

NOVARTIS AG
Form 6-K
February 18, 2011

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 18, 2011

(Commission File No. 1-15024)

Novartis AG

(Name of Registrant)

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4056 Basel

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:

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Yes: ☐ **No:** ☒

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- Investor Relations Release -

Novartis gains positive CHMP opinion for Rasilamlo – a single-pill combination of aliskiren and amlodipine to treat high blood pressure

- *Rasilamlo combines in a single pill the only approved direct renin inhibitor, Rasilez, with the widely used calcium channel blocker amlodipine*
- *Data from over 5,000 mild-to-severe high blood pressure patients showed Rasilamlo significantly reduced blood pressure compared to amlodipine or Rasilez alone(1)*
- *Up to 85 percent of patients may need multiple medications to help control their high blood pressure underscoring the need for effective combination treatments(2),(3)*

Basel, February 18, 2011 The European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion for Rasilamlo (aliskiren and amlodipine) to treat high blood pressure patients not adequately controlled by either aliskiren or amlodipine alone. Rasilamlo combines in a single pill the only approved direct renin inhibitor worldwide, Rasilez®, with the widely used calcium channel blocker amlodipine.

The CHMP recommendation forms the basis for a European Commission licensing decision, which is expected in approximately three months.

We are delighted with the CHMP opinion because it means that Rasilamlo could soon be made available to patients in the EU in need of effective combination treatments to help control their high blood pressure, said David Epstein, Division Head of Novartis Pharmaceuticals. Novartis understands the complex needs of high blood pressure patients and is committed to furthering cardiovascular research and to developing innovative and effective treatments.

The CHMP positive opinion of Rasilamlo is based on clinical trial data involving more than 5,000 patients with mild-to-moderate high blood pressure. An eight-week, randomized, double-blind, placebo-controlled, multi-factorial study showed that the combination of Rasilez and amlodipine resulted in decreases in systolic/diastolic blood pressure at trough of 14-17/9-11 mmHg, compared to 4-9/3-4 mmHg for Rasilez alone, and 9-14/6-8 mmHg for amlodipine alone(1).

In two additional double-blind, active-controlled studies of similar design evaluating patients with moderate-to-severe high blood pressure (systolic blood pressure [SBP] 160 - 200 mmHg), Rasilamlo demonstrated significantly greater reductions in systolic and diastolic blood pressures when compared to amlodipine alone(1). In one study of 443 patients, the systolic/diastolic treatment difference between Rasilez and amlodipine was 5.2/3.8 mmHg at the primary endpoint of eight weeks(1). In the other study of 484 patients, the treatment difference between Rasilez and amlodipine was 7.1/3.8 mmHg at endpoint(1).

The single-pill combination Rasilamlo works to lower blood pressure in two ways. The Rasilez component targets the activity of the renin angiotensin aldosterone system (RAAS), an important

regulator of blood pressure. Rasilez directly binds to and inhibits renin, an enzyme produced by the kidneys that starts a process that can make blood vessels narrow and lead to high blood pressure(4). The calcium channel blocker amlodipine lowers blood pressure by relaxing the blood vessel walls through the inhibition of calcium. Both of these medicines enable blood to flow more easily therefore lowering blood pressure.

Single-pill combination therapies can simplify the challenging treatment regimens of high blood pressure patients on multiple medications, said Professor Gordon McInnes, Professor of Clinical Pharmacology, Institute of Cardiovascular & Medical Sciences, University of Glasgow.

Rasilez demonstrated greater blood pressure reductions than either aliskiren or amlodipine alone in clinical studies and can be expected to provide a convenient new treatment option to consider for uncontrolled patients.

It is estimated that about one billion people globally have high blood pressure(5),(6), and many of these remain either untreated or treated but not at their blood pressure target(7). High blood pressure can cause damage to the vital organs of the body, including the heart, brain and kidneys(6). However, if high blood pressure is properly controlled, the incidence of stroke and heart failure can be reduced by almost half and heart attacks by one quarter(6).

Tekturna/Rasilez is approved in over 80 countries. Tekturna was approved in the US in March 2007 and in the European Union in August 2007 under the trade name Rasilez. Rasilez received approval in Canada in June 2008, Japan in July 2009 and China in March 2010. Tekturna HCT®, a single-pill combination of aliskiren and hydrochlorothiazide (HCT), was approved in the US in January 2008 for second-line treatment of high blood pressure, and in July 2009 for first-line treatment of high blood pressure. The single-pill combination Rasilez HCT® was approved for add-on and replacement therapy in the European Union in January 2009. In September 2009, Valturna®, a single-pill combination of aliskiren and valsartan (Diovan®), was approved in the US. Tekamlo®, the single-pill combination of aliskiren and amlodipine was approved in the US in August 2010. Amturnide®, the triple-combination of aliskiren, amlodipine and hydrochlorothiazide (HCTZ), was approved in the US in December 2010.

Novartis has a strong cardiovascular and metabolic portfolio, focusing on innovative treatments for high blood pressure and diabetes. These include Diovan® (valsartan), the number one selling blood pressure medication worldwide(8), Exforge® (valsartan/ amlodipine), a single-pill combining two leading medicines for high blood pressure; Exforge HCT® (amlodipine/valsartan/HCT); and Rasilez® (aliskiren), the first and only approved direct renin inhibitor, and two single-pill combinations of Rasilez®, Rasilez HCT® (aliskiren/HCT) and Valturna® (aliskiren/valsartan). For the treatment of type 2 diabetes, these include Galvus® (vildagliptin, a DPP-4 inhibitor) and Eucreas® (vildagliptin and metformin).

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as expected, committed, or similar expressions, or by express or implied discussions regarding potential future approvals for Rasilez or regarding potential future revenues from Rasilez. 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 Rasilez to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Rasilez will be approved for sale in any market. Nor can there be any guarantee that Rasilez will achieve any particular levels of revenue in the future. In particular, management's expectations regarding Rasilez 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; 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 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, cost-saving generic pharmaceuticals, preventive vaccines, diagnostic tools and consumer health products. 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 activities throughout the Group. Headquartered in Basel, Switzerland, Novartis Group companies employ approximately 119,000 full-time-equivalent associates (including 16,700 Alcon associates) and operate in more than 140 countries around the world. For more information, please visit <http://www.novartis.com>.

References

- (1) Rasilamlo (aliskiren and amlodipine) Tablets DRAFT Prescribing Information. February 2011.
- (2) Dahlof B, et al. Cardiovascular Morbidity and Mortality in the Losartan Intervention for Endpoint Reduction in Hypertension Study (LIFE): a Randomised Trial Against Atenolol. *Lancet* 2002;359:995-1003.
- (3) Pepine CJ, Handberg EM, Cooper-DeHoff RM, et al. A Calcium Antagonist vs. a Non-Calcium Antagonist Hypertension Treatment Strategy for Patients with Coronary Artery Disease. The International Verapamil-Trandolapril Study (INVEST): a Randomized Controlled Trial. *JAMA* 2003;290:2805-2816.
- (4) Rasilez Summary of Product Characteristics (SmPC) for European Union.
- (5) Kearney P, et al. Global Burden of Hypertension: Analysis of Worldwide Data. *Lancet* 2005;365:217-23.
- (6) Chobanian AV, et al. Seventh Report of the Joint National Committee on Prevention, Detection Evaluation and Treatment of High Blood Pressure. *Hypertension* 2003;42:1206-1251.
- (7) Lloyd-Jones D, Adams R, Brown T, et al. for the American Heart Association Statistics Committee and Stroke Statistics Subcommittee. Heart disease and stroke statistics 2010 update. A report from the American Heart Association Statistics Committee and Stroke Statistics Subcommittee. *Circulation*. 2010;121:e46-e215.
- (8) IMS Midas Worldwide Sales Data 2010.

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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 18, 2011

By: /s/ MALCOLM B. CHEETHAM

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