NOVARTIS AG
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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 December 14, 2012

(Commission File No. 1-15024)

Novartis AG

(Name of Registrant)

Lichtstrasse 35

4056 Basel

Switzerland

(Address of Principal Executive Offices)

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Novartis International AG
Novartis Global Communications
CH-4002 Basel
Switzerland

http://www.novartis.com

MEDIA RELEASE • COMMUNIQUE AUX MEDIAS • MEDIENMITTEILUNG

Novartis drug Signifor® gains FDA approval as the first medication to treat Cushing s disease, a serious endocrine disorder

- *As the only pituitary-directed therapy, Signifor represents a novel therapeutic approach by addressing the underlying mechanism of Cushing s disease(1)*

- *In the Phase III trial, most patients experienced a sustained decrease in mean urinary-free cortisol levels, a key measure of disease, with a subset normalizing(2)*

- *In the EU, Signifor has been previously approved for the treatment of adult patients with Cushing s disease; other worldwide regulatory filings are underway*

Basel, December 14, 2012 Novartis announced today that the US Food and Drug Administration (FDA) has approved Signifor® (pasireotide) injection for the treatment of adult patients with Cushing s disease for whom pituitary surgery is not an option or has not been curative(3). Signifor is the first medicine to be approved in the US that addresses the underlying mechanism of Cushing s disease, a serious, debilitating endocrine disorder caused by the presence of a non-cancerous pituitary tumor which ultimately leads to excess cortisol in the body(1),(4). This approval follows a unanimous recommendation from the FDA Endocrinologic and Metabolic Drugs Advisory Committee (EMDAC) in support of the use of Signifor.

The FDA approval of Signifor for Cushing s disease brings a novel pituitary-directed therapy to patients with limited treatment options, said Hervé Hoppenot, President, Novartis Oncology. Today s milestone reinforces Novartis commitment to addressing unmet needs and advancing treatments for rare pituitary-related disorders.

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. Cushing s disease can cause severe illness and death with mortality up to four times higher than in the healthy

population(1),(4),(5),(6),(7).

The approval is based on data from 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(3). Results from the PASPORT-CUSHINGS study found that a decrease in mean urinary-free cortisol (UFC), the key measure of biochemical control of the disease, was sustained during the treatment period in most patients with a subset of patients reaching normal levels. The study also showed that certain clinical manifestations of Cushing s disease tended to improve(2).

Patients with Cushing s disease may suffer from debilitating manifestations, and there are many serious health complications associated with the disease, said Mary Andrews, CEO and Co-Founder of the US non-profit, The MAGIC Foundation. The FDA approval of Signifor offers the option of a medical therapy that may help certain patients with Cushing s disease.

In April 2012, the European Commission approved 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.

About Cushing s disease

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 a pituitary adenoma secreting excess adrenocorticotropic hormone (ACTH). It is a rare but serious disease that affects approximately one to two patients per million per year. The first line and most common treatment approach for Cushing s disease is surgical removal of the tumor(4),(6),(8).

About PASPORT-CUSHINGS

PASPORT-CUSHINGS is a prospective, randomized, double-blind, Phase III study conducted at 68 sites in 18 countries. The study evaluated the efficacy and safety of Signifor in 162 adult patients with persistent or recurrent Cushing s disease, as well as in patients with newly diagnosed Cushing s disease who were not candidates for surgery(2).

Patients with UFC levels greater than 1.5 times the upper limit of normal (ULN) were randomized to receive Signifor subcutaneous (sc) injection in doses of 0.9 mg (n=80) or 0.6 mg (n=82) twice daily(2).

The primary endpoint, the proportion of patients who achieved normalization of UFC after six months without dose up-titration relative to randomized dose, was met in patients treated with 0.9 mg twice daily. Mean UFC levels were normalized in 26% and 15% of the patients randomized to receive Signifor 0.9 mg and 0.6 mg, respectively, at month six(2).

The median reduction in mean UFC from baseline to month six was around 47% in both dose groups. Reductions in UFC were observed after one month of treatment with Signifor and were sustained during the treatment period in most patients. In addition, 34% and 41% of patients experienced a reduction in mean UFC from baseline ≤ULN or ≥50% in the 0.6 mg and 0.9 mg groups, respectively(2).

Decreases in blood pressure, weight, body mass index and waist circumference were observed during the study. Limited conclusions can be drawn on these decreases due to variability of response across patients and the absence of a control group(2).

The most frequently reported adverse events (AE) (frequency >10%) by investigators for Signifor 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 tolerability profile of Signifor was similar to that of other somatostatin analogs with the exception of the greater degree of hyperglycemia(2).

About Signifor (pasireotide)

Signifor® (pasireotide) is approved in the US for the treatment of adult patients with Cushing s disease for whom pituitary surgery is not an option or has not been curative, and in the European Union for the treatment of adult patients with Cushing s disease for whom surgery is not an option or for whom surgery has failed.

For the treatment of Cushing s disease, Signifor 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. Signifor is a multireceptor targeting somatostatin

analog that binds with high affinity to four of the five somatostatin receptor subtypes (sst 1, 2, 3 and 5)(6),(9),(10).

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

Important Safety Information about Signifor

Signifor is contraindicated in patients with hypersensitivity to the active substances in Signifor or to any of the excipients and in patients with severe liver impairment.

Alterations in blood glucose levels have been frequently reported in healthy volunteers and patients treated with Signifor. Glycemic status should be assessed prior to starting treatment with Signifor. Patients need to be monitored for hyperglycemia; if hyperglycemia develops, the initiation or adjustment of antidiabetic treatment is recommended. Dose reduction or treatment discontinuation should be considered if uncontrolled hyperglycemia persists. After treatment discontinuation, glycemic monitoring (e.g. FPG or HbA1c) should be done according to clinical practice.

Monitoring of liver function is recommended prior to starting treatment with Signifor and after one, two, four, eight and twelve weeks during treatment and thereafter as clinically indicated. Therapy should be discontinued if the patient develops jaundice, other clinical signs of significant liver dysfunctions, sustained AST (aminotransferases) or ALT (alanine aminotransferase) increase five times the upper limit of normal or greater, or if ALT or AST increase three times ULN with concurrent bilirubin elevation greater than two times ULN.

Patients with cardiac disease and/or risk factors for bradycardia need to be closely monitored. Caution is to be exercised in patients who have or may develop QT prolongation. Hypokalemia or hypomagnesemia must be corrected prior to initiating therapy and monitored thereafter. Electrocardiography should be performed prior to the start of Signifor therapy and as clinically indicated thereafter.

Treatment with Signifor leads to rapid suppression of adrenocorticotropic hormone (ACTH) secretion in Cushing s disease patients. Patients need to be monitored and instructed how to monitor for signs and symptoms of hypocortisolism. Temporary exogenous steroid (glucocorticoid) replacement therapy and/or dose reduction or interruption of Signifor therapy may be necessary.

Monitoring of gallbladder and pituitary hormones is recommended prior to initiating treatment and periodically thereafter.

Signifor should not be used during pregnancy unless clearly necessary. Breast feeding should be discontinued during treatment with Signifor.

Signifor may affect the way other medicines work, and other medicines can affect how Signifor works. Caution is to be exercised with the concomitant use of drugs with low therapeutic index mainly metabolized by CYP3A4, bromocriptine, cyclosporine, anti-arrhythmic medicines or drugs that may lead to QT prolongation.

The most frequently reported adverse events (AE) (>10%) by investigators for Signifor 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 tolerability profile of Signifor was similar to that of other somatostatin analogs with the exception of the greater degree of hyperglycemia.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as underway, commitment, or similar expressions, or by express or

implied discussions regarding potential additional 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 additional markets, 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; competition in general; government, industry and general public pricing pressures; 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.

Novartis is on Twitter. Sign up to follow @Novartis at http://twitter.com/novartis.

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Novartis Media Relations

Central media line : +41 61 324 2200

Eric Althoff

Novartis Global Media Relations

+41 61 324 7999 (direct)

+41 79 593 4202 (mobile)

eric.althoff@novartis.com

Nicole Riley

Novartis Oncology

+1 862 778 3110 (direct)

+1 862 926 9040 (mobile)

nicole.riley@novartis.com

e-mail: media.relations@novartis.com

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For questions about the site or required registration, please contact: journalisthelp@thenewsmarket.com.

Novartis Investor Relations

Central phone:	+41 61 324 7944		
Samir Shah, MD	+41 61 324 7944	**North America:**	
Pierre-Michel Bringer	+41 61 324 1065	Helen Boudreau	+1 212 830 2404
Thomas Hungerbuehler	+41 61 324 8425	Jill Pozarek	+1 212 830 2445
Isabella Zinck	+41 61 324 7188	Edwin Valeriano	+1 212 830 2456
e-mail: investor.relations@novartis.com		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:	December 14, 2012	By:	/s/ MALCOLM B. CHEETHAM
		Name:	Malcolm B. Cheetham
		Title:	Head Group Financial Reporting and Accounting