

NOVARTIS AG
Form 6-K
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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 July 24, 2009

(Commission File No. 1-15024)

Novartis AG

(Name of Registrant)

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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:

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Yes: ☐ **No:** ☒

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- Investor Relations Release -

Ilaris® recommended for European approval as new biologic drug to treat a rare but serious group of auto-inflammatory diseases

- *Set to become first medicine in EU to treat patients aged four and older suffering from life-long cryopyrin-associated periodic syndrome (CAPS)(1)*
- *Ilaris targets interleukin-1 beta (IL-1 β), a key driver of inflammation(1),(2),(3) studies ongoing in other diseases involving IL-1 β such as gout, COPD and type 2 diabetes*
- *EU opinion follows US and Swiss approvals based on data showing Ilaris produced rapid and sustained remission in CAPS patients after one dose(2)*
- *CAPS comprises three disorders of increasing severity with potentially fatal complications(2),(3) most patients suffer from severe and disabling symptoms(1),(3)*

Basel, July 24, 2009 The biotechnology medicine Ilaris® (canakinumab) has passed another major milestone with a recommendation for approval in the European Union to treat patients with a life-long and potentially fatal auto-inflammatory disease called cryopyrin-associated periodic syndrome (CAPS). When approved, Ilaris will be the only treatment in the EU indicated for CAPS patients aged four years and older(1).

Ilaris represents an important advance in the development of personalized medicines because it targets a condition that is triggered by a specific genetic mutation. In CAPS patients, this mutation drives the overproduction of interleukin 1-beta (IL-1 β) which causes the widespread sustained inflammation and tissue damage associated with the disease(3),(4),(5).

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Because Ilaris normalizes the production of IL-1 β (1),(2),(3), it is also being studied in other diseases in which IL-1 β plays a pivotal role such as systemic juvenile idiopathic arthritis (SJIA), gout, chronic obstructive pulmonary disorder (COPD), and type 2 diabetes.

By concentrating initially on a rare syndrome with a well-defined disease process such as CAPS, we have been able to demonstrate a clear therapeutic advantage with Ilaris, said Trevor Mundel, MD, Head of Global Development at Novartis Pharma AG. Our focus now is to establish whether this could also provide a new approach to the treatment of other diseases involving a similar underlying process.

A positive opinion recommending the approval of Ilaris for CAPS was issued by the Committee for Medicinal Products for Human Use (CHMP), which reviews medicines for the European Commission. The recommendation comes shortly after approvals in the US and Switzerland where Ilaris was granted priority review based on its potential to fulfill an important unmet need for CAPS patients.

The EU submission was supported by data showing that Ilaris, a monoclonal antibody formerly known as ACZ885, produced rapid and sustained remission of symptoms in up to 97% of CAPS patients, with most responding from the first injection(2).

Ilaris is given by subcutaneous injection only once every two months making it a convenient treatment, especially for younger patients(2). More than 90% of patients studied were free from painful injection-site reactions(2).

CAPS includes three distinct auto-inflammatory disorders. These are familial cold auto-inflammatory syndrome (FCAS) which is the mildest form of CAPS, Muckle-Wells syndrome (MWS), and neonatal-onset multisystem inflammatory disease (NOMID, also known as chronic infantile neurological cutaneous articular syndrome or CINCA) the most severe form of the disease(2),(3).

CAPS is a life-long and potentially fatal condition for which there are currently no approved medications in the European Union, said Helen J. Lachmann, MD of the UK National Amyloidosis Centre at UCL Medical School in London, UK. In clinical trials, canakinumab has been shown to switch off disease activity in as little as 24 hours following a single dose. It has the potential to transform patients' lives, not only providing relief from their debilitating daily symptoms but also offering the possibility of long-term control of the disease.

The symptoms of CAPS, 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(2),(3). Serious long-term consequences may include deafness, bone deformities, erosive joint destruction, and central nervous system damage leading to loss of vision(1),(2),(3). Around 25% of CAPS patients develop amyloidosis, a condition in which the build-up of proteins can cause vital organs to fail, resulting in renal failure and death within five to 10 years(1).

CAPS is believed to occur in around 6,500 patients worldwide and 2,500 in the EU(3),(6). However due to lack of diagnosis or misdiagnosis, fewer than 1,000 cases have been officially reported worldwide(1),(3).

The Ilaris filing was based on a clinical trial program involving more than 100 CAPS patients. The pivotal study is a three-part, one-year Phase III study involving 35 patients aged nine to 74 years old with varying degrees of disease severity(2). Data published in *The New England Journal of Medicine* in June 2009 show that Ilaris produced a rapid, complete and sustained response in the majority of patients(2).

Results for the primary endpoint showed that 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 general, Ilaris was well tolerated with 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 reported in Ilaris-treated patients were nasopharyngitis, diarrhea, influenza, headache and nausea(2).

No impact on the type or frequency of adverse events was seen with longer-term treatment(2). Ilaris was not associated with any severe reactions at the injection site, and those that did occur were mild-to-moderate in nature(2).

The CHMP recommended approval under exceptional circumstances, granted when comprehensive data are not yet available due to the rarity of the disease or limited scientific knowledge. The approval is subject to certain obligations for the company and is re-assessed each year until normal approval can be given.

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. A study in NOMID patients is under way in the US and priority reviews are being conducted in other countries, including Australia and Canada.

In addition to orphan drug status for CAPS, Ilaris has also been designated as an orphan drug for treating systemic juvenile idiopathic arthritis (SJIA) 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)(7) or fewer than five out of 10,000 people (in the EU)(8).

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as potentially, will, could, potential, may, or similar expressions, or by express or implied discussions regarding potential future regulatory filings or marketing approvals for Ilaris, or the timing of any such potential filings or approvals, 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, or that any such approvals will occur at any particular time. 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 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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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: July 24, 2009

By: /s/ MALCOLM B. CHEETHAM

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