NOVARTIS AG
Form 6-K
February 17, 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 February 17, 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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Yes: o **No**: x

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Yes: o **No**: x

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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MEDIA RELEASE • COMMUNIQUE AUX MEDIAS • MEDIENMITTEILUNG

Novartis to revise product information in the European Union for high blood pressure drug Rasilez® following assessment by CHMP

- *CHMP concluded the risk-benefit review of Rasilez* (aliskiren) and confirmed it remains positive for the treatment of essential hypertension*

- *CHMP has requested that the Rasilez (aliskiren) product information be updated in the EU to include a contraindication against combined use of aliskiren with an ACE inhibitor or an ARB in patients with diabetes and/or patients with moderate to severe renal impairment*

- *CHMP has also requested the inclusion of a warning against the use of aliskiren in patients who are taking an ACE inhibitor or an ARB*

- *This decision follows extensive interactions between Novartis and the CHMP following the Novartis decision in December 2011 to halt the ALTITUDE study after unexpected preliminary findings*

- *Patient safety is the highest priority for Novartis, and we will continue to work with health authorities worldwide in the best interest of patients*

Basel, February 17, 2012 Novartis announced today that the European Medicines Agency s (EMA) Committee for Medicinal Products for Human Use (CHMP) has 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. In addition, the CHMP has requested an update to the product information of Rasilez® (aliskiren) and combination products containing aliskiren available in the EU.

The CHMP has requested that Rasilez and combination products containing aliskiren are contraindicated in patients who are receiving an angiotensin converting enzyme (ACE) inhibitor or angiotensin receptor blocker (ARB) who also have diabetes and/or moderate to severe renal impairment (GFR < 60 ml/min/1.73 m(2)). In addition, the CHMP has requested the inclusion of a warning against the use of Rasilez and combination products containing aliskiren in patients who are also taking an ACE inhibitor or an ARB.

This decision comes after extensive interactions between Novartis and the CHMP. Patient safety continues to be the highest priority for Novartis, and we are working closely with the CHMP, EMA and other health authorities worldwide to continue to provide Rasilez and combination products containing aliskiren to the most appropriate patient population who would benefit, said David Epstein, Division Head of Novartis Pharmaceuticals.

The product information for Rasilez and combination products containing aliskiren in the EU are being updated. Novartis will also write to physicians in the EU informing them of these changes to the product information.

* Rasilez is sold in the United States under the brand name Tekturna®.

The CHMP review of Rasilez risk-benefit began in December 2011 following the Novartis decision to halt the ALTITUDE study after the Data Monitoring Committee reviewed preliminary interim analyses and concluded that study patients were unlikely to benefit from aliskiren and there was a higher incidence of adverse events related to non-fatal stroke, renal complications, hyperkalaemia and hypotension in this high-risk population.

Starting in December 2011, Novartis wrote to physicians worldwide recommending that patients with type 2 diabetes should not be treated with aliskiren, or combination products containing aliskiren, if they are also receiving an ACE inhibitor or ARB. This recommendation remains in place in countries outside of the EU as Novartis continues discussions with the respective health authorities, including the US FDA. As a precautionary measure, in December 2011 Novartis stopped promotion of Rasilez/Tekturna and combination products containing aliskiren in combination with an ACE inhibitor or ARB.

Based on the revised product information, physicians in the EU will now be advised that patients who have diabetes and/or moderate to severe renal impairment, who are also taking Rasilez and an ACE inhibitor or an ARB, should receive alternate treatment under a physician s supervision. In other patients taking Rasilez or combination products containing aliskiren in combination with an ACE inhibitor or an ARB, the balance of benefits and risks of continuing treatment should be considered carefully.

Any patients using Rasilez or combination products containing aliskiren who may have questions about their medication should consult their healthcare provider. For more information visit http://www.novartis.com/newsroom/rasilez-tekturna-information-center/index.shtml.

The label changes in the EU will be applied to all approved aliskiren-based products. These products include Rasilez®, Sprimeo®, Riprazo®, Rasilez HCT®, Sprimeo HCT®, Riprazo HCT®, Rasilamlo®, and Rasitrio®.

About Aliskiren

Aliskiren was approved in the EU and US in 2007 under the brand names Rasilez and Tekturna 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.

Rasilez-based products available in the EU include:

- Rasilez/ Sprimeo/ Riprazo
- Rasilez HCT/ Sprimeo HCT/ Riprazo HCT, a single-pill combination of Rasilez and hydrochlorothiazide (HCT)
- Rasilamlo, a single-pill combination of Rasilez and amlodipine
- Rasitrio, a triple combination of Rasilez, amlodipine and hydrochlorothiazide (HCT)

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).

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as to revise, will, continue, or similar expressions, or by express or implied discussions regarding the potential outcome of our ongoing discussions with health authorities concerning aliskiren, or regarding the potential future impact of the ALTITUDE study on Novartis, or regarding potential future revenues from aliskiren. 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 aliskiren to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee as to the outcomes of our ongoing discussions with health authorities concerning. Neither can there be any guarantee as to what future impacts the ALTITUDE study may have on Novartis in the future. Nor can there be any guarantee that aliskiren will achieve any particular levels of revenue in the future. In particular, management s expectations regarding aliskiren 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; uncertainties regarding actual or potential legal proceedings; unexpected manufacturing issues; 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 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: February 17, 2012

By: /s/ MALCOLM B. CHEETHAM

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