NOVARTIS AG
Form 6-K
March 15, 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 March 15, 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 -

Second Phase III study of Novartis JAK inhibitor INC424 meets primary endpoint in patients with myelofibrosis

- *COMFORT-II data show INC424 provides marked clinical improvement in patients with myelofibrosis, measured by reduction in spleen size at 48 weeks compared to best available therapy*

- *Myelofibrosis is a debilitating disease with a poor prognosis and limited available therapies, presenting a critical unmet medical need*

- *Complete data to be submitted to an upcoming medical meeting*

- *Two Phase III trials provide basis for worldwide regulatory filings in Q2 2011*

Basel, March 15, 2011 Novartis announced today that a pivotal Phase III trial of the investigational Janus kinase (JAK) inhibitor INC424 (ruxolitinib) has met its primary endpoint of significantly reducing spleen size in patients with myelofibrosis (MF). INC424 is a potent, selective inhibitor of the JAK1 and JAK2 tyrosine kinases.

The European study, called COMFORT-II (COntrolled MyeloFibrosis Study with ORal JAK Inhibitor Therapy), showed treatment with INC424 provided a statistically significant reduction in spleen size in patients with primary MF, post-polycythemia vera myelofibrosis (PPV-MF), or post-essential thrombocythemia myelofibrosis (PET-MF), when compared with best available therapy, administered at doses and schedules determined by the investigator. The safety profile of INC424 was consistent with previous studies. Complete study data will be submitted to an upcoming medical meeting.

These results support findings from another large Phase III clinical trial (COMFORT-I) conducted by the collaboration partner, Incyte Corporation, in the US, Canada and Australia comparing treatment with INC424 to placebo in patients with MF at 24 weeks. In addition, a Phase I/II study published in the September 16, 2010 issue of *The New England Journal of Medicine* showed that treatment with INC424 resulted in marked, fast and durable clinical benefits in patients with MF. These benefits included alleviation of debilitating symptoms and reduction of spleen size, an accepted measurement of clinical improvement in MF(1),(2).

Results of the COMFORT-II and COMFORT-I clinical trials will form the basis of worldwide regulatory filings, planned to begin in the second quarter of 2011. The INC424 investigational studies constitute the largest clinical trial program in MF to date.

We are pleased to reach this important milestone in our collaboration to develop INC424, a compound representing potential progress for patients with myelofibrosis, a serious malignant disease with limited treatment options, said Hervé Hoppenot, President, Novartis Oncology. INC424 illustrates our mission to turn the promise of innovative, pathway-based compounds into the reality of therapies for patients with unmet medical needs.

Myelofibrosis is an uncommon, life-threatening blood cancer characterized by bone marrow failure, enlarged spleen (splenomegaly), debilitating symptoms including fatigue, night sweats and pruritus, poor quality of life, weight loss and shortened survival. Myelofibrosis has a poor prognosis and limited treatment options(1),(3). Although allogeneic stem cell transplantation may cure MF, the procedure is associated with significant morbidity and mortality and is usually appropriate only in younger patients(3). The five-year survival rate after transplantation is approximately 50%(4).

Novartis licensed INC424 from Incyte for development and potential commercialization outside the US. Incyte has retained rights for the development and potential commercialization of INC424 in the US. Both the European Commission (EC) and the US Food and Drug Administration (FDA) have granted INC424 orphan drug status for MF.

Study details

COMFORT-II is a randomized, open-label Phase III study of INC424 versus best available therapy that enrolled 219 patients with primary MF, PPV-MF or PET-MF in 56 study locations in Europe. Two-thirds received INC424 and one-third received best available therapy, administered at doses and schedules determined by the investigator. The primary endpoint for COMFORT-II is the proportion of patients achieving a reduction in spleen volume of 35% or more from baseline to week 48 as measured by MRI (or CT scan in applicable patients). Reduction of spleen size is an accepted measurement for clinical improvement in MF(1),(2). COMFORT-II is sponsored by Novartis(5).

About myelofibrosis

Myelofibrosis is a Philadelphia chromosome-negative myeloproliferative neoplasm(1). Of the JAK-associated myeloproliferative neoplasms, MF carries the greatest risk of a poor prognosis, including transformation to fatal acute myelogenous leukemia. For MF patients in general, clinical findings such as splenomegaly and constitutional symptoms may be associated with significantly reduced quality of life(3),(6)-(8).

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as to be submitted, filings in Q2 2011, will, planned, potential, mission, promise, or similar expressions, or by express or implied discussions regarding potential marketing submissions or approvals for INC424, or the potential timing of such submissions or approvals, or regarding potential future revenues from INC424. 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 INC424 to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that INC424 will be submitted or approved for sale in any market, or at any particular time. Nor can there be any guarantee that INC424 will achieve any particular levels of revenue in the future. In particular, management s expectations regarding INC424 could be affected by, among other things, 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; 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.

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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:	March 15, 2011	By:	/s/ MALCOLM B. CHEETHAM
		Name:	Malcolm B. Cheetham
		Title:	Head Group Financial Reporting and Accounting