

NOVARTIS AG  
Form 6-K  
December 14, 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 December 13, 2011**

(Commission File No. 1-15024)

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**Novartis AG**

(Name of Registrant)

**Lichtstrasse 35**

**4056 Basel**

**Switzerland**

(Address of Principal Executive Offices)

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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:** ☒

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**Novartis International AG**

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**- Investor Relations Release -**

**Novartis pivotal study of Exjade® shows significant reduction of iron overload in patients with non-transfusion-dependent thalassemia**

- *Trial shows Exjade, an iron chelator, is significantly better than placebo at reducing liver iron concentration in patients with NTDT*
- *Non-transfusion-dependent thalassemia (NTDT) is a genetic blood disorder in which patients may accumulate excess iron in the body*
- *Data will serve as basis for first regulatory filings in US and Europe by year end*

**Basel, December 13, 2011** Results from THALASSA, the first pivotal placebo-controlled study examining the benefit of iron chelation with Exjade® (deferasirox) in patients with non-transfusion-dependent thalassemia (NTDT), show that Exjade can significantly reduce iron overload. These data were presented today at the 53rd Annual Meeting of the American Society of Hematology in San Diego.

THALASSA investigated whether patients with NTDT and iron overload can benefit from iron chelation therapy as determined by liver iron concentration (LIC). The study met its primary endpoint, showing that Exjade at a 10mg/kg/day starting dose significantly reduced LIC from baseline by 3.8 mg of iron per gram of liver dry weight (Fe/g dw) compared to an increase of 0.38 mg Fe/g dw in patients on placebo (p<0.001). The study also determined that a 10 mg/kg/day dose was superior to a 5 mg/kg/day dose (p=0.009).

In the 10 mg/kg arm, 49% of patients had a LIC decrease of at least 30% from baseline versus only 2% in the placebo arm. In addition, 56% of patients in the 10 mg/kg arm had a LIC decrease of  $\geq 3$  mg at one year compared to 11% in the placebo arm. The most common adverse events reported were nausea, rash, diarrhea, headache and upper abdominal pain.(1) Adverse events were similar in all patient groups, including the placebo arm.(1)

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Thalassemia refers to a diverse group of genetic disorders that affect red blood cell production, causing anemia. Unlike types of thalassemia in which patients require regular blood transfusions, NTDT patients can live without frequent transfusions. However, patients with NTDT are still at risk of accumulating excess iron.(2)

Results from THALASSA show that Exjade is effective in reducing liver iron levels in patients with NTDT, said Ali Taher, the lead study investigator and Professor of Medicine, Division of Hematology and Oncology, American University of Beirut Medical Center, Lebanon. Iron chelation therapy is the only option for decreasing these patients' iron burden. These are significant findings for patients with a major unmet need. (1)

NTDT refers to a group of clinically milder forms of thalassemias, including beta-thalassemia intermedia(3), Hemoglobin H disease (Hb H-alpha-thalassemia)(4) and Hemoglobin E/beta-thalassemia.(5) Despite a slower rate of iron accumulation, the burden of iron overload in NTDT patients is similar to that observed in thalassemia patients who receive regular blood transfusions. NTDT patients are not symptomatic at birth, when most thalassemias are diagnosed. Therefore they are often underdiagnosed and untreated even when symptoms appear at age 10 or later. NTDT is most commonly found in Southeast Asian, South Asian, Middle Eastern and Mediterranean populations.

Over the past six years, Exjade has provided thalassemia patients an effective option for the treatment of chronic iron overload due to blood transfusions, said Hervé Hoppenot, President, Novartis Oncology. These new clinical trial data show that Exjade may also benefit NTDT patients who often are at risk for serious health complications.

Regulatory submissions for Exjade based on the THALASSA results are planned by the end of 2011.

## Study details

The THALASSA study assessed the efficacy of Exjade versus placebo in NTDT patients  $\geq 10$  years of age with iron overload.

THALASSA was a one-year, randomized, double-blind, placebo-controlled pivotal study, including 166 patients with beta-thalassemia intermedia (n=95), alpha-thalassemia (n=22) or Hemoglobin E/beta-thalassemia (n=49). Patients  $\geq 10$  years of age with LIC  $\geq 5$  mg Fe/g dw and serum ferritin  $>300$  ng/mL were randomized to starting Exjade doses of 5 mg/kg/day (n=55) or matching placebo (n=28) and 10 mg/kg/day (n=55) or matching placebo (n=28).(1)

## About Exjade

Exjade is indicated for the treatment of chronic iron overload due to blood transfusions (transfusional hemosiderosis) in adult and pediatric patients (aged 2 years and over). It is approved in over 100 countries including the US, Switzerland, Japan, and the countries comprising the European Union. The approved indication may vary depending upon the individual country.

### **Exjade Important Safety Information**

Exjade is contraindicated in patients with an estimated creatinine clearance  $<60$  mL/min, with hypersensitivity to the active substance or any of the excipients, or in combination with other iron chelator therapies. Exjade is not recommended in patients with severe hepatic impairment.

There have been postmarketing reports of acute renal failure, hepatic failure, and cytopenias. Renal failure requiring temporary or permanent dialysis, renal tubulopathy, and interstitial nephritis have been reported. Upper gastrointestinal ulceration and hemorrhage, sometimes fatal, have been reported. Caution should be used in elderly patients due to a higher frequency of adverse reactions. Exjade is not recommended in patients with a short life expectancy (e.g., high-risk myelodysplastic syndromes), especially when co-morbidities could increase the risk of adverse events.

Skin rashes, serious hypersensitivity reactions, decreased hearing, and lens opacities have been reported. The most common adverse reactions are nausea, vomiting, diarrhea, abdominal pain, rash, non-progressive increases in serum creatinine, increased transaminases, abdominal distension, constipation, dyspepsia, proteinuria, and headache.

Please visit [www.exjade.com](http://www.exjade.com) for more information.

### **Disclaimer**

The foregoing release contains forward-looking statements that can be identified by terminology such as *will*, *may*, *planned*, or similar expressions, or by express or implied discussions regarding potential new indications or labeling for Exjade or regarding potential future revenues from Exjade. 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 Exjade to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Exjade will be submitted or approved for any additional indications or labeling in any market, or at any particular time. Nor can there be any guarantee that Exjade will achieve any particular levels of revenue in the future. In particular, management's expectations regarding Exjade 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; competition in general; government, industry and general public pricing pressures; 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>.

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- (4) Fucharoen S, Viprakasit V. Hb H disease: clinical course and disease modifiers. Hematology Am Soc Hematol Educ Program. 2009;26-34
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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: December 13, 2011

By: /s/ MALCOLM B. CHEETHAM

Name: Malcolm B. Cheetham

Title: Head Group Financial Reporting and Accounting