NOVARTIS AG
Form 6-K
January 10, 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 January 10, 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 -

Sandoz announces phase II clinical trial for biosimilar version of leading monoclonal antibody rituximab

- *Start of phase II clinical study in patients for Sandoz biosimilar rituximab (Roche s Rituxan® / Mabthera®)(1)*
- *Sandoz already has robust, high-yield in-house production process*
- *Milestone reinforces Sandoz s commitment to maintain global biosimilar market leadership, with a total of 8-10 molecules at various stages of development*

Holzkirchen, January 10, 2011 Sandoz announced today that it has begun a phase II clinical trial in patients for biosimilar rituximab (Roche s Rituxan® / Mabthera®), a leading monoclonal antibody indicated in conditions including non-Hodgkin s lymphoma and rheumatoid arthritis.

The phase II study in patients suffering from rheumatoid arthritis aims to demonstrate bioequivalence to the reference product, and will collect data on pharmacokinetics and pharmacodynamics as well as efficacy and safety data.

Over the past few years Sandoz has developed a robust, high-yield and large-scale process for the production of biosimilar rituximab in its own facilities in Schaftenau, Austria. To ensure biosimilarity with the reference product, a comprehensive physico-chemical and functional analysis of the product was conducted using modern bioanalytic techniques, followed by further studies. The data suggest that Sandoz s biosimilar rituximab is highly similar to the reference product, justifying initiation of clinical studies in patients.

This key development milestone demonstrates that Sandoz, the pioneer in biosimilars, is on track to maintain its global leadership position in the medium to long term, said Sandoz global head Jeff George.

With nearly 50% market share within the global regulated biosimilar market, and with three marketed products, Sandoz plans to continue to broaden patient access to essential high-quality biologics by consistently advancing our industry-leading development pipeline.

Ameet Mallik, global head of Sandoz Biopharmaceuticals, added: Our pipeline is particularly focused on monoclonal antibodies, the largest and fastest-growing segment of the biologics market. We are confident that we can leverage our unrivalled development and manufacturing capabilities as well as our Novartis-wide synergies in areas including clinical trial design and execution, to succeed in this exciting new field.

Monoclonal antibodies are protein-based therapeutics that are produced using genetically engineered cell lines. They function as targeted treatments that offer genuine therapeutic hope for many areas of unmet need, particularly complex therapeutic areas such as oncology and autoimmune diseases.

Mabthera® / Rituxan®, an antibody directed against the CD20 protein found on the surface of B-cells, is one of the leading monoclonal antibodies on the market. It ranks among the top three biologic (biopharmaceutical) drugs worldwide, with 2009 sales of USD 5.6 billion (IMS).

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as commitment, will, on track, plans, pipeline, confident, or similar expressions, or

by express or implied discussions regarding potential future marketing approvals of a biosimilar version of rituximab or of other biosimilar products, or regarding potential future revenues from rituximab or from any of Sandoz s other biosimilar products. You should not place undue reliance on these statements. Such forward-looking statements reflect the current views of the Company 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 rituximab will be submitted or approved for sale in any market, or at any particular time. Neither can there be any guarantee that Sandoz will succeed in developing and bringing to market any additional biosimilar productions. Nor can there be any guarantee that rituximab or any other biosimilar products will achieve any particular levels of revenue in the future. In particular, management s expectations regarding such products could be affected by, among other things, unexpected development difficulties; unexpected manufacturing difficulties; unexpected clinical trial results, including unexpected new clinical data and unexpected additional analysis of existing clinical data; unexpected regulatory actions or delays or government regulation generally; competition in general; government, industry and general public pricing pressures; unexpected patent litigation outcomes; the impact that the foregoing factors could have on the values attributed to the 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.

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About Sandoz

Sandoz, a Division of the Novartis group, is a global leader in the field of generic pharmaceuticals, offering a wide array of high-quality, affordable products that are no longer protected by patents. Sandoz has a portfolio of approximately 1000 compounds and sells its products in more than 130 countries. Key product groups include antibiotics, treatments for central nervous system disorders, gastrointestinal medicines, cardiovascular treatments and hormone therapies. Sandoz develops, produces and markets these medicines along with pharmaceutical and biotechnological active substances and anti-infectives. In addition to strong organic growth in recent years, Sandoz has made a series of acquisitions including Lek (Slovenia), Sabex (Canada), Hexal (Germany), Eon Labs (US), and EBEWE Pharma (Austria). In 2009, Sandoz employed approximately 23,000 people worldwide and posted sales of USD 7.5 billion.

For further information

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References:

(1) All registered trademarks named in this release are the property of the respective companies

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:	January 10, 2011	By:	/s/ MALCOLM B. CHEETHAM
		Name:	Malcolm B. Cheetham
		Title:	Head Group Financial Reporting and Accounting