NOVARTIS AG
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SECURITIES AND EXCHANGE COMMISSION

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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 October 28, 2009

(Commission File No. 1-15024)

Novartis AG

(Name of Registrant)

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- Investor Relations Release -

Novartis biological drug Ilaris® approved in EU to treat children and adults with CAPS, a rare debilitating auto-inflammatory disease

- *First drug approved in EU for patients as young as four years old with cryopyrin-associated periodic syndrome (CAPS)(1)*

- *Approval based on positive data showing Ilaris produced rapid and sustained remission of CAPS symptoms in up to 97% of patients(2)*

- *Ilaris is a monoclonal antibody that selectively targets and blocks interleukin-1 beta (IL-1ß), the trigger for inflammation and tissue damage in CAPS patients(1),(2),(3)*

- *Studies ongoing in groups of patients with other diseases involving IL-1ß such as COPD, type 2 diabetes and gout one of the most painful forms of arthritis*

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Basel, October 28, 2009 The new biological medicine Ilaris® (canakinumab) has been approved in the European Union (EU) to treat adults and children as young as four years old with cryopyrin-associated periodic syndrome (CAPS), a rare life-long auto-inflammatory disease with debilitating symptoms and few treatment options(1),(2),(3).

The accelerated EU decision follows approvals in the US and Switzerland, where Ilaris was granted priority review in view of the significant unmet medical need. Ilaris is the only medicine approved in the EU for CAPS patients as young as four years old, and for patients with the most debilitating form of CAPS, neonatal-onset multisystem inflammatory disease (NOMID)(4). It is a fully human monoclonal antibody given by injection under the skin once every two months the longest dosing interval of any available treatment(2),(5),(6).

We are excited by the latest approval because Ilaris represents a significant therapeutic advance for patients with this debilitating and sometimes fatal disease, said Joe Jimenez, CEO of the Novartis Pharmaceuticals Division. Ilaris is the outcome of our pathways-driven search for innovative medicines that are tailored to the needs of patients. Initially we studied Ilaris in a very rare disease with a well-understood genetic profile, and now that its efficacy has been proven, we are able to move ahead rapidly with development in other diseases characterized by the

same inflammatory process.

The regulatory submission was supported by data showing that Ilaris produced rapid and sustained remission of symptoms in up to 97% of CAPS patients, with most of them responding within hours of the first injection(2).

Ilaris, previously known as ACZ885, targets and normalizes the production of a protein within the immune system called interleukin-1 beta (IL-1ß)(1),(3),(7). In CAPS patients, IL-1ß is overproduced

causing widespread inflammation and tissue damage(3),(8),(9). Symptoms, such as debilitating fatigue, fever, joint pain and conjunctivitis, can be present from infancy and continue throughout the patient s life(2),(3).

If left untreated, CAPS may have serious consequences such as deafness, bone deformities, erosive joint destruction, and central nervous system damage leading to loss of vision(1),(2),(3). Around 25% of patients develop amyloidosis, a condition in which the build-up of proteins can cause vital organs to fail, resulting in renal failure and requiring kidney transplantation. Approximately 20% of patients with NOMID, the most severe form of CAPS, die before reaching adulthood(2),(3),(10).

CAPS is believed to occur in around one in 2,500 people in the EU(3),(11), but fewer than 1,000 cases have been reported worldwide due to poor diagnosis(1),(3). CAPS includes three distinct autoinflammatory disorders of increasing severity: familial cold auto-inflammatory syndrome (FCAS), Muckle-Wells syndrome (MWS), and NOMID(2),(3). Ilaris is the only treatment indicated in the EU and Switzerland to treat all three disorders(1),(4).

Studies with ACZ885 are ongoing in other diseases in which IL-1ß plays an important role, such as chronic obstructive pulmonary disease (COPD), type 2 diabetes, systemic juvenile idiopathic arthritis (SJIA), and gout one of the most painful forms of arthritis. Not all potential patients with these diseases would be eligible for treatment with ACZ885, if approved.

The CAPS filing was based on a clinical trial program involving more than 100 patients. Data from a pivotal study published in *The New England Journal of Medicine* show that Ilaris produced a rapid, complete and sustained response in most patients(2). None of the patients treated with Ilaris (0 out of 15) experienced a disease outbreak or flare compared to 13 of the 16 patients who received placebo (0% vs. 81% respectively, $p<0.001$)(2).

In CAPS studies, symptoms improved within 24 hours after patients received a single dose of Ilaris. The disease was barely detectable in the blood after two weeks and the remission of symptoms was sustained for six months, said Helen J. Lachmann, MD of the UK National Amyloidosis Centre at the Royal Free and University College Medical School in London, UK. By effectively turning off the disease activity, Ilaris has the potential to transform patients lives by offering long-term control of their disease.

Ilaris was generally well tolerated and there was no consistent pattern of adverse events apart from a slight increase in infections(2). Two patients experienced serious adverse events, namely a lower urinary tract infection and vertigo(2). The most common adverse events were nasopharyngitis, diarrhea, influenza, headache and nausea(2). Ilaris was not associated with any severe injection-site reactions and those that did occur were classified as mild-to-moderate(2).

The EU approval was granted under exceptional circumstances, a common practice with so-called orphan drugs. This reflects a need for additional data due to factors such as the rarity of the disease or lack of scientific knowledge. The situation is reviewed every year until the European Medicines Agency (EMEA) is able to grant a normal approval.

In addition to its orphan drug status for CAPS, Ilaris has been designated as an orphan drug for treating SJIA, the most severe form of arthritis in children, in the US, EU and Switzerland, and 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)(12) or fewer than five out of 10,000 people (in the EU)(13).

Ilaris was approved in Switzerland in July 2009 to treat all three forms of CAPS in adults and children over four years old, and in the US in June 2009 to treat two forms of CAPS, namely FCAS and MWS, while a study in NOMID patients is under way. Priority reviews are ongoing in other countries including Australia, Brazil and Canada.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as potential, long-term, or similar expressions, or by express or implied discussions regarding potential additional indications 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 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 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 each of 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 99,000 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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(12) Orphan Drug Act. US Food and Drug Administration. Section 526 (2), Line 2.

(13) The orphan drug strategy. Europa: Gateway to the European Union. Paragraph 1, Line 1.

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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: October 28, 2009	By:	/s/ MALCOLM B. CHEETHAM
	Name:	Malcolm B. Cheetham
	Title:	Head Group Financial Reporting and Accounting