

NOVARTIS AG  
Form 6-K  
July 23, 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 July 21, 2009**

**(Commission File No. 1-15024)**

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**Novartis AG**

(Name of Registrant)

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(Address of Principal Executive Offices)

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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 -**

**FDA approves Tekturna HCT® as initial treatment in patients unlikely to achieve their blood pressure goal with a single agent**

- *Tekturna HCT combines the only approved direct renin inhibitor, Tekturna®, with widely used diuretic, hydrochlorothiazide, in a single pill(1)*
- *Data show combination of Tekturna and hydrochlorothiazide resulted in significant additional blood pressure reductions compared to either drug alone(1)*
- *Up to 85% of patients may require multiple medications to help control their blood pressure, underscoring the need for more effective combination treatments(2),(3)*
- *US guidelines recommend consideration for combination therapy as first-line therapy in patients unlikely to get to goal with a single agent(4)*

**Basel, July 21, 2009** The US Food and Drug Administration (FDA) has approved Tekturna HCT® (aliskiren and hydrochlorothiazide) tablets as initial therapy for patients who are likely to need multiple drugs to achieve their blood pressure goals. Tekturna HCT is a single-pill combination of Tekturna® (aliskiren), the first and only approved direct renin inhibitor(1), and the diuretic hydrochlorothiazide (HCTZ), one of the most commonly used high blood pressure medications(5).

The FDA approval of Tekturna HCT as initial therapy was based on clinical trial data involving more than 2,700 patients, which showed that treatment with the combination of Tekturna and HCTZ offered greater blood pressure reductions than either drug alone(1).

Up to 85% of patients will need more than one medication to reach their blood pressure goals, said Dr. Alan Gradman, Cardiologist at The Western Pennsylvania Hospital and Professor of Medicine at Temple University. This approval gives doctors the opportunity to aggressively treat their patients with a single-pill combination of the only approved drug, Tekturna, that works by directly targeting renin and decreasing the activity of the renin angiotensin aldosterone system (RAAS) and, HCTZ, a diuretic. This results in more significant blood pressure reductions, compared to taking either drug alone.

High blood pressure affects nearly one billion individuals globally(4) and is a major risk factor for cardiovascular disease, the number one leading cause of death worldwide(6). If left untreated, patients with high blood pressure are at risk of cardiovascular events such as stroke, heart attack and heart failure, and of organ damage including kidney failure and vision problems(4). Up to 65% of patients with high blood pressure do not have the condition under control(7).

Current US treatment guidelines support the first-line use of combination therapy in appropriate high blood pressure patients. The Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC7) recommends that

physicians consider starting their high blood pressure patients with two treatment agents, one of which should be a diuretic, if blood pressure is >20/10 mmHg above goal(4). The use of multiple medications may help patients achieve blood pressure goals in a more timely fashion(4).

We are very pleased the FDA recognizes the benefit of Tekturna HCT for the first-line treatment of patients with moderately high blood pressure, said Trevor Mundel, MD, Global Head of Development at Novartis Pharma AG. Novartis is committed to supporting the research and development of effective treatments for high blood pressure that will help patients reach their blood pressure treatment goals.

### **About Rasilez/Tekturna**

Tekturna, a direct renin-inhibitor, is the only drug that works by directly targeting renin to decrease the activity of the RAAS(1). Renin is an enzyme produced by the kidneys that starts a process that narrows blood vessels and, when inappropriately activated, may lead to high blood pressure. Tekturna reduces renin activity and helps blood vessels relax and widen so blood pressure is lowered(1). Diuretics work to lower blood pressure by removing excess water and salt from the body(1).

The heart and kidney protection potential of Rasilez/Tekturna, independent of its blood pressure lowering ability, is currently being investigated further in the landmark ASPIRE HIGHER program, the largest ongoing cardio-renal outcomes program worldwide involving more than 35,000 patients in 14 trials.

Rasilez/Tekturna is approved in over 70 countries. Tekturna was approved in the US in March 2007 and in the European Union in August 2007 under the trade name Rasilez. In July 2009, Rasilez also received approval in Japan. Tekturna HCT, the first single-pill combination involving Tekturna, was approved in the US in January 2008 for second-line treatment of high blood pressure. The single-pill combination Rasilez HCT was approved in the European Union in January 2009. Other single-pill combinations with Rasilez are currently in development including a combination with Diovan and a single pill combination with amlodipine.

Novartis is focused on improving the lives of the hundreds of thousands of people with cardiovascular and metabolic diseases. As a global leader in cardiovascular and metabolic health for nearly 50 years, Novartis provides innovative therapies and support programs to treat high blood pressure and diabetes both major public health issues. The portfolio includes the world's most-prescribed angiotensin receptor blocker, the first and only approved direct renin inhibitor, a single pill combining two leading high blood pressure medicines, and a DPP-4 inhibitor.

Tekturna HCT is available in four strengths as tablets containing aliskiren and hydrochlorothiazide: 150 mg/12.5 mg tablets, 150 mg/25 mg tablets, 300 mg/12.5 mg tablets and 300 mg/25 mg tablets(1).

### **Study Details**

The FDA approvals of Tekturna HCT were based on a clinical trial program involving over 6,200 patients and evaluated more than 2,700 patients exposed to combinations of Tekturna and hydrochlorothiazide. The safety and efficacy of Tekturna HCT were evaluated in patients with mild-to-moderate hypertension in an eight-week, randomized, double-blind, placebo-controlled, parallel-group, 15-arm factorial trial (n=2762). Patients were randomized to receive various combinations of Tekturna (75 mg to 300 mg) plus hydrochlorothiazide (6.25 mg to 25 mg) once daily (without titrating up from monotherapy) and followed for blood pressure response. The combination of Tekturna and hydrochlorothiazide resulted in additive placebo-adjusted decreases in systolic and diastolic blood pressure at trough of 10-14/5-7 mmHg at doses of 150-300 mg/12.5-25 mg, compared to 5-8/2-3 mmHg for Tekturna 150 mg to 300 mg and 6-7/2-3 mmHg for hydrochlorothiazide 12.5 mg to 25 mg

alone. Blood pressure reductions with the combinations were greater than the reductions with the monotherapies. The safety and efficacy of Tekturna

HCT as initial therapy was evaluated in this trial. All patients randomized to the combination groups received the combination treatment of Tekturna HCT at assigned doses as initial therapy without titration from monotherapy. The antihypertensive effect of Tekturna HCT was largely manifested within one week. The maximum antihypertensive effect was generally attained after about four weeks of therapy.

## Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as may, risk, committed, will, potential, similar expressions, or by express or implied discussions regarding potential future indications or labelling for Rasilez/Tekturna or Tekturna HCT, or regarding potential future revenues from Rasilez/Tekturna or Tekturna 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 Rasilez/Tekturna or Tekturna HCT to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Rasilez/Tekturna or Tekturna HCT will be approved for any additional indications or labelling. Nor can there be any guarantee that Rasilez/Tekturna or Tekturna HCT will achieve any particular levels of revenue in the future. In particular, management's expectations regarding Rasilez/Tekturna or Tekturna HCT could be affected by, among other things, 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; unexpected regulatory actions or delays or government regulation generally; 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 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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## References

- (1) Tekturna HCT Annotated Initial Therapy DRAFT Label. September 2008.
- (2) 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.
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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: July 21, 2009

By: /s/ MALCOLM B. CHEETHAM

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