NOVARTIS AG
Form 6-K
January 23, 2009

# 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 21, 2009**

**(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 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

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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**

Novartis Global Communications

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**- Investor Relations Release -**

**Four innovative Novartis medicines for cancer, asthma, high blood pressure and wet AMD approved in Japan**

- *Tasigna®, Xolair®, Co-Dio® and Lucentis® provide novel and effective treatment options for serious diseases*

- *Japanese clinical trials support approvals*

- *Four major drug approvals in one day could benefit millions of Japanese patients*

**Basel, January 21, 2009** Patients in Japan stand to benefit from the approval of four innovative medicines Tasigna® for the treatment of a life-threatening form of leukemia, Xolair® for severe asthma, Co-Dio®(1) for high blood pressure, and Lucentis® for wet age-related macular degeneration (AMD), an eye disease that is a major cause of blindness in people over the age of 50 in Japan.

It is a significant achievement to secure the approval of so many important new medicines for the benefit of Japanese patients in a single day, said Joe Jimenez, CEO of Novartis Pharma AG. We are proud to be able to offer these innovative medications that provide new options to treat serious, and in some cases life-threatening diseases affecting millions of Japanese patients and their families.

Tasigna (nilotinib) is approved in Japan for the treatment of certain forms of Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML), a rare and potentially fatal cancer of the white blood cells, in adult patients who are resistant to Glivec/Gleevec® (imatinib).

The approval was supported by two studies investigating efficacy in different phases of the disease. In an international Phase II study, 42% of patients in the chronic phase of CML achieved a major cytogenetic response, while 66% of patients in CML accelerated phase achieved a hematological response. In the Japanese study the percentages were 94% and 71% respectively(1). Cytogenetic response refers to reduction or elimination of the abnormal Ph+ chromosome, while hematological response involves normalization of patients white blood cell counts. Japan is currently taking part in a multinational study to explore the potential of Tasigna in newly-diagnosed CML patients.

Xolair (omalizumab) offers an entirely new approach to the treatment of severe asthma by targeting the immunoglobulin E (IgE) antibody, a root cause of allergic disease. It is approved in Japan for treating severe bronchial asthma in adult patients who are uncontrolled despite use of standard medications. Xolair is manufactured by Novartis Pharma AG. In the US, it is co-promoted by Novartis Pharmaceuticals Corporation and Genentech, Inc.

(1) Available as Co-Diovan®, Co-Tareg® or Diovan HCT® in other markets.

An estimated four million people suffer from asthma in Japan(2). Although the number of fatalities is decreasing, it is estimated that about 2,500 people die of the disease in Japan each year(3). The filing was supported by data from a Japanese clinical study showing an improvement in lung function and control of asthma symptoms in patients treated with Xolair(1).

Co-Dio is a single-pill combination of Diovan® (valsartan), the world s leading branded high blood pressure medication(4), and hydrochlorothiazide (HCT), another high blood pressure treatment from the diuretics drug class. It is approved in Japan as second-line therapy at a dosage of 80 mg valsartan combined with either 6.25 or 12.5 mg HCT.

High blood pressure affects an estimated 40 million people in Japan nearly a third of the population(5) and with a majority of patients not reaching their blood pressure treatment goal, there is a growing need for effective single-pill combination therapies. Approval was based on a multicenter clinical trial in Japanese patients demonstrating superior blood pressure lowering efficacy compared to monotherapy with good tolerability in patients with mild-to-moderate high blood pressure(1).

Lucentis (ranibizumab) was developed specifically for use in the eye and is the only approved therapy shown to improve vision and vision-related function in a vast majority of patients with wet AMD. Lucentis is indicated in Japan for subfoveal wet AMD, a condition for which an estimated 20,000 people in Japan sought treatment in 2007(6).

The application was supported by a clinical study in Japan showing that Lucentis enabled patients to improve their vision significantly compared to before treatment(1). Lucentis, an anti-VEGF (vascular endothelial growth factor) therapy, is developed in collaboration with Genentech and is marketed by Novartis in all countries except the USA.

In addition, an application for the approval of Rasilez® (aliskiren) tablets for the treatment of high blood pressure was submitted to the Japanese health authorities in February 2008.

Novartis Pharma K.K. is a Japanese affiliate of Novartis AG, Switzerland. For more information on NPKK, please visit http://www.novartis.co.jp/

**Disclaimer**

The foregoing release contains forward-looking statements that can be identified by terminology such as stand to benefit, estimated, or similar expressions, or by express or implied discussions regarding potential future approvals of additional Novartis products in Japan or regarding potential future revenues from the products referred to in this release. 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 Rasilez or any other additional Novartis products will be approved for sale in Japan. Nor can there be any guarantee that the products referred to in this release will achieve any particular levels of revenue in the future. In particular, management s expectations regarding these products a 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; competition in general; government, industry and general public pricing pressures; 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 AG 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 2007, the Group s continuing operations (excluding divestments in 2007) achieved net sales of USD 38.1 billion and net income of USD 6.5 billion. Approximately USD 6.4 billion was invested in R&D activities throughout the Group. Headquartered in Basel, Switzerland, Novartis Group companies employ approximately 97,000 full-time associates and operate in over 140 countries around the world. For more information, please visit http://www.novartis.com.

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**References**

(1) Data on file. Novartis Pharma K.K.

(2) Mitsuru A, et al. Asthma mortality and burden of asthma in Japan. Allergology & Immunology, Vol. 12 No. 10, p1438-1447, 2005.

(3) Ministry of Health, Labour and Welfare. Population Survey Report 2007.

(4) IMS MIDAS sales data, Mar 2007-Feb 2008.

(5) National Health and Nutrition Survey Report, 2006.

(6) Obana A. Jpn J Clin Ophthalmol 55(6), 1229-4, 2001.

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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: January 21, 2009

By: /s/ MALCOLM B. CHEETHAM

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