NOVARTIS AG
Form 6-K
March 02, 2007

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 2, 2007

(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

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- Investor Relations Release -

Sebivo® approved in China for treatment of chronic hepatitis B, the nation s second leading cause of death

- *China is the country worst impacted by hepatitis B, with more than half a million deaths each year*[1,2]
- *Data show Sebivo gives better viral suppression than lamivudine, the most widely prescribed treatment for chronic hepatitis B*
- *Sebivo recently recommended for European approval, and already available in US under brand name Tyzeka®*

Basel, March 2, 2007 Novartis announced today the Chinese regulatory approval of Sebivo® (telbivudine) as a treatment for chronic hepatitis B, a disease estimated to affect more than 100 million people in China[1-3] and considered the second leading cause of death in the country[1]. The decision comes shortly after Sebivo was recommended for approval in the European Union.

Sebivo meets an urgent demand for effective therapies that can provide profound and sustained suppression of the hepatitis B virus, reducing the risk of liver disease and improving long-term outcomes for patients[4]. Sebivo will be available in China in April.

The need for new therapies is especially pressing in China, where an estimated 10% of the population suffer from chronic hepatitis B[2,5]. The number of infected people in China represents about one-third of those with the disease worldwide[2]. Despite existing treatments, nearly half a million people in mainland China die each year from liver damage and liver cancer caused by chronic hepatitis B[1,2].

Chronic hepatitis B is a major health problem in China, and through treatment, we aim to prevent the progression of the disease by getting the viral load to as low a level as possible, said Prof. Jidong Jia, Director of the Liver Research Center, Beijing Friendship Hospital, Capital Medical University, China. Sebivo s demonstrated ability to rapidly and profoundly drive down virus levels within the first 24 weeks of treatment, in addition to its favorable safety profile, make it a promising treatment option for patients with chronic hepatitis B.

Worldwide regulatory submissions have been based primarily on one-year data from the GLOBE study, the largest worldwide registration trial ever conducted in patients with chronic hepatitis B and the first to include patients from mainland China. The study results demonstrated that Sebivo provided greater viral suppression and significantly greater response on all virologic markers after one year compared to lamivudine, the most widely prescribed treatment. An additional Chinese Phase III trial corroborated these findings and supplemented the filing in China.

The approval of Sebivo in China represents a milestone in treatment for the millions of patients suffering from chronic hepatitis B, said James Shannon, MD, Global Head of Development at Novartis Pharma AG. We now look forward to receiving final European Commission approval, and to providing chronic hepatitis B patients in Europe with access to this promising new treatment.

The positive opinion in Europe was issued on February 22 by the Committee for Medicinal Products for Human Use (CHMP), which reviews drug applications for all 27 countries in the European Union as well as Iceland and Norway. The European Commission generally follows the CHMP s advice and is expected to issue a final decision within two to three months.

Sebivo, a once-daily oral treatment, is already approved in 12 countries including Switzerland and the US, where it is marketed as Tyzeka®.

Novartis in China

Novartis and its predecessor companies have been active in China since 1938 when Ciba opened its office in Shanghai, initially as a provider of dyestuffs and later expanding into the pharmaceutical arena.

The Chinese name for Novartis (pronounced Nuo Hua) means Commitment to China, which reflects the company s long-term strategy in the region. The total investment in China now totals over USD 400 million, with two major developments announced in 2006: a manufacturing and development center in Changshu, to be fully operational by the end of 2007, and an integrated biomedical research and development center in Shanghai expected to open in May.

Novartis currently ranks as the fourth largest pharmaceutical company in the Chinese hospital market with a compound annual sales growth rate of over 30% during the last five years, and currently has around 2,400 full-time employees in China.

About Idenix/Novartis collaboration

Novartis Pharma AG and Idenix are co-promoting Sebivo, for the treatment of hepatitis B, and co-developing valtorcitabine, a second hepatitis B compound, and valopicitabine, a hepatitis C compound, under a development and commercialization arrangement established in May 2003. Under this agreement, Novartis and Idenix will co-promote Sebivo, valtorcitabine and valopicitabine in the US, France, Germany, Italy, Spain and the UK. Novartis has the exclusive right to commercialize Sebivo, valtorcitabine and valopicitabine in the rest of the world.

Novartis is committed to infectious diseases and is developing a portfolio of complementary mechanisms of action in the treatment of hepatitis B and C, while working to bring innovation for serious hospital infections.

Disclaimer

The foregoing release contains forward-looking statements which can be identified by the use of terminology such as will, aim to, promising, look forward to, expected, to be, committed, developing, working to bring, or similar expressions, or by express or implied discussions re the potential marketing approvals of Sebivo in the EU or in additional countries, or potential future revenue from Sebivo. Such forward-looking statements 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 Sebivo will be approved for any indications in the EU or any other market, or that Sebivo will reach any particular sales levels. In particular, management s expectations regarding the approval and commercialization of Sebivo could be affected by, among other things, unexpected regulatory actions or delays or government regulation generally;

competition in general; increased government, industry, and general public pricing pressures; unexpected clinical trial results, including additional analysis of clinical data, or new clinical data; our ability to obtain or maintain patent or other proprietary intellectual property protection; 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 (NYSE: NVS) is a world leader in offering medicines to protect health, cure 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. 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. Novartis is the only company with leadership positions in these areas. In 2006, the Group s businesses achieved net sales of USD 37.0 billion and net income of USD 7.2 billion. Approximately USD 5.4 billion was invested in R&D. Headquartered in Basel, Switzerland, Novartis Group companies employ approximately 101,000 associates and operate in over 140 countries around the world. For more information, please visit http://www.novartis.com.

References

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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 02, 2007

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