NOVARTIS AG
Form 6-K
November 08, 2012

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 November 7, 2012

(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:

Form 20-F: x Form 40-F: o

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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: o **No**: x

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Novartis drug Signifor® recommended by FDA advisory committee for approval to treat patients with Cushing s disease

- *Committee votes unanimously in favor of Signifor (pasireotide) as the first medication to treat US patients with Cushing s disease*

- *Pasireotide represents the first targeted approach for this potentially debilitating endocrine disorder caused by a pituitary tumor that triggers excess cortisol(1),(2)*

- *Majority of patients in the Phase III clinical trial experienced a rapid and sustained decrease in mean cortisol levels with subset of patients achieving normalization(3)*

Basel, November 7, 2012 The US Food and Drug Administration s (FDA) Endocrinologic and Metabolic Drugs Advisory Committee (EMDAC) has voted unanimously in support of the use of Signifor® (pasireotide) for the treatment of patients with Cushing s disease who require medical therapeutic intervention.

We are encouraged by today s favorable advisory committee recommendation for pasireotide in Cushing s disease and will work closely with the FDA as it completes its review of our application, said Hervé Hoppenot, President, Novartis Oncology. There is a significant unmet medical need for Cushing s disease patients and Novartis is committed to providing the endocrinology community with a novel therapeutic approach for this rare and debilitating endocrine disorder.

The recommendation was based on data from clinical trials of pasireotide, including PASPORT-CUSHINGS (PASireotide clinical trial PORTfolio - CUSHING S disease), the largest randomized Phase III study to evaluate a medical therapy in patients with Cushing s disease. Although not obliged to follow the recommendation, the FDA can seek the advice of its advisory committees as it reviews and decides whether to approve treatments(1),(4).

Results from the PASPORT-CUSHINGS study found that mean urinary-free cortisol (UFC), the key measure of biochemical control of the disease, was rapidly decreased and sustained in a majority of patients, with a subset of patients reaching normalized levels. The study also showed that, on average, as UFC levels were reduced, clinical manifestations of Cushing s disease improved. The most frequently reported

adverse events (AEs) (>10%) by investigators for pasireotide were diarrhea, nausea, hyperglycemia, cholelithiasis, abdominal pain, diabetes mellitus, injection site reactions, fatigue and increased glycosylated hemoglobin (HbA1c), with most events being Grade 1-2. The safety profile of pasireotide was similar to that of other somatostatin analogs (SSA) with the exception of the greater degree of hyperglycemia(3).

Cushing s syndrome is an endocrine disorder caused by excessive cortisol, a vital hormone that regulates metabolism, maintains cardiovascular function and helps the body respond to stress. Cushing s disease is a form of Cushing s syndrome, in which excess cortisol production is triggered by an adrenocorticotropic hormone (ACTH)-secreting pituitary adenoma. It is a rare but serious disease that affects approximately

one to two patients per million per year. Cushing s disease most commonly affects adults as young as 20 to 50 years and affects women three times more often than men. It may present with weight gain, central obesity, a round, red full face, severe fatigue and weakness, striae (purple stretch marks), high blood pressure, depression and anxiety. The first line and most common treatment approach for Cushing s disease is surgical removal of the tumor(1),(2),(5),(6),(7).

About pasireotide

Pasireotide is a multireceptor targeting somatostatin analog (SSA) that binds with high affinity to four of the five somatostatin receptor subtypes (sst 1, 2, 3 and 5)(2). In April 2012, the European Commission approved pasireotide under the brand name Signifor for the treatment of adult patients with Cushing s disease for whom surgery is not an option or for whom surgery has failed. Other worldwide regulatory filings for pasireotide for this use are also underway.

For the treatment of Cushing s diseasepasireotide has been studied as a twice-daily subcutaneous (sc) injection and is currently being evaluated as a long-acting release (LAR), once-monthly intramuscular (IM) injection as part of a global Phase III program in Cushing s disease and acromegaly(8),(9).

There is no guarantee that pasireotide will become commercially available anywhere else in the world. As an investigational compound, the safety and efficacy profile of pasireotide has not yet been established in all countries for the treatment of Cushing s disease or any other indications. Access to pasireotide outside of the approved indications has been carefully controlled and monitored in clinical trials designed to better understand the potential benefits and risks of the compound.

Information about Novartis clinical trials for pasireotide can be obtained by healthcare professionals at www.pasporttrials.com.

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The foregoing release contains forward-looking statements that can be identified by terminology such as recommended, potentially, encouraged, will, committed, recommendation, underway, potential, or similar expressions, or by express or implied discussions regarding potential marketing approvals for Signifor or regarding potential future revenues from Signifor. 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 Signifor to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Signifor will be approved for sale in any market, or at any particular time. Nor can there be any guarantee that Signifor will achieve any particular levels of revenue in the future. In particular, management s expectations regarding Signifor 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; unexpected manufacturing issues; 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 innovative healthcare solutions that address the evolving needs of patients and societies. Headquartered in Basel, Switzerland, Novartis offers a diversified portfolio to best meet these needs: innovative medicines, eye care, cost-saving generic pharmaceuticals, preventive vaccines and diagnostic tools, over-the-counter and animal health products. Novartis is the only global company with leading positions in these areas. In 2011, the Group s continuing operations achieved net sales of USD 58.6 billion, while approximately USD 9.6 billion (USD 9.2 billion excluding impairment and amortization charges) was invested in R&D throughout the Group. Novartis Group companies employ approximately 127,000 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:	November 7, 2012	By:	/s/ MALCOLM B. CHEETHAM
		Name:	Malcolm B. Cheetham
		Title:	Head Group Financial Reporting and Accounting