

NOVARTIS AG
Form 6-K
June 19, 2009

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, 2009

(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:

Edgar Filing: NOVARTIS AG - Form 6-K

Form 20-F: ☒ **Form 40-F:** ☐

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: ☐ **No:** ☒

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: ☐ **No:** ☒

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: ☐ **No:** ☒

Novartis International AG

Novartis Global Communications
CH-4002 Basel
Switzerland
<http://www.novartis.com>

- Investor Relations Release -

New biological therapy Ilaris® approved in US to treat children and adults with CAPS, a serious life-long auto-inflammatory disease

- *Phase III data show rapid and sustained remission in more than 90% of Ilaris-treated patients with cryopyrin-associated periodic syndrome (CAPS)(1)*
- *Ilaris is the first approved treatment for children as young as four and is given only every eight weeks(2)*
- *Highly selective in targeting and blocking interleukin-1 β (IL-1 β), which is overproduced in CAPS patients causing inflammation(1),(3),(4),(5),(6)*
- *Studies under way in other inflammatory disorders involving IL-1 β , such as some forms of gout, systemic juvenile idiopathic arthritis and type 2 diabetes*

Basel, June 18, 2009 The US Food and Drug Administration (FDA) has approved Ilaris® (canakinumab) for the treatment of children and adults with cryopyrin-associated periodic syndrome (CAPS), which includes a number of rare but life-long auto-inflammatory disorders with debilitating symptoms and limited treatment options(1),(2),(3),(4). The FDA granted priority review to Ilaris based on its potential to meet an important clinical need for patients with CAPS.

Ilaris is the first approved treatment for patients as young as four years old suffering from two forms of CAPS: familial cold auto-inflammatory syndrome (FCAS) and Muckle-Wells syndrome (MWS)(2).

CAPS is caused by a single gene mutation that leads to overproduction of interleukin-1 beta (IL-1 β), which causes sustained inflammation and tissue damage(1),(3),(5),(6). Symptoms, such as debilitating fatigue, rash, fever, headaches, joint pain and conjunctivitis, can be present from birth or infancy, and can occur daily throughout patients' lives(1),(3),(7). Long-term consequences may be serious and potentially fatal, including deafness, bone and joint deformities, central nervous system damage leading to visual loss, and amyloidosis resulting in renal failure and early death(1),(3),(4),(7).

Edgar Filing: NOVARTIS AG - Form 6-K

Ilaris, previously known as ACZ885, is a fully human monoclonal antibody that rapidly and selectively blocks IL-1 β (1),(3),(4),(7). The dosing schedule for Ilaris is once every eight weeks, which is less frequent than the current approved therapy(2),(8). Also, more than 90% of patients studied did not experience any injection site reactions and those that did occur were of a mild-to-moderate nature(1),(2).

Until now, treatments for CAPS patients have been limited to traditional inflammatory-disease medications that work by suppressing the entire immune system, and newer therapies that control the disease better but require more frequent injections, said Hal Hoffman, MD, Associate Professor of Pediatrics and Medicine at University of California, San Diego, USA.

He added: CAPS is a life-long disease and the convenience of administration of medicine is of the utmost importance for these patients. With rapid and sustained response, good tolerability, and a significantly less-frequent dosing schedule, Ilaris represents an important treatment advance for children and adults with CAPS.

CAPS comprises three disorders of increasing severity: FCAS, MWS and neonatal-onset multisystem inflammatory disease (NOMID)(1),(3). There are believed to be approximately 300 cases in the US, but many patients may remain undiagnosed due to poor disease recognition(3). A clinical study is ongoing to evaluate the potential of Ilaris to treat patients with NOMID. There are currently no approved therapies for the treatment of NOMID.

Children and adults affected by these inflammatory diseases have to cope daily with distressing and debilitating symptoms, said Trevor Mundel, MD, Head of Global Development at Novartis Pharma AG. We are excited about this first Ilaris approval which reflects our commitment to developing innovative treatments that address unmet medical needs, regardless of the size of the patient population.

In addition to ongoing studies in CAPS, clinical trials are also under way with Ilaris in systemic juvenile idiopathic arthritis (SJIA), and more common disorders such as some forms of gout, chronic obstructive pulmonary disorder (COPD) and type 2 diabetes. Further development in rheumatoid arthritis (RA) is not planned.

The approval of Ilaris is based on a three-part, one-year Phase III study involving 35 patients aged nine to 74 years old with varying degrees of disease severity(1). Results published in *The New England Journal of Medicine* on June 4, 2009 show that Ilaris produced a rapid, complete and sustained response in the majority of patients(1).

Part two of the study included the primary endpoint, a comparison between the number of patients treated every two months with Ilaris who experienced disease outbreaks or flares vs. those on placebo(1). Results showed that none of the patients in the Ilaris group (0 out of 15) experienced a disease flare compared to 13 out of 16 patients in the placebo group (0% vs. 81% respectively, $p < 0.001$)(1).

Ilaris was generally well tolerated, with no consistent pattern of adverse events beyond an increase in all suspected infections(1). Two patients experienced serious adverse events, which were a lower urinary tract infection and vertigo(1). The most common adverse events reported by patients treated with Ilaris were nasopharyngitis, diarrhea, influenza, headache and nausea. No impact on the type or frequency of adverse events was seen with longer-term treatment(1),(2).

Ilaris has orphan drug designation for CAPS in the US, as well as in the EU, Switzerland and Australia, where it is currently under health authority review. Priority review has

been granted in Switzerland, Australia and Canada. Ilaris has been granted orphan drug designation for SJIA in the US, EU and Switzerland, and also has fast-track status for SJIA in the US. Orphan drugs are those developed to treat diseases affecting fewer than 200,000 people (in the US)(9) or fewer than five out of 10,000 people (in the EU)(10).

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as priority review, potential, can, may, potentially, commitment, planned, fast-track status, or similar expressions, or by express or implied discussions regarding potential future regulatory filings or marketing approvals for Ilaris or regarding potential future revenues from Ilaris. You should not place undue reliance on these statements. Such forward-looking statements reflect the current views of the Company regarding future events, and involve known and unknown risks, uncertainties and other factors that may cause actual results with Ilaris to be

materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Ilaris will be approved for sale in any additional market, or for any additional indication. Nor can there be any guarantee that Ilaris will achieve any levels of revenue in the future. In particular, management's expectations regarding Ilaris 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; the company's ability to obtain or maintain patent or other proprietary intellectual property protection; competition in general; government, industry and general public pricing pressures; the impact that the foregoing factors could have on the values attributed to the 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 AG 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 2008, the Group's continuing operations achieved net sales of USD 41.5 billion and net income of USD 8.2 billion. Approximately USD 7.2 billion was invested in R&D activities throughout the Group. Headquartered in Basel, Switzerland, Novartis Group companies employ approximately 98,000 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) Lachmann HJ, Kone-Paut I, Kuemmerle-Deschner JB, *et al.* Use of Canakinumab in the Cryopyrin-Associated Periodic Syndrome. *N Engl J Med*, 360;23. June 4, 2009.
- (2) Ilaris (canakinumab) prescribing information.
- (3) K. L.W Durrant, R. Goldbach-Mansky, H. Hoffman, K.Leslie, B. Rubin. CAPS Cryopyrin-Associated Periodic Syndromes 2008. Available at: <http://www.nomidalliance.net/Download1.html>. Last accessed April 19, 2009.
- (4) National Horizon Scanning Centre. Canakinumab for cryopyrin associated periodic syndrome. November 2008. Available at: <http://www.pcpoh.bham.ac.uk/publichealth/horizon/outputs/documents/2008/sept-dec/Canakinumab.pdf> Last accessed April 21, 2009.
- (5) Joost PH, Drenth MD, Jos W.M. van der Meer. The Inflammasome - A Linebacker of Innate Defense. *N Engl J Med* 2006. Vol 355:730-732. Number 7.
- (6) 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.
- (7) Kastner DL. Hereditary Periodic Fever Syndromes. *Hematology* 2005 American Society of Hematology Education Program. 2005: 74-81. Available at: <http://asheducationbook.hematologylibrary.org/cgi/reprint/2005/1/74>
- (8) Arcalyst (rilonacept) prescribing information.
- (9) Orphan Drug Act. US Food and Drug Administration. Section 526 (2), Line 2.
- (10) The orphan drug strategy. Europa: Gateway to the European Union. Paragraph 1, Line 1.

###

Novartis Media Relations

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

Novartis Investor Relations

Central phone:

Ruth Metzler-Arnold	+41 61 324 7944
Pierre-Michel Bringer	+41 61 324 9980
John Gilardi	+41 61 324 1065
Thomas Hungerbuehler	+41 61 324 3018
Isabella Zinck	+41 61 324 8425
	+41 61 324 7188

e-mail: investor.relations@novartis.com

North America:

Richard Jarvis	+1 212 830 2433
Jill Pozarek	+1 212 830 2445
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, 2009

By: /s/ MALCOLM B. CHEETHAM

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