NOVARTIS AG
Form 6-K
June 24, 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 June 21, 2011

(Commission File No. 1-15024)

Novartis AG

(Name of Registrant)

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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:

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- Investor Relations Release -

FDA panel endorses efficacy but not safety of Novartis drug ACZ885 for gouty arthritis; did not support approval in proposed indication

- *Advisory committee strongly endorsed the efficacy of ACZ885 (canakinumab)*

- *Committee voted against approval of ACZ885 for proposed indication; potential identified for use in more narrow patient population*

- *Gouty arthritis is a chronic and progressive inflammatory disease of the joints characterized by recurrent attacks of severe pain(1), lasting a week or more(2)*

Basel, June 21, 2011 An advisory committee of the Food and Drug Administration (FDA) today voted in favor of the overall efficacy but not the overall safety of ACZ885 (canakinumab) to treat gouty arthritis attacks in patients who cannot obtain adequate relief with non-steroidal anti-inflammatory drugs (NSAIDs) or colchicine. Committee members raised the potential for use in a more narrow population of gouty arthritis patients.

ACZ885, a fully human monoclonal antibody that neutralizes interleukin-1 beta (IL-1 beta)(3), would represent the first new class of therapies in nearly half a century to treat the pain and inflammation of gouty arthritis. Excessive production of IL-1 beta is believed to play a major role in many inflammatory diseases, including gouty arthritis(4).

We continue to believe in the benefits of ACZ885 for this painful and debilitating disease and will work closely with the FDA to identify the right patient population who will benefit from this therapy, said Trevor Mundel, MD, Global Head of Development at Novartis Pharmaceuticals. We are encouraged by the committee s enthusiasm and robust discussion and remain committed to addressing the needs of people with gouty arthritis.

The committee s recommendation will be considered by the FDA in its review of the supplemental biologics license application (sBLA) that Novartis submitted for ACZ885. The FDA has the option of seeking the advice of its advisory committees when it is reviewing a new drug approval, although it is not obliged to follow the recommendations.

The recommendation by the committee was based on the results of two pivotal Phase III trials in patients with gouty arthritis. The studies showed patients treated with ACZ885 experienced superior pain relief at 72 hours and a significant reduction in the risk of new attacks over six months, compared to patients treated with the injectable steroid, triamcinolone acetonide (TA)(5).

Gouty arthritis is the most common form of inflammatory arthritis in adults(6). Chronic and progressive, the disease is characterized by recurrent attacks in the joints(1). These 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(1),(7). The intense inflammatory response associated with these attacks may cause severe pain and debilitating symptoms that can last a week or more(1),(2),(7).

About ACZ885 Phase III Studies

The committee reviewed results of two pivotal Phase III studies in which the efficacy of ACZ885 150 mg over 24 weeks was studied in more than 450 gouty arthritis patients. Both trials used an internationally recognized pain scale to measure differences in pain 72 hours after treatment. Patients treated with ACZ885 had a significantly lower mean pain score a 49.1 millimeter (mm) decrease from baseline resulting in a statistically significant and clinically meaningful 10.7 mm difference ($p<0.0001$) compared to TA 40 mg(5). Patients receiving ACZ885 also experienced a significant reduction in the relative risk of suffering a new gouty arthritis attack within 24 weeks, by 56%, compared to patients receiving TA ($p<0.0001$)(5). Importantly, only 28% of patients treated with ACZ885 experienced new attacks over 24 weeks compared to 49% treated with TA(5).

ACZ885 was generally well tolerated in the two studies, with most adverse events being mild to moderate in severity(5). Across both studies, 69.6% of patients had adverse events (AEs) with ACZ885 vs. 57% with TA(5). Serious events (SAEs) were reported by 18 patients treated with ACZ885 vs. nine patients on TA(5). None of the SAEs were considered by clinical investigators to be related to study medication(5).

About Gouty Arthritis

Gouty arthritis, commonly referred to as gout, is a painful and debilitating inflammatory disease that affects up to 8.3 million Americans(1),(6),(7). The most common form of inflammatory arthritis in adults, gouty arthritis is estimated to be five times more prevalent than rheumatoid arthritis in the US(8),(9).

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 certain coexisting medical problems(2),(10),(11). As a result, there is a significant unmet medical need among individuals with gouty arthritis. In the US, over 95% of gouty arthritis patients or those with high levels of uric acid (hyperuricemia) have at least one coexisting disease(12).

About ACZ885

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. ACZ885 is being assessed by the FDA with a priority review voucher (PRV), which expedites review time from 10 to six months. A decision is expected in the third quarter of 2011.

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(3). 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 potential, would, believed, will, encouraged, committed, recommendation, priority review, expected, 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 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: June 21, 2011

By: /s/ MALCOLM B. CHEETHAM

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