NOVARTIS AG
Form 6-K
April 20, 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 April 19, 2012

(Commission File No. 1-15024)

Novartis AG

(Name of Registrant)

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(Address of Principal Executive Offices)

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

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MEDIA RELEASE • COMMUNIQUE AUX MEDIAS • MEDIENMITTEILUNG

Novartis announces Aliskiren will continue to be available to appropriate patients, as FDA interim assessment is concluded; product information updated

- *Combination product Valturna® to be voluntarily withdrawn from the US market as of July 20, 2012*

Basel, Switzerland April 19, 2012 Novartis announced today that the Tekturna® labels have been updated in the US, following the US Food and Drug Administration s (FDA) review of the preliminary findings from the ALTITUDE study.

The label change includes a contraindication against combined use of aliskiren-based products with angiotensin converting enzyme (ACE) inhibitors or angiotensin receptor blockers (ARBs) in patients with diabetes. The FDA has also requested the inclusion of a warning against the use of aliskiren-based products in patients with moderate renal (kidney) impairment (eGFR < 60 ml/min) who are also taking an ACE inhibitor or an ARB. Aliskiren-based products will continue to be available in the US for the treatment of high blood pressure in appropriate patients.

Furthermore, and in consultation with the FDA, Novartis has decided to voluntarily cease marketing in the US of Valturna® (aliskiren and valsartan, USP), a single pill combination of aliskiren and the ARB valsartan. Valturna sales in the US represented less than 10% of Aliskiren sales in 2011. Novartis advises US patients to seek guidance from their prescribing healthcare provider at their next (non-urgent) visit to determine appropriate alternate therapy. Novartis has also decided to voluntarily withdraw marketing authorization of the same combination pill in Switzerland, Rasival® (aliskiren and valsartan), which received marketing approval for export but was not launched.

These decisions come after extensive discussions with the FDA and Swissmedic, said David Epstein, Division Head of Novartis Pharmaceuticals. Patient safety continues to be our highest priority and we will continue to work with health authorities worldwide to provide aliskiren-based products to the most appropriate patient population who would benefit.

These updates follow the Novartis announcement on February 17, 2012 that the European Medicines Agency s (EMA) Committee for Medicinal Products for Human Use (CHMP) concluded the risk-benefit review of Rasilez and combination products containing aliskiren and confirmed it remains positive in the European Union (EU) for the treatment of essential hypertension, with label changes.

About Aliskiren-based products in the US

The US Prescribing Information has been updated for Tekturna, Tekturna HCT® (aliskiren and hydrochlorothiazide), Tekamlo (aliskiren and amlodipine) and Amturnide (aliskiren, amlodipine and hydrochlorothiazide).

In view of the importance of controlling high blood pressure and to enable physicians to transition patients to alternate therapies, Novartis will make Valturna available in the US until July 20, 2012. Novartis advises patients in the US to seek guidance from their

prescribing healthcare provider at their next (non-urgent) visit, prior to July 20, 2012, to determine appropriate alternate therapy. Novartis will communicate to US physicians informing them of the above actions.

About ALTITUDE

ALTITUDE was a multinational study in 8,606 patients from 36 countries evaluating the potential benefits of aliskiren to reduce the risk of cardiovascular and renal events in this patient population.

ALTITUDE was the first randomized, double-blind, placebo-controlled study to investigate aliskiren for more than one year in a specific population of patients with type 2 diabetes and renal impairment. These patients are known to be at high risk of cardiovascular and renal events. In the study, aliskiren was given in addition to optimal cardiovascular treatment including an angiotensin converting enzyme (ACE) inhibitor or angiotensin receptor blocker (ARB).

About Aliskiren

Aliskiren was approved in the US and EU in 2007 under the brand names Tekturna and Rasilez, respectively, for the treatment of hypertension either as monotherapy or in combination with other medications. It is available in 63 countries. These products remain available for appropriate patients. For additional information, please visit http://www.novartis.com/newsroom/product-related-info-center/resilez-tekturna.shtml.

US Important Safety Information

TEKTURNA, TEKTURNA HCT, TEKAMLO, and AMTURNIDE are indicated for the treatment of hypertension in adults, to lower blood pressure. Lowering blood pressure reduces the risk of fatal and nonfatal cardiovascular events, primarily strokes and myocardial infarctions. Control of high blood pressure should be part of comprehensive cardiovascular risk management, including, as appropriate, lipid control, diabetes management, antithrombotic therapy, smoking cessation, exercise, and limited sodium intake. Many patients will require more than one drug to achieve blood pressure goals.

AMTURNIDE is not indicated for initial therapy of hypertension

Use TEKTURNA HCT or TEKAMLO as initial therapy in patients who are likely to need multiple drugs to achieve their blood pressure goals. Switch a patient whose blood pressure is not adequately controlled with aliskiren or hydrochlorothiazide (HCTZ) monotherapy to TEKTURNA HCT. Switch a patient whose blood pressure is not adequately controlled with aliskiren or amlodipine (or another dihydropyridine calcium channel blocker [DHP-CCB]) alone to combination therapy with TEKAMLO.

Use AMTURNIDE for patients not adequately controlled with any two of the following: aliskiren, DHP-CCB, and thiazide diuretics. Switch a patient who experiences dose-limiting adverse reactions attributed to an individual component while on any dual combination of components of AMTURNIDE to AMTURNIDE at a lower dose of that component to achieve similar blood pressure reductions.

TEKTURNA HCT, TEKAMLO, and AMTURNIDE may be substituted for their titrated components.

Safety and efficacy of aliskiren in pediatric patients have not been established.

Base the choice of TEKTURNA HCT or TEKAMLO as initial therapy on an assessment of potential benefits and risks. Individualize the decision to use a combination as initial therapy by weighing factors such as baseline blood pressure, the target goal, and the incremental likelihood of achieving goal with a combination compared to monotherapy.

IMPORTANT SAFETY INFORMATION

WARNING: AVOID USE IN PREGNANCY

When pregnancy is detected, discontinue TEKTURNA, TEKTURNA HCT, TEKAMLO, or AMTURNIDE as soon as possible. Drugs that act directly on the renin-angiotensin-aldosterone system can cause injury and even death to the developing fetus. See Warnings and Precautions (5.1).

Contraindications: Do not use aliskiren with angiotensin receptor blockers (ARBs) or ACE inhibitors (ACEIs) in patients with diabetes because of increased risk of renal impairment, hyperkalemia, and hypotension.

Because of the HCTZ component, TEKTURNA HCT and AMTURNIDE are contraindicated in patients with anuria or hypersensitivity to sulfonamide-derived drugs like HCTZ. Hypersensitivity reactions may range from urticaria to anaphylaxis.

Angioedema: Angioedema of the face, extremities, lips, tongue, glottis and/or larynx has been reported in patients treated with aliskiren and has necessitated hospitalization and intubation. This may occur at any time during treatment and has occurred in patients with and without a history of angioedema with ACEIs or angiotensin receptor antagonists. Discontinue TEKTURNA, TEKTURNA HCT, TEKAMLO, or AMTURNIDE immediately in patients who develop angioedema, and do not readminister.

Hypotension: In patients with an activated renin-angiotensin-aldosterone system (RAAS), such as volume- and/or salt-depleted patients receiving high doses of diuretics, symptomatic hypotension may occur in patients receiving RAAS blockers. Correct these conditions before administering TEKTURNA, TEKTURNA HCT, TEKAMLO, or AMTURNIDE, or start the treatment under close medical supervision.

Risk of MI or Angina: Rarely, initiation or change to the dose of a calcium channel blocker has resulted in the increased frequency, duration, or severity of angina or acute myocardial infarction, particularly in patients with severe obstructive coronary artery disease.

Impaired Renal Function: Avoid use of TEKTURNA, TEKTURNA HCT, TEKAMLO, or AMTURNIDE with ARBs or ACEIs in patients with moderate renal impairment (GFR <60 mL/min). Monitor renal function periodically in patients receiving aliskiren, as changes in renal function, including acute renal failure, can be caused by drugs that affect the RAAS. Patients whose renal function may depend in part on the activity of the RAAS (eg, patients with renal artery stenosis, severe heart failure, post-MI, or volume depletion) or patients receiving ARB, ACEI or NSAID therapy may be at particular risk for developing acute renal failure on aliskiren. Consider withholding or discontinuing therapy in patients who develop a clinically significant decrease in renal function.

Hepatic Considerations: Amlodipine is extensively metabolized by the liver, and the plasma elimination half-life is 56 hours in patients with impaired hepatic function. In patients with severe hepatic impairment, start amlodipine at 2.5 mg per day, a dose not available in TEKAMLO and AMTURNIDE.

Hyperkalemia: Monitor serum potassium periodically in patients receiving aliskiren. Drugs that affect the RAAS can cause hyperkalemia. Risk factors for the development of hyperkalemia include renal insufficiency, diabetes, and combination use of aliskiren with ARBs or ACEIs, NSAIDs, potassium supplements, or potassium-sparing diuretics.

Cyclosporine, Itraconazole, or Lithium: Avoid use of TEKTURNA, TEKTURNA HCT, TEKAMLO, or AMTURNIDE with cyclosporine or itraconazole. Additionally, avoid use of TEKTURNA HCT or AMTURNIDE with lithium.

Important Considerations Due to the HCTZ Component: Hypersensitivity reactions to HCTZ may occur in patients with or without a history of allergy or bronchial asthma, but

are more likely in those with such a history. Thiazides have been reported to cause exacerbation or activation of systemic lupus erythematosus.

HCTZ can cause hypokalemia and hyponatremia. Hypomagnesemia can result in hypokalemia which appears difficult to treat despite potassium repletion. HCTZ may alter glucose tolerance and raise serum levels of cholesterol and triglycerides. HCTZ may raise serum uric acid level and may cause or exacerbate hyperuricemia and precipitate gout in susceptible patients. Monitor calcium levels in patients with hypercalcemia receiving TEKTURNA HCT or AMTURNIDE, as HCTZ may cause elevations of serum calcium.

HCTZ, a sulfonamide, can cause an idiosyncratic reaction resulting in transient myopia and angle-closure glaucoma. Symptoms include acute onset of decreased visual acuity or ocular pain and typically occur within hours to weeks of drug initiation. Discontinue HCTZ as rapidly as possible in these patients. Risk factors for developing acute angle-closure glaucoma may include a history of sulfonamide or penicillin allergy.

Common AEs: Adverse events (AE) with increased rates for TEKTURNA compared with placebo included: diarrhea (2.3% vs 1.2%), cough (1.1% vs 0.6%), rash (1.0% vs 0.3%), elevated uric acid (0.4% vs 0.1%), gout (0.2% vs 0.1%), and renal stones (0.2% vs 0%).

Adverse events with increased rates for TEKTURNA HCT compared with placebo included: dizziness (2.3% vs 1.0%), influenza (2.3% vs 1.6%), diarrhea (1.6% vs 0.5%), cough (1.3% vs 0.5%), vertigo (1.2% vs 0.5%), asthenia (1.2% vs 0%), and arthralgia (1.0% vs 0.5%).

The AE in a placebo-controlled trial that occurred in at least 2% of patients treated with TEKAMLO and at a higher incidence than placebo was peripheral edema (6.2% vs 1.0%). The incidence of peripheral edema at high dose was 8.9%.

The most common AEs in a short-term controlled trial that occurred in at least 2% of patients treated with AMTURNIDE were peripheral edema (7.1%), dizziness (3.6%), headache (3.6%), and nasopharyngitis (2.6%).

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as to be withdrawn, will, potential, or similar expressions, or by express or implied discussions regarding potential future revenues from Tekturna. 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 Tekturna to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Tekturna will achieve any particular levels of revenue in the future. In particular, management s expectations regarding Tekturna 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; 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 124,000 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: April 19, 2012

By: /s/ MALCOLM B. CHEETHAM

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