NOVARTIS AG
Form 6-K
June 27, 2006

UNITED STATES

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 June 26, 2006

(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**

Investor Relations

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- Investor Relations Release -

Novartis submits Xolair® for approval in Japan as first-in-class treatment for severe asthma

- ***Filing represents important milestone for the treatment of severe allergic asthma in Japan***

- ***Asthma affects four million people in Japan and causes 3,000 deaths a year - symptoms remain poorly-controlled in 20% of those with severe disease***

- ***Xolair offers highly innovative approach to controlling potentially life-threatening symptoms, even in patients already receiving the best available therapies***

Basel, June 26, 2006 - Novartis has submitted an application to the Japanese health authorities for the approval of Xolair® (omalizumab), a novel therapy which targets a root cause of allergic disease and offers an entirely new approach to the treatment of severe asthma.

Worldwide clinical trials have shown the potential of Xolair which is already approved in the US and European Union for controlling symptoms and reducing asthma exacerbations (or attacks) and the need for emergency medical treatment, even in patients with the most severe disease that is poorly controlled by existing drugs.

An estimated four million people suffer with asthma in Japan (1). Despite advances in therapy, approximately 20% of those with severe asthma have symptoms that remain inadequately controlled2. Although the number of fatalities is decreasing, it is estimated that more than 3,000 people still die of the disease in Japan each year (3).

We believe Xolair can potentially represent one of the most significant advances in asthma treatment for the last 15 years, so this is encouraging news for all those patients in Japan who are at high risk of potentially life-threatening asthma attacks, said James Shannon, MD, Global Head of Development at Novartis Pharma AG. Xolair offers the potential for effective control even in patients with the most severe disease, whose lives have been dominated by the need to take multiple medications and to avoid any situation that could trigger their symptoms, Dr. Shannon said.

If the application is successful, Xolair will be the first monoclonal antibody to be approved for the treatment of asthma in Japan. Unlike other asthma therapies, Xolair is given by injection every two or four weeks and is unique in blocking the action of the Immunoglobin E (IgE) antibody, a root cause of inflammation of the airways in patients with diseases such as allergic asthma.

By targeting the underlying mechanism of the disease, Xolair can prevent the onset of serious and debilitating symptoms such as wheezing and shortness of breath, even in severely affected patients. The efficacy of the new therapy has already been recognized in international treatment guidelines such as those

issued by the Global Initiative for Asthma (GINA), which recommend anti-IgE therapy as add-on treatment for patients with severe allergic asthma that is inadequately controlled by standard clinical options (4).

Xolair was launched in the US in July 2003, and was granted marketing approval in the European Union in October 2005. It is now approved in 47 countries and available in 15 including Australia, Brazil, Canada, Germany, Israel, Spain, UK and US. Xolair has been developed under an agreement between Novartis Pharma AG, Genentech, Inc. and Tanox, Inc.

About the Japanese filing

The application submitted to the Japanese Ministry of Health, Labor and Welfare (MHLW) was supported by data from a clinical study showing a significant improvement in patients lung function (measured by peak expiratory flow, or PEF) when treated with Xolair.

The multicenter, randomized, double-blind, parallel-group, placebo-controlled study involved 315 patients with moderate to severe allergic asthma who received 16 weeks treatment with Xolair or placebo, with a 24-week follow-up period. Results showed that morning PEF in patients receiving Xolair increased by a mean of 15.45 L/min over baseline, compared to only 2.25 L/min in patients receiving placebo (P<0.0004) (5).

The distinct and significant improvement of asthma control in Japanese severe asthma patients demonstrates that Xolair could be used as a controller drug in Japan, in the same manner that it is used outside of Japan based on GINA guidelines, said Professor Ken Ohta, Medicine Department, Teikyo University School of Medicine, Japan.

I hope that Xolair soon becomes available in clinical practice in Japan. I anticipate that it will play a significant role in the treatment of patients whose asthma is inadequately controlled, Dr. Ohta said.

If approved in Japan, it is anticipated that Xolair will be indicated as add-on therapy for patients who have:

- positive reaction to a perennial aeroallergen
- an IgE concentration in the serum of 30-700 IU/mL before starting treatment
- inadequately controlled asthma despite recommended therapy, including high dose inhaled corticosteroids and other controller medications

Inadequate control is defined as reduced lung function (i.e. less than 80% of predicted capacity measured by forced expiratory volume in one second (FEV1)), daily day-time symptoms or weekly night-time awakening due to asthma

Disclaimer

The foregoing release contains certain forward-looking statements that can be identified by terminology such as believe , encouraging news , potential , if the application is successful, Xolair will be , hope , anticipate , will , if approved in Japan, it is anticipated that Xolair will be , or similar expressions, or by express or implied discussions regarding the potential that Xolair will be approved for sale in Japan or other additional markets, or regarding any potential future revenues from Xolair. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results with Xolair to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Xolair will be approved for sale in Japan or any additional market, or that it will achieve any particular sales level. In particular, management s expectations regarding commercialization of Xolair could be affected by, among other things, uncertainties relating to clinical trials, including new clinical data, or 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; as well as other risks and factors referred to in the Company 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 (NYSE: NVS) is a world leader in offering medicines to protect health, treat disease and improve well-being. Our goal is to discover, develop and successfully market innovative products to treat patients, ease suffering and enhance the quality of life. Novartis is the only company with leadership positions in both patented and generic pharmaceuticals. We are strengthening our medicine-based portfolio, which is focused on strategic growth platforms in innovation-driven pharmaceuticals, high-quality and low-cost generics, human vaccines and leading self-medication OTC brands. In 2005, the Group s businesses achieved net sales of USD 32.2 billion and net income of USD 6.1 billion. Approximately USD 4.8 billion was invested in R&D. Headquartered in Basel, Switzerland, Novartis Group companies employ approximately 96,000 people and operate in over 140 countries around the world. For more information, please visit http://www.novartis.com.

References

1. Mitsuru Adachi, et al. Asthma mortality and burden of asthma in Japan. *Allergology & Immunology,* Vol. 12 No.10, p1438-1447, 2005

2. Mitsuru Adachi, et al. Asthma Insights & Reality in Japan. *Japanese Journal of Allergology, Vol*. 51 No.5, p411-420, 2002

3. Ministry of Health, Labour and Welfare. Population Survey Report 2005

4. Global Initiative for Asthma (GINA). Global Strategy for Asthma Management and Prevention 2004; 126-132. *http://www.ginasthma.com*

5. Submission Study Data on File

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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: June 26, 2006

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