

NOVARTIS AG  
Form 6-K  
May 25, 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 May 25, 2011**

(Commission File No. 1-15024)

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**Novartis International AG**

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**- Investor Relations Release -**

**Novartis data shows ACZ885 for severe gouty arthritis provided better pain relief and reduced risk of new attacks by up to 68% vs. steroid**

- *Two pivotal Phase III studies showed ACZ885 may meet significant unmet need for patients for whom many standard therapies are inadequate or inappropriate(1),(2)*
- *Gouty arthritis, commonly referred to as gout, is an inflammatory disease affecting 1-4% of adults, causing severe pain and long-term consequences(3-7)*
- *Regulatory filings for the use of ACZ885 in gouty arthritis patients with limited treatment options have been submitted in the EU, US, Canada and Switzerland*

**Basel, May 25, 2011** Novartis announced positive results of two pivotal Phase III trials in patients with severe gouty arthritis, showing that ACZ885 (canakinumab) provided superior pain relief and reduced the risk of new attacks by up to 68% compared to an injectable steroid (triamcinolone acetonide, TA) used to treat gouty arthritis attacks(1),(2). ACZ885 is an investigational, fully human monoclonal antibody.

The studies involved more than 450 gouty arthritis patients for whom the standard anti-inflammatory therapies, non-steroidal anti-inflammatory drugs (NSAIDs) or colchicine, were inadequate or inappropriate(1),(2). Results will be presented for the first time at the 2011 European League Against Rheumatism (EULAR) Congress in London.

These findings show that ACZ885 may represent an important advance in the treatment of gouty arthritis in sufferers whose disease cannot be appropriately managed with currently available treatments, said Professor Alexander So, Rheumatology Department, CHUV, Lausanne, Switzerland, and one of the studies' investigators. Scientists only recently learned that the root cause of the pain in gouty arthritis is interleukin-1 beta. Through specifically targeting interleukin-1 beta, these studies show ACZ885 can effectively treat painful attacks while extending the time to new attacks.

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Both trials used an internationally recognized pain scale to measure differences in pain 72 hours after treatment, and found ACZ885 reduced pain by an additional -11.4 millimeters (mm) ( $p=0.0005$ ) in one study and -9.8 mm in the other ( $p=0.0018$ ), compared to TA(1). ACZ885 also significantly reduced the risk of suffering a new gouty arthritis attack within three months, by 55% in one study ( $p=0.0014$ ) and 68% in the other ( $p<0.0001$ ), compared to TA(2).

Gouty arthritis, commonly referred to as gout, is a serious, chronic and progressive inflammatory disease that affects 1-4% of adults(3-7). In the UK, an estimated 1.4% of the population suffers from gouty arthritis(6), while in the US, 3.9% of the population has the condition(7). Gouty arthritis is the most common form of inflammatory arthritis in adults, with a prevalence comparatively higher than rheumatoid arthritis, which is estimated to affect 0.5-1% of adults(8).

We are very excited about these results, which indicate that ACZ885 may become a significant new alternative for gouty arthritis patients where many standard anti-inflammatory treatments are inadequate or inappropriate, said David Epstein, Head of the Pharmaceuticals Division of Novartis. Novartis is committed to meeting this unmet medical need and to further investigating the potential of ACZ885 in a number of other conditions where interleukin-1 beta may play a role.

Gouty arthritis attacks occur when the body has a strong inflammatory response to uric acid crystals forming in the affected joint, typically of the toe, foot, ankle or knee(9-11). This intense inflammatory response causes the severe pain associated with gouty arthritis attacks, which can last for a week or more(3),(11-13). Gouty arthritis may also result in chronic disability and joint destruction(14-16).

Treatments currently available to manage the pain and inflammation of gouty arthritis attacks, such as NSAIDs or colchicine, may be inadequate or inappropriate in patients who have coexisting medical problems(17-19). This poses a significant unmet treatment need in gouty arthritis. New data presented at EULAR today indicates nearly 90% of gouty arthritis patients in the EU and the US have at least one coexisting disease(20), a portion of whom may be unable to take these standard anti-inflammatory therapies.

Regulatory filings for the use of ACZ885 in gouty arthritis patients with limited treatment options were submitted in the EU in 2010 and in the US, Canada and Switzerland in the first quarter of 2011.

### **About the Studies**

The two studies were Phase III, 12-week, randomized, multicenter, double-blind, double dummy, active-controlled studies involving 228 and 226 patients who met the American College of Rheumatology (ACR) criteria for acute gouty arthritis(1),(2). Patients had suffered from three or more gouty arthritis attacks in the previous 12 months and were either unresponsive or intolerant to common therapies such as NSAIDs or colchicine, or these treatments were contraindicated. Patients were randomized to receive a single dose of ACZ885 150 milligrams (mg) via subcutaneous (s.c.) injection or TA 40 mg via intramuscular (i.m.) injection(1),(2). In the case of a new attack, patients received a new dose of the same treatment they were randomized to at baseline.

Both studies had the same two primary endpoints: pain intensity at 72 hours post-dose; and time to the first new gouty arthritis attack(1),(2). Pain in the affected joint was measured according to an internationally recognized pain scale, the Visual Analog Scale (VAS).

In one study, patients treated with ACZ885 had significantly lower mean pain scores from baseline compared to TA, pain intensity at 72 hrs was 28.1 mm for ACZ885 and 39.5 mm for TA ( $p=0.0005$ )(1). Similarly, patients in the other study receiving ACZ885 had significantly lower mean pain scores from baseline compared to TA, pain intensity at 72 hrs was 22.1 mm for ACZ885 and 31.9 mm for TA ( $p=0.0018$ )(1). In both studies, the respective decreases of 46 and 53 mm from baseline with ACZ885 exceeded those of 35 and 43 mm seen with TA(1).

The number of patients with new attacks across both studies was also significantly reduced with ACZ885 compared to TA(2). In the first study, nearly twice as many patients experienced a new gouty arthritis attack in the TA group compared to ACZ885 (40 vs. 21 patients respectively [ $p=0.0061$ ])(2). In addition, in the second study nearly three times as many patients in the TA group experienced a new attack compared to ACZ885 (42 vs. 15 patients respectively [ $p=0.0001$ ])(2). In the previous year, patients in both studies suffered an average of at least six attacks (6.5 for ACZ885 and seven for TA in study one; and 6.5 and 5.9 respectively in study two)(21),(22).

ACZ885 was generally well tolerated in the two studies. In one study, 55.8% of patients had adverse events (AEs) with ACZ885 vs. 38.3% with TA(21). In the other study, 54.5% of patients had

AEs with ACZ885 vs. 50.9% with TA(22). Serious adverse events (SAEs), 10 for ACZ885 vs. five for TA in one study and three for ACZ885 vs. one for TA in the other study, were not considered to be related to study medication by the investigators(21),(22).

#### **About ACZ885**

ACZ885 is a fully human monoclonal antibody that provides selective inhibition of interleukin-1 beta (IL-1 beta), which is part of the body's immune system defenses(23). Excessive production of IL-1 beta plays a major role in many inflammatory diseases, including gouty arthritis(24). ACZ885 works by neutralizing IL-1 beta for a sustained period of time, therefore inhibiting inflammation(23).

Under the brand name Ilaris®, ACZ885 is approved in more than 45 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(24). ACZ885 is also being studied in other diseases in which IL-1 beta plays a key role in causing inflammation, such as Systemic Juvenile Idiopathic Arthritis (SJIA), 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 may, will, committed, 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, or at any particular time. Nor can there be any guarantee that ACZ886 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 regulatory actions or delays or government regulation generally; unexpected clinical trial results, including unexpected new clinical data and unexpected additional analysis of existing clinical data; 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 119,000 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: May 25, 2011

By:

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