NOVARTIS AG
Form 6-K
April 12, 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 April 11, 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:

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):

Yes: o **No: x**

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7):

Yes: o **No: x**

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 discontinues clinical trial of Tasigna® for investigational use in newly diagnosed patients with unresectable and/or metastatic GIST

- *Independent data monitoring committee recommends stopping ENESTg1 trial as interim efficacy results show Tasigna is unlikely to show superiority*

- *Novartis remains committed to advancing treatment options for patients with GIST*

Basel, April 11, 2011 Novartis announced today it is discontinuing a Phase III trial of Tasigna® (nilotinib) for investigational use in the first-line treatment of gastrointestinal stromal tumors (GIST) based on the recommendation of an independent data monitoring committee. Interim results showed Tasigna is unlikely to demonstrate superiority compared to Glivec® (imatinib)*, the current standard of care in this setting.

The trial is a randomized, open-label, multicenter study evaluating the efficacy and safety of nilotinib versus imatinib in adult patients with unresectable and/or metastatic GIST(1). The side effect profile seen in this trial was consistent with previous studies of Tasigna.

Novartis is committed to further advancing treatment options for patients with GIST and continues to explore studies for these patients.

About ENESTg1

ENESTg1 (Evaluating Nilotinib Efficacy and Safety in Clinical Trials Versus Imatinib in Adult Patients With Unresectable and/or Metastatic GIST) began in 2009 in centers across the world with the goal of recruiting more than 700 GIST patients. These patients were newly diagnosed with unresectable and/or metastatic GIST and were not permitted to receive any prior cancer therapies other than adjuvant Glivec.

The trial s primary endpoint was a comparison of progression-free survival between Tasigna and Glivec when used as initial therapy in these patients.

For more information about Tasigna or Glivec please visit www.tasigna.com or www.glivec.com.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as committed, continues to explore, or similar expressions, or by express or implied discussions regarding potential new indications or labeling for Tasigna or regarding potential future revenues from Tasigna or Glivec. 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 to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Tasigna will be submitted or approved for any additional indications or labeling in any market. Nor can

there be any guarantee that Tasigna or Glivec will achieve any particular levels of revenue in the future. In particular, management s expectations 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; unexpected regulatory actions or delays or government regulation generally; government, industry and general public pricing pressures; competition in general; 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 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 119,000 full-time-equivalent associates (including 16,700 Alcon associates) and operate in more than 140 countries around the world. For more information, please visit http://www.novartis.com.

References

(1) Novartis. Phase III, Open-label Study of Nilotinib Versus Imatinib in GIST Patients (ENESTg1). http://clinicaltrials.gov/ct2/show/NCT00785785?term=Nilotinib+Versus+Imatinib+in+Adult+Patients+With+Unresectable+or+Metastatic+Gastrointest Accessed March 2011.

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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: April 11, 2011

By: /s/ MALCOLM B. CHEETHAM

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