NOVARTIS AG
Form 6-K
June 18, 2010

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 June 18, 2010

(Commission File No. 1-15024)

Novartis AG

(Name of Registrant)

Lichtstrasse 35

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

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):

Yes: o **No**: **x**

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7):

Yes: o **No**: **x**

Indicate by check mark whether the registrant by furnishing the information contained in this form is also thereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934.

Yes: o **No**: **x**

Novartis International AG

Novartis Global Communications

CH-4002 Basel

Switzerland

http://www.novartis.com

- Investor Relations Release -

New Phase II study in gout patients shows Novartis ACZ885 prevented acute flares better than standard anti-inflammatory therapy

- *ACZ885 significantly reduced rate of acute flares up to 75% vs. anti-inflammatory colchicine in gout patients starting uric acid lowering therapy (UALT)(1)*

- *ACZ885 blocked major inflammation trigger (interleukin IL-1β)(2),(3) for sustained period and reduced gout symptoms (4)*

- *Data indicate potential of ACZ885 to both treat and prevent painful gout flares - Phase III program in gout currently underway*

Basel, June 18, 2010 New phase II data demonstrate that the human monoclonal antibody ACZ885 (also known as canakinumab) provided highly statistically significant risk reduction of acute flares in gout patients initiating uric acid lowering therapy (UALT) compared to the anti-inflammatory standard of care (colchicine)(1).

In this six month Phase II study, canakinumab significantly reduced the rate of flares by 48% to 75% compared to colchicine ($p \leq 0.05$)(1). Similarly, canakinumab reduced the risk of developing at least one flare by 61% to 80% vs. colchicine p ($p \leq 0.05$)(1). Preliminary results were presented today at the annual European League Against Rheumatism (EULAR) meeting in Rome, Italy.

Gout patients frequently experience painful flares with debilitating consequences on their quality of life because current treatment strategies are not well tolerated and have limited efficacy(5), said Trevor Mundel, MD, Head of Global Development at Novartis Pharma AG. These new results reinforce previous positive data suggesting that canakinumab, if approved, can more effectively address the unmet needs of patients to both treat and prevent acute gout flares.

Gout is one of the most painful forms of arthritis and affects at least 1% of adults in Western countries(5),(6),(7). It is caused by the accumulation in joints and surrounding tissues of uric acid crystals(8) that trigger the overproduction of interleukin-1β (IL-1β). IL-1β activates

the inflammatory process leading to excruciating pain and debilitating consequences such as joint erosion and destruction(8).

Uric acid lowering therapy, while helping to reduce uric acid levels in the blood, does not address patient inflammation and pain. In addition, at the start of therapy, UALTs actually increase the risk of painful gout attacks due to an initial peak of uric acid. To prevent these side effects, the prophylactic use of anti-inflammatory drugs is recommended(8).

Standard anti-inflammatory therapies are commonly used to reduce the inflammation and pain of acute gout flares but it is recognized that they are not always effective. Gout patients also have comorbidities making it more difficult for them to find an appropriate treatment, said Dr Naomi Schlesinger, Department of Medicine, University of Medicine and Dentistry of New Jersey, US.

These promising data indicate that the blockade of IL-1β provided by canakinumab was effective in preventing acute flares for a sustained period of time compared to anti-inflammatory standard of care and may represent a future novel advance in the treatment of debilitating gout attacks.

These new findings reinforce data from another Phase II study(4) that involved patients with acute gout attacks who are intolerant, contraindicated or not responsive to common anti-inflammatory therapies. Data from this study showed that canakinumab provided better pain relief and reduced risk of acute flares by 94% versus a potent injectable corticosteroid (triamcinolone acetonide)(4). Canakinumab is in Phase III development for the treatment and prevention of acute gout attacks and submission is planned later this year in the EU and US.

The Phase II data presented today at EULAR is a 24-week, multi-center, double-blind study and involved 432 gout patients ranging from 20 to 70 years in age who were initiating UALT (allopurinol)(1). The study explored a number of doses of canakinumab versus colchicine and the primary endpoint sought to determine the dose of canakinumab that provides the same efficacy to the dose of the anti-inflammatory colchicine (0.5 mg) with respect to the mean number of gout flares experienced by patients during 16 weeks. All canakinumab tested doses were better than colchicine. Secondary endpoints included among others the number of patients with flares after 16 weeks and safety assessment at 24 weeks(1).

Canakinumab was generally well tolerated with similar incidence of adverse events across all treatment groups(1). The most frequent adverse events in all treatment groups were headache, arthralgia and hypertension. Infections (predominantly upper respiratory tract infection and nasopharyngitis) were slightly more frequent in the canakinumab groups (15.1% to 20.4%) than in the colchicine group (12.0%)(1).

Under the brand name Ilaris®, canakinumab is approved in the EU, US, Brazil, Canada, Australia and Switzerland for the treatment of adults and children as young as four with cryopyrin-associated periodic syndrome (CAPS), a rare life-long auto-inflammatory disease(9). Due to a genetic mutation in CAPS patients, IL-1β is overproduced causing widespread inflammation and tissue damage that can lead to debilitating symptoms and life-threatening complications if left untreated(2),(3).

Studies are also ongoing in other diseases in which IL-1β is believed to play an important role in driving inflammation, such as systemic juvenile idiopathic arthritis (SJIA), chronic obstructive pulmonary disease (COPD) and type 2 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 potential, risk, suggesting, can, promising, may, planned, believed, could, or similar expressions, or by express or implied discussions regarding potential new indications or labeling for ACZ885 (canakinumab) 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; government, industry and general public pricing pressures; competition in general; 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, cost-saving generic pharmaceuticals, preventive vaccines, diagnostic tools and consumer health products. Novartis is the only company with leading positions in these areas. In 2009, the Group s continuing operations achieved net sales of USD 44.3 billion, while approximately USD 7.5 billion was invested in R&D activities throughout the Group. Headquartered in Basel, Switzerland, Novartis Group companies employ approximately 100,000 full-time-equivalent associates and operate in more than 140 countries around the world. For more information, please visit http://www.novartis.com.

References

(1) Schlesinger, N et al. Efficacy of canakinumab (ACZ885) in the prevention of flares in gout patients initiating allopurinol therapy . Abstract presented at the EULAR meeting, 18 June 2010, Rome, Italy.

(2) Lachmann HJ, Lowe P, Felix SD et al. In vivo regulation of interleukin 1 in patients with cryopyrin-associated periodic syndromes. *J. Exp. Med*, 2009. Published online April 13 2009. Available at: www.jem.org/cgi/doi/10.1084/jem.20082481. Accessed: 15 May 2010.

(3) Lachmann HJ, Kone-Paut I, Kuemmerle-Deschner JB, et al. Use of Canakinumab in the Cryopyrin-Associated Periodic Syndrome. *N Engl J Med* 2009; 360: 2416 2425.

(4) So A et al. Canakinumab (ACZ885) vs. triamcinolone acetonide for treatment of acute flares and prevention of recurrent flares in gouty arthritis patients refractory to or contraindicated to NSAIDs and/or colchicine. First presentation at American Congress of Rheumatology October 2009.

(5) Mikuls TR, Farrar JT, Bilker WB et al. Gout epidemiology: results from the UK General Practice Research Database, 1990 1999*Ann Rheum Dis*, 2005; 64; 267-272.

(6) So A. Developments in the scientific and clinical understanding of gout. *Arthritis Res Ther*, 2008; 10: 221-226.

(7) Kramer HM, Curhan G. The association between gout and nephrolithiasis: The National Health and Nutrition Examination Survey III, 1988-1994. *Am J Kidney Dis,* 2002; 40: 37 42.

(8) Halpern R, Fuldeore MJ, Mody RR et al. The Effect of Serum Urate on Gout Flares and Their Associated Costs. An Administrative Claims Analysis. *J Clin Rheumatol*, 2009; 15(1): 3-7.

(9) Ilaris Prescribing Information, Novartis Pharma, October 2009.

# # #

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

Irina Ferluga

Novartis Pharma Communications

+41 61 324 2422 (direct)

+41 79 824 1121 (mobile)

irina.ferluga@novartis.com

e-mail: media.relations@novartis.com

For Novartis multimedia content, please visit www.thenewsmarket.com/Novartis
For questions about the site or required registration, please contact: journalisthelp@thenewsmarket.com.

Novartis Investor Relations

Central phone:	+41 61 324 7944
Susanne Schaffert	+41 61 324 3769
Pierre-Michel Bringer	+41 61 324 1065
Thomas Hungerbuehler	+41 61 324 8425
Isabella Zinck	+41 61 324 7188

e-mail: investor.relations@novartis.com

North America:	
Richard Jarvis	+1 212 830 2433
Edwin Valeriano	+1 212 830 2456

e-mail: 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: June 18, 2010	By:	/s/ MALCOLM B. CHEETHAM
	Name:	Malcolm B. Cheetham
	Title:	Head Group Financial Reporting and Accounting