substantial symptom relief in 84% of patients with the most serious form of childhood arthritis**

- *ACZ885, which neutralizes key inflammatory driver interleukin-1 beta(1), provided significant symptom improvement vs. placebo in Phase III pivotal trial(2)*
- *Systemic juvenile idiopathic arthritis is a rare, disabling and potentially fatal auto-inflammatory disease, with daily spiking fever and arthritic joint pain*
- *Second pivotal Phase III trial ongoing; worldwide regulatory submissions planned for 2012*

**Basel, September 16, 2011** Novartis announced today positive results of the first pivotal Phase III trial of ACZ885 (canakinumab) in patients with systemic juvenile idiopathic arthritis (SJIA), a rare and serious childhood auto-inflammatory disease(3). The results, presented at the 2011 European Pediatric Rheumatology Congress in Bruges, Belgium, showed all primary and secondary endpoints of the study were met(2).

Most ACZ885 patients (83.7%) experienced at least a 30% improvement in symptoms vs. 9.8% for placebo ( $p < 0.0001$ ) and a third of ACZ885 patients (32.6%) achieved a 100% improvement vs. 0% for placebo ( $p = 0.0001$ )(2). ACZ885 is an investigational, fully human monoclonal antibody that neutralizes interleukin-1 beta (IL-1 beta)(1), which is a key driver of inflammation in SJIA(4).

These data suggest that ACZ885 could become an important treatment option for children living with SJIA, the most difficult-to-treat and severe form of juvenile arthritis, potentially transforming their lives, said Professor Pierre Quartier, MD, one of the study investigators and Pediatric Rheumatologist Pediatric Immuno-Haematology and Rheumatology Unit, Necker-Enfants Malades Hospital, Paris, France. ACZ885 provided rapid and long-lasting symptom relief by targeting interleukin-1 beta, a key inflammatory mediator of the disease.

SJIA affects less than one child per 100,000(5). 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 and recurrent arthritis flares, which can involve skin rash, daily spiking fever, joint

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pain and swelling(6),(7). These young patients can face joint destruction and growth retardation(5),(6), with serious developmental and psychological consequences(6).

In this study, patients were measured according to the adapted American College of Rheumatology (ACR) Pediatric criteria, which includes absence of fever. The ACR criteria are regularly used to assess the success of treatments in SJIA.

These results are a positive development for patients suffering from this very severe auto-inflammatory condition, said David Epstein, Head of the Pharmaceuticals Division of Novartis. We are committed to investigating ACZ885 in a range of inflammatory diseases where interleukin-1 beta plays a key role and high unmet medical needs exist.

Therapies traditionally used to treat SJIA can only partially mitigate symptoms and do not prevent the long-term damage of the disease(5),(6). Long-term steroid use designed to treat SJIA symptoms can also contribute to slowed growth and delayed puberty(6),(8),(9).

The results of a second pivotal Phase III trial, aimed at determining whether ACZ885 can extend the time to next flare and reduce or eliminate corticosteroid use, will be presented later this year. Worldwide regulatory submissions for ACZ885 in SJIA are planned for 2012.

### **About the Study**

The study was a Phase III, 4-week, randomized, double-blind, placebo-controlled study involving 84 patients between the ages of 2 and 19 years, with active SJIA(2). Patients were treated with either a single subcutaneous (s.c.) dose of ACZ885 (4 mg/kg, up to 300 mg) or placebo(2).

The primary endpoint was the proportion of patients achieving the adapted ACR Pediatric 30 criteria, demonstrating a 30% improvement in at least three of the six variables, from baseline at Day 15(2). The six variables included physician's assessment of disease activity, parent's or patient's assessment of overall well-being, functional ability, number of joints with active arthritis, number of joints with limitation of motion and C-reactive protein, a laboratory measure of inflammation(2).

Secondary endpoints included the proportion of patients achieving the adapted ACR Pediatric 50, 70, 90 and 100 criteria, demonstrating a 50%, 70%, 90% and 100% improvement in at least three variables from baseline at Day 15 and 29(2).

ACZ885 was generally well tolerated. During the study, 55.8% of patients experienced adverse events (AEs), including infections, with ACZ885 vs. 39% with placebo(2). Serious adverse events (SAEs), including infections, were reported for two patients for ACZ885 vs. two for placebo(2). These did not lead to discontinuation and were resolved without complications(2).

### **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(1). Excessive production of IL-1 beta plays a major role in certain inflammatory diseases, including SJIA(4). ACZ885 works by neutralizing IL-1 beta for a sustained period of time, therefore inhibiting inflammation(1).

Under the brand name Ilaris®, ACZ885 is approved in more than 50 countries, including the EU, US and Switzerland for the treatment of adults and children as young as four with Cryopyrin-Associated Periodic Syndromes (CAPS), a rare, lifelong, inflammatory disorder with debilitating symptoms(1). ACZ885 is also being studied in other diseases in which IL-1 beta plays a key role in causing inflammation, such as gouty arthritis and cardiovascular disease. 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 planned, could, potentially, committed, will, potential, 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 approved for any additional indications or labeling in any market. 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; 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>.

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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 16, 2011

By: /s/ MALCOLM B. CHEETHAM

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