

NOVARTIS AG
Form 6-K
November 28, 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 November 28, 2011

(Commission File No. 1-15024)

Novartis AG

(Name of Registrant)

Lichtstrasse 35

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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Form 20-F: ☒ **Form 40-F:** ☐

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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: ☐ **No:** ☒

Novartis International AG

Novartis Global Communications
CH-4002 Basel
Switzerland
<http://www.novartis.com>

- Investor Relations Release -

Novartis gains European Commission approval for Rasitrio®, a Rasilez-based triple combination pill to treat high blood pressure

- *Pivotal phase III data showed significantly greater blood pressure reductions with Rasitrio compared to dual combinations of each of its individual components(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, November 28, 2011 Novartis announced today that Rasitrio®, the first triple combination of aliskiren, amlodipine and hydrochlorothiazide (HCT) in a single pill,(1) has received approval from the European Commission (EC) for the treatment of high blood pressure.

For the first time, high blood pressure patients in Europe with complex needs will have access to a single pill combining the unique properties of Rasilez with two well-established and effective high blood pressure treatments, said David Epstein, Division Head of Novartis Pharmaceuticals.

Rasitrio is the first Rasilez-based triple combination pill available in Europe to help patients requiring multiple medications reach their treatment goal.

Rasitrio combines the first and only approved direct renin inhibitor (DRI) worldwide, Rasilez, with the widely used calcium channel blocker amlodipine and the diuretic hydrochlorothiazide(4). Rasilez is an important component of the treatment as it targets renin for optimal control of the RAAS (renin angiotensin aldosterone system) (5), which is a key regulator of high blood pressure. Rasitrio has been approved as substitution therapy for patients with high blood pressure that are adequately controlled by the combination of the three components at the same dose.

The approval of Rasitrio is based on pivotal phase III data involving more than 1,181 high blood pressure patients. The 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(1). 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(1).

(1) Sold in the US as Amturnide®.

Up to 85 percent of high blood pressure patients may need several medications to help them reach their goal(2),(3). However, the management of multiple drugs can lead to compliance concerns, a major challenge for primary care physicians(6).

Simplification of treatment for high blood pressure patients on three or more therapies is key to improving patient compliance and outcomes, said Professor Josep Redon, M.D., Hospital Clinico, University of Valencia, Spain. This innovative triple combination therapy, which has demonstrated significant reductions in blood pressure during clinical trials, offers patients a new and convenient treatment option.

The single pill combination Rasitrio works to lower blood pressure in three ways. The Rasilez component 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(7),(8), with many remaining uncontrolled despite treatment(9). High blood pressure alone can cause damage to the vital organs of the body, including the heart, brain and kidneys(8). 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(10). 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(8).

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 tradename 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 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 branded blood pressure medication worldwide(11), 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*, *will*, *can*, or similar expressions, or by express or implied discussions 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 achieve any particular levels of revenue in the future. In particular, management's expectations regarding Rasitrio could be affected by, among other things, competition in general; government, industry and general public pricing pressures; 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; 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 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. 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) Data on file. Novartis 2011 (Study SAH2302).
- (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, 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) Rasitrio Summary of Product Characteristics (SmPC) for European Union.
- (5) Rasilez Summary of Product Characteristics (SmPC) for European Union.
- (6) Burnier M, et al. Medication adherence and persistence as the cornerstone of effective antihypertensive therapy. *Am J Hypertens* 2006; 19:1190-6.
- (7) Kearney P, et al. Global Burden of Hypertension: Analysis of Worldwide Data. *Lancet* 2005;365:217-23.
- (8) 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.
- (9) Lloyd-Jones D, 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.
- (10) El-Atat F, et al. Diabetes, Hypertension, and Cardiovascular Derangements: Pathophysiology and Management. *Curr Hypertens Rep* 2004;6:215-23.

(11) IMS Midas Worldwide Sales Data 2010.

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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

e-mail: media.relations@novartis.com

Catherine Peloquin

Novartis Pharma Communications

+41 61 696 8315 (direct)

+41 79 826 7452 (mobile)

catherine.peloquin@novartis.com

Novartis Investor Relations

Central phone:	+41 61 324 7944		
Susanne Schaffert	+41 61 324 7944	North America:	
Pierre-Michel Bringer	+41 61 324 1065	Richard Jarvis	+1 212 830 2433
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: November 28, 2011

By: /s/ MALCOLM B. CHEETHAM

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