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 September 27, 2011

(Commission File No. 1-15024)

Novartis AG

(Name of Registrant)

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(Address of Principal Executive Offices)

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- Investor Relations Release -

Novartis receives approval in Japan for two innovative therapies, Gilenya® in MS and Ilaris® in CAPS

- *Gilenya first high efficacy oral therapy approved in Japan for the prevention of relapse and delay of progression of physical disability in adults with multiple sclerosis (MS)*

- *Ilaris the first drug approved in Japan for the treatment of cryopyrin-associated periodic syndrome (CAPS), a rare and debilitating auto inflammatory disease*

- *Approvals demonstrate ongoing Novartis commitment to bringing innovative treatments to patients in Japan*

Basel, September 27, 2011 Novartis announced today that it received regulatory approval in Japan from the Ministry of Health, Labor and Welfare (MHLW) for once-daily Gilenya (fingolimod) 0.5mg for the prevention of relapse and delay of progression of physical disability in adults with multiple sclerosis (MS), and for Illaris (canakinumab) subcutaneous (s.c.) injection 150mg, the first treatment for adults and children with cryopyrin-associated periodic syndrome (CAPS).

In the US, Gilenya is approved for relapsing forms of MS. In the EU, Gilenya is approved for people with highly active relapsing-remitting MS despite treatment with beta interferon, or in patients with rapidly evolving severe relapsing-remitting MS.

The Ilaris approval is also extended to include all CAPS disease phenotypes: familial cold auto-inflammatory syndrome (FCAS), Muckle-Wells syndrome (MWS) and neonatal-onset multisystem inflammatory disease (NOMID).

Today s announcement demonstrates our continued commitment to bringing innovative new treatments to patients where there is significant unmet need, said David Epstein, Head of the Pharmaceuticals Division of Novartis. Strengthening our presence in Japan is a major priority for Novartis and we are pleased that the Japanese Health Authority have acknowledged the positive benefit-risk profiles of both Gilenya and Ilaris.

The Japanese approval of Gilenya was based on the largest clinical trial program submitted to date for a new MS drug, including Phase II data in Japan, and comprised data from clinical studies showing significant efficacy in reducing relapses, the risk of disability progression, and the

number of brain lesions detected by magnetic resonance imaging (MRI), a measure of disease activity(1)-(4) .

MS, an autoimmune disease, is designated as a specified disease by the Ministry of Health, Labor and Welfare and reportedly affects approximately 14,000 patients diagnosed and registered in Japan.(5)

Until now, there has been only interferon beta as an approved treatment for prevention of relapse in patients with MS in Japan, said Dr. Yasuto Itoyama, Director, National Center Hospital, National Center of Neurology and Psychiatry. Fingolimod has a novel mechanism of action that is different from existing drugs and its high efficacy has been confirmed in clinical studies in Japan and overseas. With its convenience as a once-daily oral formulation, we expect that fingolimod will become an important treatment option for MS patients in Japan.

Gilenya (fingolimod), licensed from Mitsubishi Tanabe Pharma Corporation, is the first in a new class of drugs that modulates sphingosine 1-phosphate (S1P) receptors(1),(2). It has been approved in more than 50 countries, including the US, Australia, Canada, EU members, Switzerland, Brazil, and Japan.

Gilenya demonstrated superior efficacy in relapse rates compared to interferon-beta-1a (IM), a commonly prescribed treatment, showing a 52% relative reduction in annualized relapse rate at one year in a pivotal head-to-head trial in patients with relapsing-remitting multiple sclerosis(1). In a two-year, placebo controlled study, Gilenya showed a 30% relative reduction in risk of sustained disability progression over two years versus placebo, as measured by the EDSS (Expanded Disability Statue Scale) and confirmed after three months(2).

In clinical trials, the most common Gilenya side effects were headache, liver enzyme elevations, influenza, diarrhea, back pain, and cough. Other Gilenya-related side effects include transient, generally asymptomatic, heart rate reduction and atrioventricular block upon treatment initiation, mild blood pressure increase, macular edema, and mild bronchoconstriction(1)-(4).

The rates of infections overall, including serious infections, were comparable among treatment groups, although a slight increase in lower respiratory tract infections (primarily bronchitis) was seen in patients treated with Gilenya. The number of malignancies reported across the clinical trial program was small, with comparable rates between the Gilenya and control groups(1)-(4).

Ilaris is a fully human monoclonal antibody that binds selectively to interleukin-1 beta (IL-1 beta), one of the inflammatory cytokines, neutralizing its activity(6). Ilaris is administered by subcutaneous injection once every eight weeks(6).

CAPS is a disease that comprises three different phenotypes, FCAS, MWS and NOMID, that are caused by the overproduction of IL-1 beta which induces an inflammatory reaction(7)-(9). Onset of symptoms starts at birth or childhood, and various symptoms such as fever, joint pain, rash, headaches, fatigue and conjunctivitis recur throughout patients lives(7),(10). In severe cases these may induce impaired hearing and vision, bone and joint deformities and nephropathy(7),(10).

Since no treatment was established for CAPS in the past and only symptomatic therapies were available in Japan, the needs of patients and their families had not been sufficiently met, said Professor Shunpei Yokota of the Department of Child Health and

Development, Yokohama City University School of Medicine. This is a very exciting development for the treatment of CAPS, as Ilaris produces a rapid remission of symptoms and inherently has the potential to improve patients quality of life and their outcome.

The clinical trial program of Ilaris for CAPS in Japan started in October 2009 and the drug received orphan drug status in August 2010. The submission in Japan was supported by a clinical program that included a local clinical study involving 19 patients and it comprised data from both non-Japanese and Japanese CAPS patients. In this study, Ilaris rapidly produced complete remission of symptoms in 94.7% and 100% of patients, at 24 and 48 weeks of administration respectively. Ilaris was generally well tolerated and there was no consistent pattern of adverse events apart from a slight increase in upper respiratory infections. The most common adverse events were nasopharyngitis and stomatitis.

Ilaris (canakinumab) is approved in more than 50 countries, including the EU, US and Switzerland for the treatment of adults and children as young as four with CAPS. Canakinumab is also being studied in other diseases in which IL-1 beta plays a key role in causing inflammation, such as JIA, gouty arthritis and secondary prevention of cardiovascular events. Not all potential patients with these diseases would be eligible for treatment with canakinumab, if approved.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as commitment, priority, expect, will, potential, or similar expressions, or by express or implied discussions regarding potential future marketing approvals for Gilenya, potential future marketing approvals or new indications or labeling for Ilaris, or regarding potential future revenues from Gilenya or Ilaris, or from the sales of Pharmaceutical Division products in Japan generally. 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 to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Gilenya will be submitted or approved for sale in any additional markets, or at any particular time. Nor can there be any guarantee that Ilaris will be submitted or approved sale in any additional markets, or for any additional indications or labeling in any market, or at any particular time. Nor can there be any guarantee that Gilenya or Ilaris, or the Novartis Pharmaceuticals Division portfolio in Japan will achieve any particular levels of revenue in the future. In particular, management s expectations regarding these products 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; 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, 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 121,000 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: September 27, 2011	By:	/s/ MALCOLM B. CHEETHAM
	Name:	Malcolm B. Cheetham
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