NOVARTIS AG
Form 6-K
March 27, 2006

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 27, 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: ý 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**: ý

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**: ý

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**: ý

Enclosures:

New data show telbivudine superior to lamivudine in treatment of Chinese patients with chronic hepatitis B (Shanghai, China, March 27, 2006)

Novartis provides update on regulatory status of Zelnorm® in Europe (Basel, March 24, 2006)

Investor Relations

Novartis International AG
CH-4002 Basel
Switzerland

Novartis Corporation
608 Fifth Avenue
New York, NY 10020
USA

- Investor Relations Release -

New data show telbivudine superior to lamivudine in treatment of Chinese patients with chronic hepatitis B

Regulatory submission completed in China following US and EU filings

Potential new standard of care for over 120 million patients in China estimated to be infected with hepatitis B virus

Shanghai, China, March 27, 2006 Novartis has announced new clinical data demonstrating that telbivudine an oral, once-daily nucleoside analogue in development for the treatment of chronic hepatitis B (CHB) provides both superior antiviral and clinical efficacy in Chinese patients with this disease after one year of use when compared with the commonly used treatment lamivudine.

The results from this Phase III trial in China, a country estimated to have more than 120 million people infected with hepatitis B, were consistent with the findings from the GLOBE study. This study, the largest registration trial ever conducted for chronic hepatitis B, showed that telbivudine provided a rapid and profound viral suppression.

The new data were included in the recent regulatory submission of telbivudine to Chinese health authorities together with the one-year data from the GLOBE study. China is the latest in a series of filings for marketing approval of telbivudine following earlier submissions in the US and EU.

The study results were presented today at the biennial meeting of the International Liver Congress in Shanghai by Dr. Jinlin Hou, Director and Professor of the Hepatology Unit and Department of Infectious Diseases at Nanfang Hospital, Southern Medical University, Guangzhou, China.

Telbivudine displayed statistically superior efficacy compared to lamivudine on the key viral and clinical markers, including statistically superior viral suppression, a higher percentage of patients with normalization of liver enzymes and a higher proportion of patients with HBeAg loss at one year, said Dr. Hou. This data suggests that telbivudine could become an important new first-line treatment option for the millions of

Chinese patients suffering from this potentially life-threatening disease.

In China alone, this devastating disease accounts for nearly 10 percent of all the chronic hepatitis B cases worldwide, said Dr. James Shannon, Global Head of Development, Novartis Pharma AG. We are very pleased about these positive results and look forward to working with the Chinese authorities to make telbivudine available to patients as fast as possible. Despite advances in chronic hepatitis B treatment, a high unmet need remains for potent therapies. Novartis is committed to developing innovative and more effective therapies such as telbivudine to treat this disease.

About one-year results of Chinese Phase III trial[1]

This trial is an ongoing, randomized, double-blinded, double-dummy trial comparing two years of treatment with telbivudine or lamivudine in 332 Chinese adults with chronic hepatitis B. The majority of patients in this trial were HBeAg-positive (290).

After one year of treatment, telbivudine displayed statistically superior antiviral and clinical efficacy compared with lamivudine. Telbivudine significantly reduced virus levels (HBV DNA) by 6.22 $\log_{10,}$ or more than 1 million-fold, compared with 5.4 $\log_{10}$ for lamivudine (p=0.0004). In addition, undetectable virus levels were achieved by significantly more often in telbivudine-treated patients compared to lamivudine-treated patients (70 and 43 percent, respectively; p<0.0001). Therapeutic response (defined as a reduction of HBV DNA to below 5 $\log_{10}$ copies/mL with HBeAg loss or ALT normalization) was achieved by a significantly higher percentage of telbivudine-treated patients compared with lamivudine-treated patients (87 and 64 percent, respectively; p<0.0001).

More telbivudine-treated patients achieved normalization of liver enzymes (ALT) compared to lamivudine-treated patients (89 and 76 percent respectively; p=0.0033). In addition, HBeAg loss (in HBeAg positive patients only and an indicator of a potential durable response to treatment) occurred in a statistically significantly higher percentage of telbivudine-treated patients compared with lamivudine-treated patients (31 and 20 percent, respectively; p=0.0473). Seroconversion rates (in HBeAg positive patients only) were 25 percent for telbivudine and 18 percent for lamivudine. Resistance rates were 4.5 percent for telbivudine and 10 percent for lamivudine.

Data from this trial support a favorable safety profile for telbivudine. The overall safety profiles for telbivudine and lamivudine in this study closely resemble the recently-reported results from the GLOBE trial. The rate of clinical adverse events was low and similar between the telbivudine and lamivudine treatment groups with nasopharyngitis, upper respiratory tract infection and fatigue occurring most commonly. As seen in the GLOBE study, serum ALT elevations were more common in lamivudine-treated patients compared to telbivudine-treated patients and creatine kinase elevations, not requiring treatment modification, were more common with telbivudine-treated patients compared to lamivudine-treated patients.

About the GLOBE study

The GLOBE study is an ongoing two-year Phase III clinical trial comparing telbivudine with lamivudine in the treatment of 1,367 adults with chronic hepatitis B. The study is being conducted at 112 clinical centers in 20 countries worldwide, including France, Germany, Italy, Spain and the United Kingdom. GLOBE is also the first international hepatitis B study to include clinical sites and patients in China: in fact, more than 25% of the patients enrolled in the GLOBE study (373 patients) were from China with another 25% of Asian patients coming from other countries.

About chronic hepatitis B (CHB)

Chronic hepatitis B is the tenth leading cause of death worldwide[2] with approximately 350 million people chronically infected (lifelong infection)[3]. Additionally, chronic hepatitis B is responsible for up to 80 percent of the world s primary liver cancer[4], and annually an estimated 1.2 million individuals die from chronic hepatitis B-related liver disease[2]. China

has the largest population affected by the hepatitis B virus of any nation with 120 million infected (9.8 percent of the total population) and, of those infected, 30 million of them have chronic disease[5].

Novartis/Idenix collaboration

Idenix is developing its hepatitis B clinical product candidates, telbivudine and valtorcitabine, in collaboration with Novartis Pharma AG under a development and commercialization arrangement established in May 2003. The collaboration arrangement further provides that Novartis Pharma AG and Idenix will co-promote telbivudine and valtorcitabine and other product candidates that Novartis Pharma AG has licensed, if successfully developed and approved for marketing, in the United States, France, Germany, Italy, Spain and the UK. Novartis Pharma AG holds the exclusive license to commercialize telbivudine and valtorcitabine in the rest of the world. The collaboration also provides Novartis Pharma AG

with an exclusive option to license and collaborate with Idenix in the development and commercialization of other product candidates in Idenix s portfolio, including valopicitabine (NM283), a direct antiviral for the treatment of chronic hepatitis C.

About Novartis

Novartis (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 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 91,000 people and operate in over 140 countries around the world. Please visit http://www.novartis.com for information.

This release contains certain forward-looking statements , relating to the Group s business, which can be identified by the use of forward-looking terminology such as potential , will , option, suggests , could become , is committed to , or similar expressions, or by express or implied discussions regarding the potential approval of telbivudine by regulatory authorities, or regarding potential future sales of telbivudine. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results with telbivudine to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that telbivudine will be approved for sale in any market, or that it will reach any particular level of revenue. Management s expectations regarding telbivudine could be affected by, among other things, uncertainties relating to clinical trials, including new clinical data and 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; Idenix s dependence on its collaboration with Novartis Pharma AG; Idenix s ability to obtain additional funding required to conduct its research, development and commercialization activities; 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.

References:

(1) Hou JL, Yin YK, Xu DZ, et al. A phase III comparative trial of telbivudine and lamivudine for treatment of chronic hepatitis B in Chinese patients: first-year results. Abstract presented at International Liver Congress March 27, 2006

(2) Lavanchy D. J Viral Hepat. 2004 Mar 11 (2): 97-107

(3) WHO Hepatitis B Fact Sheet #204

(4) World Health Organization. Expanded programme on immunization hepatitis B vaccine making global progress

(5) Nexis: BBC Monitoring Asia Pacific- Political October 24, 2004

# # #

Novartis Global Investor Relations

Karen J. Huebscher, Ph.D. +41 61 324 84 33

International office

Katharina Ambühl	+41 61 324 53 16
Nafida Bendali	+41 61 324 35 14
Richard Jarvis	+41 61 324 43 53
Silke Zentner	+41 61 324 86 12

e-mail: investor.relations@novartis.com

Fax: +41 61 324 84 44
www.novartis.com

North American office

Ronen Tamir	+1 212 830 24 33
Jill Pozarek	+1 212 830 24 45

e-mail: investor.relations@novartis.com

Fax: +1 212 830 24 05
www.novartis.com

Investor Relations

Novartis International AG
CH-4002 Basel
Switzerland

Novartis Corporation
608 Fifth Avenue
New York, NY 10020
USA

- Investor Relations Release -

Novartis provides update on regulatory status of Zelnorm® in Europe

CHMP issues opinion against European Union approval of Zelnorm for treatment of irritable bowel syndrome with constipation (IBS-C)

Extensive clinical data involving over 14,000 patients and approvals in 56 countries, including US, demonstrate clinical benefits to patients

Basel, March 24, 2006 Novartis has received an opinion from the European Medicines Evaluation Agency s review committee (CHMP) recommending against approval of Zelnorm® (tegaserod) in for the treatment of women suffering from irritable bowel syndrome with constipation (IBS-C).

This advice followed an appeal procedure undertaken by Novartis in December 2005 after the Committee for Medicinal Products for Human Use (CHMP) recommended that the European Commission not approve Zelnorm.

We are disappointed with this decision that will prevent women in Europe to have access to Zelnorm, which has proven to be clinically meaningful for the treatment of this disease, said Dr. James Shannon, Head of Global Pharma Development at Novartis Pharma AG. The extensive clinical trials program and its use by nearly four million patients in more than 30 countries, including the US, Canada, and Switzerland, clearly demonstrate the clinical benefits, efficacy and safety of Zelnorm.

Zelnorm has been studied rigorously in more than seven randomized, placebo-controlled clinical trials, including more than 14,000 patients(1) from North and South America, Europe, Asia Pacific and South Africa. The Zelnorm dossier submitted to the EMEA included data from the landmark ZENSAA trial involving more than 2,600 patients. Trial results showed a statistically significant improvement in the efficacy and tolerability of Zelnorm following initial as well as repeated use in women with IBS-C. (2)Data also showed a favorable safety profile.(2)

This opinion does not have any impact on the current labeling of Zelnorm for the treatment of IBS in those countries where Zelnorm has already been approved. Zelnorm is approved for the treatment of IBS-C in more than 56 countries, including Australia, Switzerland, Canada, the United States, Mexico, China and Brazil. Zelnorm is also approved for the treatment of chronic constipation in more than 20 countries including the United States, Canada and Mexico [(a)]

[(a)] a Novartis markets Zelnorm (tegaserod maleate) in the US, Canada, Philippines and South Africa; and under the trademark Zelmac® (tegaserod) in Switzerland, Latin America and Asia-Pacific regions.

About ZENSAA(2)

ZENSAA was a randomized, double-blinded, placebo-controlled, multi-center trial. The first treatment period involved 2,135 patients taking 6 mg of Zelnorm twice daily and 525 patients taking placebo (4:1 ratio). Patients who responded to the initial treatment entered a treatment-free interval. Only patients whose symptoms were recurring during the 12-week treatment-free interval were re-randomized. In the repeated treatment period, 488 patients were randomized to Zelnorm and 495 randomized to placebo (1:1 ratio). The trial was conducted in 262 centers in 24 countries, including the US, UK, Germany, France, Italy, Spain, Canada, Mexico and South Africa.

Data were evaluated at the end of the trial. The primary efficacy endpoints were satisfactory relief of abdominal discomfort/pain and overall IBS relief for at least three of the four weeks of treatment, also referred to as the 75% rule. The study data were also assessed using the 50% rule, meaning satisfactory relief for at least two of the four weeks of treatment for abdominal discomfort/pain and overall IBS relief.[3] The study also evaluated the impact of treatment on quality of life (measured with the IBS-QOL and EQ5D scales) and treatment satisfaction as well as work productivity using the WPAI-IBS tool.

ZENSAA trial results showed significant benefit with Zelnorm treatment for all endpoints when compared to placebo. Zelnorm s safety and tolerability were also assessed in the trial. The adverse events profile of Zelnorm was similar to placebo, with the exception of diarrhea. Diarrhea was more frequent in patients taking Zelnorm (3.8% vs. 0.6%) in treatment Period 1. For Zelnorm-treated patients, diarrhea rarely led to discontinuation (0.9%). There was a low incidence of serious adverse events in both treatment periods (0.1% in Period 1 and 0.6% in Period 2) for Zelnorm-treated patients.

Irritable bowel syndrome with constipation (IBS-C) and Zelnorm

Irritable bowel syndrome with constipation (IBS-C) is a recurrent disorder characterized by the multiple chronic symptoms of abdominal pain and discomfort, bloating and constipation. Serotonin (5HT), a naturally occurring chemical in the body that regulates motility and pain perception in the gut, is thought to play an important role in the normal activities of the gastrointestinal (GI) tract.[4],[5],[6] Serotonin is believed to influence the movement of food and waste through the body.[4],[5],[6] Researchers have found that an imbalance of serotonin in the gut leads to increased pain perception and dysfunction of the digestive muscles, leading to IBS symptoms.[7],[8],[9]

Zelnorm (tegaserod), a promotility agent, is the first in a newer class of medications known as serotonin-4 receptor agonists (5HT4 agonists) specifically developed to treat the multiple symptoms associated with dysmotility disorders like IBS-C. By activating 5HT4 receptors in the gastrointestinal tract, Zelnorm normalizes delayed motility and reduces sensitivity of the intestinal tract.[10],[11],[12],[13] In clinical studies, significantly more patients experienced a general relief of symptoms when treated with Zelnorm, such as a decrease in abdominal pain, bloating and constipation. In most patients, the onset of relief occurred within just one week.[3],[14],[15],[16],[17] This medicine has been shown to be well tolerated and shows a profile of side effects similar to that of placebo with the exception of diarrhea.[3],[12],[14],[15] The majority of patients reporting diarrhea had a single episode, typically occurring in the first week of treatment and resolving with continued therapy.

The foregoing release contains forward-looking statements that can be identified by terminology such as will or similar expressions, or by express or implied discussions regarding potential

additional marketing approvals or future sales of Zelnorm. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results with Zelnorm to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Zelnorm will receive any additional marketing approvals in any other countries or that it will reach any particular sales levels. In particular, management s expectations regarding Zelnorm could be affected by, among other things, uncertainties relating to 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; increased government, industry, and general public pricing pressures; and other risks and factors referred to in the Company s current Form 20-F on file with the U.S. 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 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 91,000 people and operate in over 140 countries around the world. For more information, please visit http://www.novartis.com.

# # #

Novartis Global Investor Relations

Karen J. Huebscher, Ph.D. +41 61 324 84 33

International office

Katharina Ambühl	+41 61 324 53 16
Nafida Bendali	+41 61 324 35 14
Richard Jarvis	+41 61 324 43 53
Silke Zentner	+41 61 324 86 12

e-mail: investor.relations@novartis.com

Fax: +41 61 324 84 44
www.novartis.com

North American office

Ronen Tamir	+1 212 830 24 33
Jill Pozarek	+1 212 830 24 45

e-mail: investor.relations@novartis.com

Fax: +1 212 830 24 05
www.novartis.com

References

(1) Shetzline MA, Cohard-Radice M, Joelsson B. Ischemic colitis, irritable bowel syndrome, and tegaserod - an alternative viewpoint. Pharmacotherapy 2005; 25:1684-1685.

(2) Tack J, Müller-Lissner S, Bytzer P, Corinaldesi R, Chang L, Viegas A, Schnekenbuehl S, Dunger-Baldauf C, Rueegg P. A randomized controlled trial assessing the efficacy and safety of repeated tegaserod therapy in women with irritable bowel syndrome with constipation. GUT 2005; 54: 1707-1713

(3) CPMP. Points to consider on the evaluation of medicinal products for the treatment of irritable bowel syndrome. 2003.

(4) Gershon MD. Review article: roles played by 5-hydroxytryptamine in the physiology of the bowel. Aliment Pharmacol Ther 1999; 13:15 30.

(5) Crowell MD. Role of serotonin in the pathophysiology of the irritable bowel syndrome. Br J Pharmacol 2004; 141:1285-1293.

(6) Gershon MD. Review article: serotonin receptors and transporters - roles in normal and abnormal gastrointestinal motility. Aliment Pharmacol Ther 2004; 20 Suppl 7:3 14.

(7) Camilleri M, Choi MG. Review article: irritable bowel syndrome. Aliment Pharmacol Ther 1997;11(1):3-15

(8) Camilleri M. Serotonergic modulation of visceral sensation: lower gut. Gut 2002;51(Suppl)1:i81-86

(9) Coates MD, Mahoney CR, Linden DR, Sampson JE, Chen J, Blaszyk H et al. Molecular defects in mucosal serotonin content and decreased serotonin reuptake transporter in ulcerative colitis and irritable bowel syndrome. Gastroenterology 2004; 126:1657 1664.

(10) Grider JR, Foxx-Orenstein AE, Jin J-G. 5-Hydroxytryptamine4 receptor agonists initiate the peristaltic reflex in human, rat and guinea-pig intestine. Gastroenterology 1998; 115:370 380.

(11) Müller-Lissner SA, Fumagalli I, Bardhan KD, Pace F, Pecher E, Nault B, et al. Tegaserod, a 5-HT4 receptor partial agonist, relieves symptoms of irritable bowel syndrome in patients with abdominal pain, bloating and constipation. Aliment Pharacol Ther 2001;15:1655-1666

(12) Prather CM, Camilleri M, Zinsmeister AR, McKinzie S, Thomforde G. Tegaserod accelerates orocecal transit in patients with constipation-predominant irritable bowel syndrome. Gastroenterology 2000; 118:463 468.

(13) Coffin B, Farmachidi JP, Rueegg P, Bastie A, Bouhassira D. Tegaserod, a 5-HT4 receptor partial agonist, decreases sensitivity to rectal distension in healthy subjects. Aliment Pharmacol Ther 2003; 17:577 585.

(14) Lefkowitz M, Shi Y, Schmitt C, Krumholz S, Tanghe J. The 5-HT4 partial agonist, tegaserod, improves abdominal discomfort/pain and normalizes altered bowel function in irritable bowel syndrome (IBS). Am J Gastroenterol 1999; 94:266.

(15) Novick J, Miner P, Krause R, Glebas K, Bliesath H, Ligozio G et al. A randomized, double-blind, placebo-controlled trial of tegaserod in female patients suffering from irritable bowel syndrome with constipation. Aliment Pharmacol Ther 2002; 16:1877 1888.

(16) Kellow J, Lee OY, Chang FY, Thongsawat S, Mazlam MZ, Yuen H et al. An Asia-Pacific, double blind, placebo controlled, randomised study to evaluate the efficacy, safety, and tolerability of tegaserod in patients with irritable bowel syndrome. Gut 2003; 52:671 676.

(17) Nyhlin H, Bang C, Elsborg L, Silvennoinen J, Holme I, Ruegg P et al. A double-blind, placebo-controlled, randomized study to evaluate the efficacy, safety and tolerability of tegaserod in patients with irritable bowel syndrome. Scand J Gastroenterol 2004; 39:119 126.

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 27, 2006

By: /s/ MALCOLM B. CHEETHAM

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