NOVARTIS AG
Form 6-K
April 11, 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 8, 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

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- Investor Relations Release -

Novartis amends current US FDA application for Afinitor® to seek indication for advanced neuroendocrine tumors of pancreatic origin

Basel, April 8, 2011 Novartis announced today that it has updated its supplemental New Drug Application (sNDA) to the US Food and Drug Administration (FDA) for Afinitor® (everolimus) tablets. The submission has been amended to only seek approval for the treatment of patients with advanced neuroendocrine tumors (NET) of pancreatic origin. The original submission included a proposed indication for patients with advanced NET of gastrointestinal, lung or pancreatic origin.

The decision by Novartis was based on feedback from the FDA. Novartis remains committed to patients with advanced NET and will continue to conduct studies in patients with advanced carcinoid tumors, where there is a critical unmet need.

The FDA requested that the application be reviewed by the Oncologic Drugs Advisory Committee (ODAC) on April 12, 2011. The FDA can seek the advice of its advisory committees as it reviews and decides whether to approve treatments, however, the recommendations put forth by the group are advisory in nature and do not always reflect the final decisions of the FDA(1),(2). There is also the potential that the discussion and outcome of this meeting could result in the FDA extending the review period.

Earlier this year, the FDA granted everolimus priority review designation for the application of advanced NET of GI, lung or pancreatic origin. Priority review status is granted to therapies that offer major advances in treatment or provide a treatment where no adequate therapy exists. This status accelerates the standard review time for everolimus from 10 to six months(3). The application is based on data from the RADIANT (RAD001 In Advanced Neuroendocrine Tumors) trial program.

Worldwide regulatory filings for everolimus as a treatment for advanced NET of gastrointestinal, lung or pancreatic origin are being reviewed by health authorities. For more information about Afinitor please visit www.afinitor.com/global.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as seek, proposed, committed, will, potential, could, priority review, or similar expressions, or by express or implied discussions regarding potential submissions or approvals for new indications or labeling for Afinitor, or regarding the potential timing of any such approvals, or regarding potential future revenues from Afinitor. 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 Afinitor to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Afinitor will be submitted or approved for any additional indications or labeling in any market. Nor can

there be any guarantee that Afinitor will achieve any particular levels of revenue in the future. In particular, management s expectations regarding Afinitor 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 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) US Food and Drug Administration. Advisory Committees. Oncologic Drugs Advisory Committee. Available at http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/OncologicDrugsAdvisoryCommittee/default.htm. Accessed April 2011.

(2) US Food and Drug Administration. The Federal Advisory Committee Act. Available at http://www.fda.gov/downloads/AdvisoryCommittees/AboutAdvisoryCommittees/LawsRegulationsGuidance/UCM154704.doc. Accessed April 2011.

(3) US Food and Drug Administration. Fast Track, Accelerated Approval and Priority Review. Available at http://www.fda.gov/forconsumers/byaudience/forpatientadvocates/speedingaccesstoimportantnewtherapies/ucm128291.htm. Accessed April 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 8, 2011

By: /s/ MALCOLM B. CHEETHAM

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