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 September 23, 2011

(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

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):

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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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- Investor Relations Release -

Novartis gains positive CHMP opinion for Rasitrio®, first Rasilez-based triple combination pill in Europe to treat high blood pressure

- *Rasitrio combines the only approved direct renin inhibitor, Rasilez®, with the calcium channel blocker amlodipine, and the diuretic hydrochlorothiazide (HCT)(1)*

- *In Phase III data, Rasitrio demonstrated significantly greater blood pressure reductions compared to dual combinations of each of its individual components(2)*

- *Up to 85 percent of patients may need multiple medications to help control their high blood pressure underscoring the need for effective combination treatments(3),(4)*

Basel, September 23, 2011 Novartis announced today that the European Medicines Agency s Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion for Rasitrio® for the treatment of high blood pressure.

Rasitrio has been recommended as replacement therapy in patients whose blood pressure is adequately controlled on a combination of its components given concurrently at the same dose level as in the combination.

This positive CHMP opinion is an important step towards approval and making this new triple combination therapy available for patients whose blood pressure is not under control and who may require multiple medications, said David Epstein, Division Head of Novartis Pharmaceuticals. Novartis is dedicated to providing innovative, patient-focused treatment options that simplify treatment plans.

Rasitrio combines in a single-pill the only approved direct renin inhibitor worldwide, Rasilez®, with the widely used calcium channel blocker amlodipine and the diuretic hydrochlorothiazide(1). The triple combination of aliskiren, amlodipine and hydrochlorothiazide (HCT), was approved in the United States in December 2010 under the trade name Amturnide®.

The European Commission generally follows the recommendations of the CHMP and delivers its final decision within three months of the CHMP recommendation.

The CHMP positive opinion of Rasitrio is based on clinical trial data involving more than 1,181 high blood pressure patients. The Phase III pivotal study showed that Rasitrio produced statistically significant blood pressure reductions compared to dual combinations of each of its individual components, including aliskiren/amlodipine 300 mg/10 mg, aliskiren/HCTZ 300 mg/25 mg and amlodipine/HCTZ 10 mg/25 mg(2). The effect of Rasitrio was observed as early as one week after initiation of therapy and was maintained over the entire 24-hour dose interval(2).

Adherence to treatment is often very challenging for patients requiring three or more medications to manage their high blood pressure, said Professor Roland E. Schmieder, M.D., University

Hospital of the University Erlangen-Nuremberg, Germany. Triple combination therapy with Rasitrio provides patients with a comprehensive and convenient high blood pressure treatment in one pill.

The single-pill combination Rasitrio works to lower blood pressure in three 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(5). The calcium channel blocker amlodipine lowers blood pressure by relaxing the blood vessel walls, and the diuretic hydrochlorothiazide increases the excretion of sodium chloride and water. All three complementary medicines enable blood to flow more easily, therefore lowering blood pressure.

It is estimated that about one billion people globally have high blood pressure(6),(7), with many remaining uncontrolled despite treatment(8). High blood pressure alone can cause damage to the vital organs of the body, including the heart, brain and kidneys(7). It is also linked with other conditions such as diabetes, where high blood pressure is estimated to cause up to 75% of diabetic cardiovascular complications(9). 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(7). Up to 85 percent of patients may need multiple medications to help control their high blood pressure(3),(4).

About Tekturna/Rasilez

Tekturna/Rasilez is approved in over 80 countries. Aliskiren was approved in the US and in the European Union in 2007 under the trade name of Tekturna and Rasilez respectively. Rasilez received approval in Canada in 2008, Japan in 2009 and China in March 2010. Tekturna HCT®, a single-pill combination of aliskiren and hydrochlorothiazide (HCT), was approved in the US in 2008 for second-line treatment of high blood pressure, and in 2009 for first-line treatment of high blood pressure. This single-pill combination was approved for add-on and replacement therapy in the European Union in 2009 under the trade name Rasilez HCT®. In 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 and in the European Union under the trade name Rasilamlo® in April 2011. Amturnide®, the triple combination of aliskiren, amlodipine and hydrochlorothiazide (HCT), was approved in the U.S. 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 branded blood pressure medication worldwide(10), Co-Diovan (valsartan and hydrochlorothiazide), a single-pill combination of valsartan with the most widely prescribed diuretic. 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 four single-pill combinations of Rasilez®, Tekamlo®/Rasilamlo® (aliskiren/amlodipine), Amturnide (aliskiren/amlodipine/HCT), Tekturna HCT®/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 may, recommended, dedicated, generally follows, recommendations, recommendation, or similar expressions, or by express or implied discussions regarding potential future marketing approvals for Rasitrio, or regarding potential future revenues from Rasitrio. 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 Rasitrio to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Rasitrio will be approved for sale in any

market. Nor can there be any guarantee that Rasitrio will achieve any particular levels of revenue in the future. In particular, management s expectations regarding Rasitrio could be affected by, among other things, unexpected regulatory actions or delays or government regulation generally; competition in general; government, industry and general public pricing pressures; 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; 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, eye care, cost-saving generic pharmaceuticals, consumer health products, preventive vaccines and diagnostic tools. 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 throughout the Group. Headquartered in Basel, Switzerland, Novartis Group companies employ approximately 121,000 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.

References

(1) Rasitrio (aliskiren, amlodipine and hydrochlorothiazide) Tablets Prescribing Information. September 2011.
(2) Data on file. Novartis 2011 (Study SAH2302).
(3) 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.
(4) 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.
(5) Rasilez Summary of Product Characteristics (SmPC) for European Union.
(6) Kearney P, et al. Global Burden of Hypertension: Analysis of Worldwide Data. *Lancet* 2005;365:217-23.
(7) 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.
(8) 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.
(9) El-Atat F, et al. Diabetes, Hypertension, and Cardiovascular Derangements: Pathophysiology and Management. Curr Hypertens Rep 2004;6:215-23.
(10) 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: September 23, 2011	By:	/s/ MALCOLM B. CHEETHAM
	Name:	Malcolm B. Cheetham
	Title:	Head Group Financial Reporting and Accounting