NOVARTIS AG
Form 6-K
October 27, 2009

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 October 23, 2009

(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

Novartis International AG

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- Investor Relations Release -

Novartis receives approval in the European Union for Exforge HCT®, a new 3-in-1 treatment for high blood pressure

- *Exforge HCT combines the efficacy of three widely prescribed blood pressure treatments, valsartan, amlodipine and hydrochlorothiazide, in a single pill*

- *Up to 85% of patients may need multiple medications to help control their blood pressure(1),(2), underscoring the need for more effective combination treatments*

- *Single-pill combinations reduce daily pill burden and simplify treatment schedules(3)*

Basel, October 23, 2009 The European Commission has granted Novartis marketing authorization for Exforge HCT®, a new 3-in-1 treatment for people with high blood pressure.

Exforge HCT combines in a once-daily single pill the efficacy of three widely prescribed blood pressure medications: the angiotensin receptor blocker valsartan (Diovan®), the calcium channel blocker amlodipine, and the diuretic hydrochlorothiazide (HCT). All three have been used extensively for many years in patients with hypertension.

Novartis is committed to helping patients improve their treatment compliance. Simplified treatment regimens and reduced pill burdens have been shown to help achieve this, said Joe Jimenez, CEO of the Novartis Pharmaceuticals Division. We are pleased that with the approval of Exforge HCT, a new 3-in-1 treatment for high blood pressure is now available to patients in the EU. With Diovan as the foundation of this new therapy, we are confident that it will become an important new treatment option.

In the EU, Exforge HCT is indicated for substitution therapy in adult patients whose blood pressure is adequately controlled on the combination of valsartan, amlodipine and HCT, taken either as three single-component formulations or as a dual-component and a single-component

formulation(4).

High blood pressure, or hypertension, is one of the most important but treatable risk factors for cardiovascular disease the number one cause of death worldwide(5). Nearly half of Europeans suffer from high blood pressure(6) and up to 85% of these patients may need multiple medications to help reach treatment goals(1),(2). The primary patient-related factor for hypertension treatment failure is non-compliance with the prescribed antihypertensive medication(7). Patients therefore may find treatment more convenient with one single pill rather than multiple separate pills. One recent, large-scale study showed that approximately 75% of patients achieved their blood pressure treatment goal after switching to a single-pill combination therapy(8).

It is not uncommon for patients with severe hypertension, or those requiring stricter blood pressure control, to need three or more medications, said Professor Rainer Düsing, MD, of the Faculty of Medicine, University of Bonn, Germany. Now that this new single-pill triple-

combination option is available, appropriate patients may find it easier to comply with their prescribed treatment regimens involving a once-daily single pill versus multiple medications, especially if it has also been proven to be highly effective at helping patients reach their blood pressure goals.

Exforge HCT was approved in the United States by the Food and Drug Administration (FDA) in April 2009 for the second-line treatment of high blood pressure(9). It was approved in Switzerland in September 2009 for the treatment of patients whose blood pressure is not adequately controlled by dual therapy(10).

The EU approval was supported by the results of Study 2302(11), a multinational, randomized, double-blind, parallel-group, Phase III study designed to compare the efficacy and safety of triple therapy (valsartan, amlodipine and HCT) with the various dual combinations of its components valsartan/HCT, amlodipine/valsartan or amlodipine/HCT in patients with moderate-to-severe hypertension. The trial was conducted in 15 countries, with 2,271 patients randomized to double-blind treatment.

Study 2302 showed that triple therapy was more effective in reducing systolic and diastolic blood pressure than dual combinations of its components in patients with moderate-to-severe hypertension(11). Reductions in mean sitting systolic blood pressure of 40 to 50 mmHg were achieved, with up to 58% more patients receiving triple therapy achieving overall blood pressure control versus dual therapy (i.e. blood pressure <140/90 mmHg). The maximum dose of triple therapy (valsartan/amlodipine/HCT 10/320/25 mg) demonstrated additional reductions of 18 29% in systolic blood pressure and 19 32% in diastolic blood pressure when compared to all dual combinations of its components at the same doses. Ambulatory blood pressure monitoring showed that the blood pressure- lowering effect of triple therapy was maintained throughout the 24-hour period(12). In addition, the study showed that triple therapy was highly effective regardless of patients age, gender, race, ethnicity or baseline blood pressure, and was generally well tolerated versus dual therapy(11).

The core of the Novartis portfolio is its cardiovascular and metabolic medications for the treatment of high blood pressure and diabetes. These include Diovan® (valsartan), the number one selling blood pressure medication worldwide; Exforge® (valsartan/ amlodipine), a single pill combining two leading medicines for high blood pressure; Exforge HCT® (valsartan/amlodipine/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 novel 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, committed, confident, will, or similar expressions, or by express or implied discussions regarding potential future revenues from Exforge HCT. 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 Exforge HCT to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Exforge HCT will achieve any particular levels of revenue in the future. In particular, management s expectations regarding Exforge HCT 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 each of these areas. In 2008, the Group s continuing operations achieved net sales of USD 41.5 billion and net income of USD 8.2 billion. Approximately USD 7.2 billion was invested in R&D activities throughout the Group. Headquartered in Basel, Switzerland, Novartis Group companies employ approximately 99,000 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: October 23, 2009	By:	/s/ MALCOLM B. CHEETHAM
	Name:	Malcolm B. Cheetham
	Title:	Head Group Financial Reporting and Accounting