

Edgar Filing: NOVARTIS AG - Form 6-K

NOVARTIS AG  
Form 6-K  
April 03, 2002

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 for the month of March 2002

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  Form 40-F

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  No

Enclosures:

1. Novartis licenses Everolimus, the active ingredient in Certican TM, to Guidant for use in drug eluting stents (March 28, 2001)
2. Novartis Consumer Health and Kao have agreed to end joint venture in Japan (March 26, 2002)
3. British study highlights women prefer Femara(R) in advanced breast cancer trial (March 20, 2002)

Page 1 of 30

## Edgar Filing: NOVARTIS AG - Form 6-K

4. Diovan(R) reduced mortality by 33 per cent in heart failure patients who did not take ACE inhibitors (March 19, 2002)
5. Landmark clinical trial demonstrates Lescol(R) protects against future fatal and non-fatal cardiac events (March 19, 2002)
6. Two further marketing approvals for Zelnorm(TM)/Zelmac(R) (March 19, 2002)
7. Novartis' new non-steroid eczema treatment, Elidel(R) cream, approved for use in babies to adults in Denmark (March 18, 2002)
8. New study shows higher long-term cure with continuous Lamisil(R) tablets compared with intermittent itraconazole in treatment of fungal toenail infection (March 14, 2002)
9. Novartis awarded Prix Galien in France for innovative cancer therapy, Glivec(R) (March 12, 2002)
10. Plaintiffs Withdrawal in New Jersey Marks Fifth and Final Dismissal of all Class Actions Filed Against Maker of Ritalin in 2000 (March 7, 2002)
11. New survey results reinforce underdiagnosis and socioeconomic impact of Irritable Bowel Syndrome (IBS) worldwide (March 4, 2002)

Page 2 of 30

NOVARTIS [LOGO]

Investor Relations

Novartis International AG  
CH-4002 Basel  
Switzerland  
Karen J Huebscher, PH.D.  
Tel +41 61 324 8433  
Nafida Bendali  
Tel +41 61 324 3514  
Sabine Moravi, MBA  
Tel + 41 61 324 8989  
Silke Zenter  
Tel +41 61 324 8612  
Francisco Bouzas  
Tel +41 61 324 8444  
Fax + 41 61 324 8844  
Internet Address:  
<http://www.novartis.com>

-----  
- Investor Relations Release -  
-----

Novartis licenses Everolimus, the active ingredient in Certican TM, to Guidant for use in drug eluting stents

Basel, Switzerland--28 March 2002 - Novartis Pharma AG announced today that it had entered into a worldwide co-exclusive license agreement with Guidant Corporation, granting Guidant rights to utilize the drug everolimus in drug eluting stents for the treatment of coronary and peripheral vascular diseases.

Novartis will provide everolimus to Guidant, supply data to support Guidant

## Edgar Filing: NOVARTIS AG - Form 6-K

filings with regulatory agencies, and receive milestone payments and a royalty on sales of Guidant products utilizing the drug. Pending regulatory approvals, Guidant expects to initiate clinical trials of everolimus-eluting coronary stents later this year.

Everolimus, a new investigational drug, is a potent proliferation inhibitor that targets primary causes of chronic rejection in organ transplantation patients. Guidant and Novartis have independently observed positive results in animal studies evaluating the drug's effectiveness for the prevention of restenosis.

"We welcome this opportunity to collaborate with Guidant on medical innovations that may offer new hope to patients with heart disease," said Thomas Ebeling, CEO, Novartis Pharma AG.

Novartis has completed Phase III human clinical trials evaluating the safety and efficacy of Certican™ (an orally administered drug containing everolimus), for the prevention of organ rejection in renal and heart transplant recipients.

The foregoing press release contains forward-looking statements that can be identified by terminology such as "will provide," "expects", "offer new hope to patients" or similar expressions. Such forward-looking statements involve known and unknown risks, uncertainties and other factors, which may cause the actual results and assumptions to be materially different from any future results, performance or achievements expressed or implied by such statements. There are no guarantees that the license agreement described above will result in the commercialization of any product in any market. Any such commercialization can be affected by, among other things, uncertainties associated with the development and

Page 3 of 30

manufacturing of the treatment, the conduct and results of clinical trials, regulatory actions or delays or government regulations generally, the ability to obtain or maintain patent and other proprietary intellectual property protection, and competition in general, as well as factors discussed in Novartis AG's Form 20-F on file, and other filings 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 described herein as anticipated, believed, estimated or expected.

Novartis AG (NYSE: NVS) is a world leader in healthcare with core businesses in pharmaceuticals, consumer health, generics, eye-care, and animal health. In 2001, the Group's businesses achieved sales of CHF 32.0 billion (USD 19.1 billion) and a net income of CHF 7.0 billion (USD 4.2 billion). The Group invested approximately CHF 4.2 billion (USD 2.5 billion) in R&D. Headquartered in Basel, Switzerland, Novartis Group companies employ about 71 000 people and operate in over 140 countries around the world. For further information please consult <http://www.novartis.com>.

# # #

Page 4 of 30

# Edgar Filing: NOVARTIS AG - Form 6-K

NOVARTIS [LOGO]

Novartis International AG  
Novartis Communications  
CH-4002 Basel  
Switzerland

Tel +41 61 324 2200  
Fax + 41 61 324 3300  
Internet Address:  
<http://www.novartis.com>

-----  
MEDIA RELEASE o COMMUNIQUE AUX MEDIAS o MEDIENMITTEILUNG  
-----

Novartis Consumer Health and Kao have agreed to end joint venture in Japan

Basel, 26 March 2002 - Novartis Consumer Health and Kao Corporation have agreed to dissolve their consumer health joint venture, Novartis KAO Co., Ltd., in Japan after one year of commercial presence in the Japanese market. Both parent companies realized that it was in their best interests to dissolve the joint venture as their initial expectations were not likely to be met within the timeframe they had originally agreed upon.

Established in July 2000, the 50/50 joint venture was set up to market consumer health care products, with a main focus on the marketing of over-the-counter (OTC) products in Japan.

Novartis Consumer Health (NCH) remains committed to expanding its presence in Japan and to bringing leading OTC healthcare products to Japanese consumers. In particular, NCH will explore the many opportunities for potential switches of successful prescription pharmaceuticals to OTC. Also the new OTC business unit structure and strategic focus will help creating new entrepreneurial opportunities and stimulating further growth in key markets.

Novartis Consumer Health (NCH) manufactures, develops and markets a wide range of branded products, designed to restore, maintain or improve consumer and animal health. The NCH business includes OTC (over-the-counter medicines), Infant and Baby (including Gerber), CIBA Vision, Animal Health, and Medical Nutrition, and - until divestment - Health and Functional Food.

Novartis AG (NYSE: NVS) is a world leader in healthcare with core businesses in pharmaceuticals, consumer health, generics, eye-care, and animal health. In 2001, the Group's businesses achieved sales of CHF 32.0 billion (USD 19.1 billion) and a net income of CHF 7.0 billion (USD 4.2 billion). The Group invested approximately CHF 4.2 billion (USD 2.5 billion) in R&D. Headquartered in Basel, Switzerland, Novartis Group companies employ about 71 000 people and operate in over 140 countries around the world. For further information please consult <http://www.novartis.com>.

# # #

Page 5 of 30

Novartis International AG

## Edgar Filing: NOVARTIS AG - Form 6-K

NOVARTIS [LOGO]

Novartis Communications  
CH-4002 Basel  
Switzerland

Tel +41 61 324 2200  
Fax + 41 61 324 3300  
Internet Address:  
<http://www.novartis.com>

-----  
MEDIA RELEASE o COMMUNIQUE AUX MEDIAS o MEDIENMITTEILUNG  
-----

British study highlights women prefer Femara(R) in advanced breast cancer trial

Trial designed by independent panel of patients and physicians compares Femara to Arimidex; study presented at major European breast cancer meeting suggests patients' preferences should play greater role in treatment decisions

Barcelona, Spain, 20 March 2002 -- A study designed by an independent patient advocacy group in the United Kingdom - the Information for Patients Research Group (IPRG) comprised of clinicians, patients, nurses and other healthcare professionals - suggests that patient preferences should be considered when determining advanced breast cancer treatment. Presented at the third European Breast Cancer Conference in Barcelona, Spain, the study compared Femara(R) (letrozole) to Arimidex(R) (anastrozole) in postmenopausal women with advanced breast cancer and found that more than twice as many women preferred Femara. The focus of the IPRG is to improve quality of life for patients, and to design clinical trials to ultimately empower patients and increase patient compliance.

"These are exciting results because this is the first trial to prove the credibility of patient preference; the choice of women to continue taking Femara at the end of the trial strongly correlated with a better quality of life and less side effects on this treatment," said Dr. Robert Thomas, consultant oncologist, Addenbrooke's Hospital (Cambridge) and Bedford Hospital NHS Trusts, UK and lead investigator of this study. "The results of this study clearly show the majority of women preferred Femara as it gave them a better quality of life due to fewer side effects."

### Study Results

The study analyzed quality of life through measurement of side effects. These side effects included lethargy, hot flushes, headache, joint pains, abdominal discomfort, nausea, appetite, fluid retention, wakefulness and thrombophlebitis. Overall, at the end of the trial, more than twice as many women (Femara 68% vs. Arimidex 32%) preferred to take Femara rather than Arimidex because they felt better overall and experienced fewer hot flushes and less stomach upset. Women generally experienced fewer side effects on Femara, but statistically significant differences were found for lethargy (Femara 8% vs. Arimidex 19%), headache (5% vs. 14%), joint pains (3% vs. 11%), abdominal discomfort (3% vs. 11%), nausea (10% vs. 22%) and poor

Page 6 of 30

appetite (2% vs. 8%). The results were reviewed by statisticians at Cambridge University and were considered to be statistically significant.

### Study Design

The primary objective of the IPRG study was to compare quality of life associated with the use of Femara and Arimidex - aromatase inhibitors used to treat postmenopausal women with advanced breast cancer. The 72 patients who

## Edgar Filing: NOVARTIS AG - Form 6-K

participated in the trial were divided into two groups. For the first four weeks, one group took Femara while the other group took Arimidex. After a six-day wash out period, the groups took the other therapy for four more weeks. Patient preference was evaluated based on WHO toxicity questionnaires completed by the women at days one, eight and 28 of each treatment. On the last day of each therapy, the women also completed quality of life questionnaires specifically designed and validated for women with breast cancer on hormone therapies. At the end of the study, women completed a patient preference questionnaire, and they were given the opportunity to evaluate the different treatments and decide which treatment they preferred.

This study was designed by the IPRG to evaluate patients' preferences for a particular treatment during approximately nine weeks of therapy; it was not designed to monitor the clinical side effects as would be measured during a trial evaluating a drugs' safety and efficacy. Therefore, the results of this trial should be considered in conjunction with the scientific and medical data of a given therapy.

### About Femara

Clinical Data Demonstrate Survival Advantage Compared to Tamoxifen;

Data presented at 2001 San Antonio Breast Cancer Symposium

In a randomised, double-blind study of 907 postmenopausal women designed to compare Femara vs. tamoxifen as first-line therapy in women with locally advanced or metastatic breast cancer, survival rates at one and two years show Femara to have a statistically significant survival advantage compared to tamoxifen. The data also demonstrated that, approximately 5 years after initiation of the study (November, 1996), more women who had begun their therapy on Femara were still alive and free of tumour progression compared to those who started on tamoxifen. In addition, patients taking Femara had a 78% greater chance of responding to treatment than patients treated with tamoxifen, and the chance that their tumours would progress was 30% less with Femara than with tamoxifen.

Pharmacokinetic Data Demonstrates Femara Suppresses Oestrogens Better than Anastrozole;

Data published in February 2002 issue of the Journal of Clinical Oncology

Data from a randomised study comparing the ability of Femara and anastrozole to inhibit total body aromatisation and suppress plasma oestrogen levels in 12 postmenopausal women with metastatic breast cancer showed that Femara more effectively inhibits total body aromatisation and suppresses plasma oestrogen levels compared to anastrozole.

The differences between the two drugs in inhibiting total body aromatisation were statistically significant. Although the clinical relevance of this finding in terms of anti-tumour efficacy is yet to be determined, it must be emphasized that the anti-tumour efficacy of all aromatase inhibitors relies on the suppression of oestrogen production. The results of this study document that in terms of oestrogen suppression, Femara reduces oestrogen production significantly better than anastrozole.

Page 7 of 30

Femara, an aromatase inhibitor, is an oral once-a-day first-line treatment for postmenopausal women with hormone receptor positive or hormone receptor unknown locally advanced or metastatic breast cancer. Femara is currently available in more than 75 countries world-wide. Femara also is approved as neo-adjuvant (pre-operative) therapy in more than 25 countries around the world.

## Edgar Filing: NOVARTIS AG - Form 6-K

### Impact of Breast Cancer

More than 200,000 women in Europe are diagnosed with breast cancer each year, accounting for more than 28% of all cancers among European women. The overall lifetime risk of developing breast cancer for women is one in nine, representing 20-25% of all malignancies in European women.

Femara is contraindicated for patients with known hypersensitivity to letrozole or any Femara excipients. Adverse reactions with Femara in the first-line study were generally mild to moderate and were consistent with those seen in the second-line studies. The most commonly reported adverse events for Femara vs. tamoxifen were bone pain (22% vs. 21%), hot flushes (19% vs. 16%), back pain (18% vs. 19%), nausea (17% vs. 17%), dyspnoea or laboured breathing (18% vs. 17%), arthralgia (16% vs. 15%), fatigue (13% vs. 13%), coughing (13% vs. 13%) and constipation (10% vs. 11%). Femara may cause foetal harm when administered to pregnant women. The incidence of peripheral thromboembolic events, cardiovascular events and cerebrovascular events was  $\leq 2\%$ . There is no clinical experience to date on the use of Femara in combination with other anticancer agents.

The foregoing release contains forward-looking statements that can be identified by terminology such as "the first trial to prove", "exciting result", "should be", "may", "potential" or similar expressions. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results with Femara to be materially different from any future results, performance or achievements expressed or implied by such statements. In particular, management's expectations regarding further commercialisation of Femara could be affected by, among other things, additional analysis of data; new data; 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; and other risks and factors referred to in the Company's current Form 20-F on file with the Securities and Exchange Commission of the United States. Should one or more of these risks or uncertainties materialise, or should underlying assumptions prove incorrect, actual results may vary materially from those anticipated, believed, estimated or expected.

Novartis AG (NYSE: NVS) is a world leader in healthcare with core businesses in pharmaceuticals, consumer health, generics, eye-care, and animal health. In 2001, the Group's businesses achieved sales of CHF 32.0 billion (USD 19.1 billion) and a net income of CHF 7.0 billion (USD 4.2 billion). The Group invested approximately CHF 4.2 billion (USD 2.5 billion) in R&D. Headquartered in Basel, Switzerland, Novartis Group companies employ about 71,000 people and operate in over 140 countries around the world. For further information please consult <http://www.novartis.com>.

# # #

Page 8 of 30

NOVARTIS [LOGO]

Investor Relations

Novartis International AG  
CH-4002 Basel  
Switzerland  
Karen J Huebscher, PH.D.  
Tel +41 61 324 8433  
Nafida Bendali  
Tel +41 61 324 3514  
Sabine Moravi, MBA

Edgar Filing: NOVARTIS AG - Form 6-K

Tel + 41 61 324 8989  
Silke Zenter  
Tel +41 61 324 8612  
Francisco Bouzas  
Tel +41 61 324 8444  
Fax + 41 61 324 8844  
Internet Address:  
<http://www.novartis.com>

-----  
- Investor Relations Release -  
-----

Diovan(R) reduced mortality by 33 per cent in heart failure patients who did not take ACE inhibitors

New findings from Val-HeFT presented at American College of Cardiology meeting

Basel, Switzerland, 19 March 2002 - Findings released today by Valsartan Heart Failure Trial (Val-HeFT) investigators demonstrate valsartan, an angiotensin II receptor blocker (ARB), significantly reduced mortality by 33.1 per cent<sup>1</sup> and morbidity by 44 per cent (risk ratios 0.67 and 0.56, respectively) compared with placebo in a cohort of heart failure patients who also took standard heart failure therapies, but not ACE inhibitors.<sup>2</sup> Findings were presented today at the American College of Cardiology (ACC) Scientific Sessions by Professor Aldo Maggioni, Val-HeFT investigator, from the GISSI Group, coordinated by the Italian Association of Hospital Cardiologists (ANMCO) and the Istituto di Ricerche Farmacologie, Mario Negri, Italy.

"Val-HeFT is a landmark trial that showed valsartan led to unprecedented improvements in heart failure patients who were already taking standard treatments with proven benefits as prescribed by their individual physicians," said Professor Maggioni. "Subsequent analysis showed valsartan not only reduced morbidity but dramatically improved survival in patients whose physicians chose not to prescribe ACE inhibitors. These data are critical because it provides insight into the independent effects of valsartan in the absence of the most commonly prescribed available heart failure treatment."

In Val-HeFT, 366 study patients were not prescribed ACE inhibitors by their physicians. Analysis of these patients showed a significant reduction in mortality (p=0.02) and morbidity (p=0.0002) in patients who took Diovan (n=185) compared with those who took placebo (n=181) along with their other types of prescribed heart failure therapy.<sup>1</sup>

Findings on secondary endpoints in the subgroup of patients not taking ACE inhibitors were also consistently positive, indicating favourable effects on disease progression.<sup>2</sup> These secondary findings included significant reductions in hospitalisations for heart failure (p=0.01),

Page 9 of 30

significant improvements in ejection fraction (p=0.0004), and significant reductions in brain natriuretic peptide (BNP) (p=0.0004), a neurohormonal marker for heart failure.<sup>2</sup>

"The new Val-HeFT analysis underscores the cardioprotective benefits of Diovan in the management of heart failure" said Joerg Reinhardt, Global Head Pharma Development, Novartis Pharma AG. "Novartis is committed to developing Diovan across the full spectrum of cardiovascular disease."

A landmark study of 5,010 patients in 302 centres in 16 countries, Val-HeFT



## Edgar Filing: NOVARTIS AG - Form 6-K

studied the effects of valsartan in heart failure patients also taking established therapies, which included beta blockers, diuretics, digoxin and ACE inhibitors.<sup>2</sup>

Val-HeFT was the largest study ever conducted in heart failure. Overall findings of Val-HeFT, published in the New England Journal of Medicine<sup>1</sup> demonstrated valsartan significantly reduced morbidity by 13.2 per cent ( $p=0.009$ ) and hospitalisation for heart failure by 27.5 per cent ( $p$