

Edgar Filing: NOVARTIS AG - Form 6-K

NOVARTIS AG  
Form 6-K  
March 05, 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 February 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 fill 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 Section Exchange Act of 1934.  
Yes  No

Enclosures:

1. New England Journal of Medicine data demonstrate improved CML response rates with Glivec(R) (February 28, 2002)
2. Data recently published in New England Journal of Medicine demonstrates zoledronic acid dosed once yearly is effective in increasing bone mineral density in post menopausal women with osteoporosis (February 28, 2002)
3. Eczema improves in 82% of adults treated with Novartis' new non-steroid, Elidel(R) Cream (February 25, 2002)
4. FDA approves Novartis drug Zometa(R) for the treatment of cancer-related bone complications (February 22, 2002)
5. Novartis breakthrough drug Glivec(R) receives positive opinion from CPMP for treatment of a rare, life-threatening GI cancer; moves closer to EU approval (February 22, 2002)
6. Novartis Venture Fund extends its strategic and geographic reach (February 21, 2002)
7. Dainippon licenses new potential Anxiety treatment to Novartis (February 12,

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

2002)

8. FDA approves Novartis drug Glivec(R) for a life-threatening GI cancer  
(February 1, 2002)

(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

---

New England Journal of Medicine data demonstrate improved  
CML response rates with Glivec(R)

An increasing number of patients in chronic phase (earlier phase) are achieving  
durable cytogenetic responses

Basel, 28 February 2002 - Glivec(R) (imatinib) induces higher haematologic and  
cytogenetic response rates than previously reported in patients in the chronic  
phase (first phase) of chronic myeloid leukemia (CML) who have been  
unsuccessfully treated with interferon-alpha, according to updated data from a  
pivotal Phase II study. The new data, based on a median follow-up of 18 months,  
indicate that overall response rates to the Novartis drug increased in CML  
patients taking the drug early in their disease. These data, an update of the  
12-month results presented at the meeting of the American Society of Haematology  
(ASH) in December 2001, are published for the first time in today's issue of The  
New England Journal of Medicine (NEJM).

"The data on Glivec in chronic phase CML are very exciting because they are  
getting continually stronger," said Hagop Kantarjian, MD, Professor of Medicine,  
Chairman, Department of Leukemia and Chief, Section of Leukemia Developmental  
Therapeutics, M.D. Anderson Cancer Centre, Houston, Texas, lead study  
investigator. "These results are extremely promising. They suggest that earlier  
use of Glivec could have a major impact in improving patients' long-term  
outcome."

#### Study Details

The Philadelphia chromosome (Ph) is the genetic abnormality that characterises  
CML in most patients. Complete cytogenetic response, the elimination of the  
Philadelphia chromosome, is regarded as the ultimate goal of CML treatment.

The NEJM report features 18-month data on 454 evaluable patients with chronic  
phase CML who had failed prior therapy with interferon-alpha. The estimated

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

progression-free survival rate at 18-months was 89%. The data demonstrated that 41% of patients (188/454) achieved a complete cytogenetic response (Ph+ cells 0%) and 60% (272/454) achieved a major cytogenetic response (Ph+ cells <35%). Of the patients who achieved a major cytogenetic response, 84% (228/272) were still maintaining that response at the time of follow-up. The achievement of a cytogenetic response at three months was associated with an improved progression-free survival rate. In addition, 95% of patients (430/454) achieved a complete haematologic response (normalisation of blood counts).

The cytogenetic response rates reported, as well as the estimated 18-month progression-free survival rate, are higher than those historically documented with other CML therapies,

Page 2 of total 24 pages

including interferon-alpha (5-7% complete cytogenetic response) and homoharringtonine (HHT) alone or in combination with low-dose cytarabine (Ara-C). Although there are no long-term data to provide clinical results regarding survival rates for CML patients taking Glivec, researchers believe that durable complete or major cytogenetic response rates improve the potential for longer-term survival.

\* Outside the U.S: Glivec(R) (imatinib); in the U.S.: Gleevec(TM) (imatinib mesylate)

"Novartis is very pleased that we continue to see increasing response rates to Glivec," said David Parkinson, MD, Vice President, Clinical Research, Novartis Oncology. "Longer-term follow-up demonstrating higher cytogenetic response rates to Glivec provides valuable insight into the overall efficacy of the drug and how this relates to longer-term survival with Glivec."

In most countries where Glivec is approved, it is indicated for the treatment of patients with chronic myeloid leukemia (CML) in blast crisis, accelerated phase, or in chronic phase after failure of interferon-alpha therapy. The effectiveness of Glivec is based on overall haematologic and cytogenetic response rates. There are no controlled trials demonstrating a clinical benefit, such as improvement in disease-related symptoms or increased survival.

### Contraindications and Adverse Events

In this study, adverse events were similar to those previously reported. The majority of patients treated with Glivec experienced adverse events at some time. Most events are of mild to moderate grade, but in clinical trials the drug was discontinued for adverse events in 1% of patients in chronic phase, 2% in accelerated phase and 5% in blast crisis. Women of childbearing potential should be advised to avoid becoming pregnant while taking Glivec. The most common side effects included nausea, fluid retention, vomiting, diarrhoea, haemorrhage, muscle cramps, skin rash, fatigue, headache, dyspepsia and dyspnoea, as well as neutropenia and thrombocytopenia. Serious and severe side effects, such as hepatotoxicity (1.1% to 3.5%), fluid retention syndrome (2% to 10%), neutropenia (8% to 46%) and thrombocytopenia (less than 1% to 31%) have also been reported in some patients. There are no long-term safety data on Glivec treatment available up to now.

The foregoing release contains forward-looking statements that can be identified by terminology such as "believe that durable complete or major cytogenetic response rates improve the potential," "continually stronger," "induces higher," "could have a major impact," "indicate that response rates to the Novartis drug are being maintained," and "suggest that earlier use" or similar expressions.

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

Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results with Glivec to be materially different from any future results, performance or achievements expressed or implied by such statements. In particular, management's ability to ensure satisfaction of the FDA's further requirements is not guaranteed and management's expectations regarding further commercialisation of Glivec could be affected by, among other things, additional analysis of data; new data; unexpected clinical trial results; 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; 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.

Page 3 of total 24 pages

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 total 24 pages

(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

---

Data recently published in New England Journal of Medicine demonstrates zoledronic acid dosed once yearly is effective in increasing bone mineral density in post menopausal women with osteoporosis

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

A once a year dose of intravenous bisphosphonate significantly increases bone mass in the spine and hip in women with post menopausal osteoporosis

Basel, 28 February 2002 - A study published today in The New England Journal of Medicine (NEJM) demonstrates that the Novartis drug zoledronic acid, a new intravenous bisphosphonate, significantly increases bone density in women with postmenopausal osteoporosis. This is the first time that a bisphosphonate, given at intervals of up to one year between doses, produces sustained suppression of bone turnover and an increase in bone mineral density in the spine and hip as great as that seen with oral daily dosing of other bisphosphonates.

"An effective therapy that offers the convenience of once yearly dosing would represent a major advance in treatment," said Ian R. Reid, MD, Professor of Medicine and Endocrinology at the University of Auckland, New Zealand, and principal investigator of the study. He added "These findings are good news for patients and physicians alike as oral bisphosphonates, although effective in treating osteoporosis, are known to cause gastrointestinal side effects that often lead to compliance problems."

This dose-finding study, conducted in 351 women at 25 centres in 10 countries, showed treatment with zoledronic acid resulted in bone mineral density increases comparable to those produced with oral daily or weekly dosing of other bisphosphonates.

The women in this randomised, controlled, Phase II study were given a placebo or one of five different doses of zoledronic acid intravenously at different dosage intervals. Some participants were given 0.25 mg, 0.5 mg or 1 mg every three months. Another group received 2 mg at the onset of the study and again at six months. The remaining group received a single 4 mg dose at the start of the study. At the end of 12 months, bone mineral density was significantly increased from placebo in all dosing groups. In addition, important biochemical markers of bone degradation were significantly and continually suppressed as soon as one month and throughout the 12-month period. The treatment was generally safe and well tolerated. In particular, zoledronic acid was not associated with GI side effects that have been observed with oral bisphosphonates. Only some myalgia (muscle pain) and fever occurred more commonly in the treatment groups at the time of injection.

Page 5 of total 24 pages

"Novartis has a long history in the discovery and development of safe and effective treatments for osteoporosis," said Thomas Ebeling, CEO of Novartis Pharma AG. "These data show that zoledronic acid offers great potential in revolutionizing the treatment of this debilitating disease."

Novartis has recently embarked on an extensive Phase III study program known as HORIZON to determine the efficacy of zoledronic acid in reducing the risk of osteoporotic fractures and as a treatment for Paget's disease. HORIZON (Health Outcomes & Reduced Incidence with Zoledronic Once Yearly) will be one of the largest osteoporotic clinical programs undertaken. All studies will involve a single dose of 5mg zoledronic acid once a year.

Osteoporosis is a worldwide epidemic. According to the National Osteoporosis Foundation, the condition represents a major health threat to almost 44 million U.S. women and men, aged 50 and older, representing 55% of the population in this age group. By the year 2010, it is estimated that more than 52 million women and men in this same age category will be affected and, if current trends

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

continue, the figure will climb to more than 61 million by 2020. The International Osteoporosis Foundation estimates that one out of every eight Europeans age 50 or older will suffer a bone fracture during their lifetime caused by osteoporosis. The annual incidence of hip fractures in the European Union is expected to double from 414,000 to 972,000 over the next 50 years.

Zoledronic acid is a new generation intravenous (IV) bisphosphonate. Novartis received its initial marketing clearance for zoledronic acid, under the brand name Zometa(R), in the treatment of hypercalcaemia of malignancy (HCM), also known as tumour-induced hypercalcaemia (TIH), in the United States, European Union and more than 65 other countries, including Switzerland, Brazil, Canada and Australia.

On 22 February 2002, Zoledronic acid, under the brand name Zometa was approved by the US Food and Drug Administration (FDA) for the treatment of patients with multiple myeloma and patients with documented bone metastases from solid tumours, in conjunction with standard antineoplastic therapy. These solid tumours include prostate cancer, lung cancer, breast cancer, and other solid tumour types.

This release contains certain forward-looking statements relating to the Company's business, which can be identified by the use of forward-looking terminology such as "would represent," "good news," "offers great potential," "significantly increases," "to determine the efficacy," "will involve" or similar expressions, or by discussions of strategy, plans or intentions. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results with zoledronic acid to be materially different from any future results, performance or achievements expressed or implied by such statements. Some of these are uncertainties relating to unexpected regulatory delays, further clinical trial results regarding efficacy or safety of zoledronic acid, government regulation or competition in general, as well as factors discussed in the Company's Form 20F filed 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.

Page 6 of total 24 pages

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 7 of total 24 pages

(Novartis Logo)

Investor Relations

Novartis International AG  
CH-4002 Basel  
Switzerland

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

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

---

Eczema improves in 82% of adults treated with Novartis' new non-steroid, Elidel(R) Cream

Basel, 25 February 2002 - Four out of five adults with the itching skin disease, atopic eczema, experienced improvement of their condition with a new treatment based on the non-steroid cream, Elidel(R) (pimecrolimus), according to study results released today. The study, presented at the annual meeting of the American Academy of Dermatology in New Orleans, USA, also showed that seven out of ten adults were considered by their doctors to have been successfully treated with the cream-based regimen, and the itching associated with eczema began to ease on average within two days of starting Elidel.

The results build on the efficacy seen with younger patients. In previous studies, itching was relieved within one week in up to 70% of babies aged 3 - 23 months treated with Elidel. Seven out of ten babies, and 61% of children aged 2 - 17 years, had their eczema under control over six months without any steroids, by using Elidel at the first signs of disease - such as redness and swelling - or itching.

"Itching is the most bothersome symptom of this disease and patients are looking for quick relief," said the study's lead investigator, Professor Michael Meurer, Professor of Dermatology at the University of Dresden, Germany. "In addition, many patients would like treatments that are free of the steroids we currently prescribe, because they fear the side effects associated with long-term steroid use, such as skin thinning. For the last half-century, we have really had nothing else to offer. I am sure those patients, and physicians, who do not like to use steroids will welcome the new generation of topical therapies such as Elidel because they do not contain steroids and are free of steroid side-effects."

Discovered and developed by Novartis, Elidel was approved last December by the US Food and Drug Administration for the short-term and intermittent long-term treatment of mild to moderate atopic dermatitis in patients aged two years and older in whom conventional therapies are inadvisable. Applications for marketing approvals are under consideration in Canada, Switzerland and Denmark (the reference member state for the European Union).

In the German multi-centre study reported by Professor Meurer, half of the 192 participating adults with moderate to severe disease were treated with an Elidel-based regimen, consisting of emollients (moisturisers) for dry skin and Elidel applied twice daily from the first sign or symptom of eczema until the skin cleared. In cases where the eczema was not controlled and flared - worsened to the stage that it was unacceptable to the patient - topical steroids were used. The control group was treated with a regimen representing the current

standard eczema therapy - emollients, with a

Page 8 of total 24 pages

vehicle cream containing no drug being applied at the first sign or symptom, and topical steroids for disease flares.

In the Elidel group, 82% of patients experienced improvement in their condition over the six months, according to their doctor, but only 51% did so in the group receiving the equivalent of current steroid-based therapy. By the end of the study, 69% of patients were considered by their doctors to have been successfully treated with the Elidel-based regimen, compared with 37% in the control group - although 49% of Elidel-treated patients did not use any steroids, compared with 22% in the control group. While itching began to ease within two days of starting treatment in the Elidel group, it worsened in the control group.

The most commonly reported drug-related adverse event was application site warmth or burning, occurring in 15% of Elidel-treated patients and in 5% of the control group; this usually resolved within 1 to 7 days in the Elidel-treated patients, and in 1-9 days in the control group. Other data presented at the AAD congress showed the incidence of application site burning with Elidel is much lower than the 34-43% reported in pediatric patients treated with another new non-steroid treatment.

There is no cure for eczema and its causes are unknown, although patients often have a family history of eczema, hay fever and/or asthma. Affecting approximately 20% of the population at some time in their life, eczema usually begins in childhood and may last until the late teenage years or even for life.

In the study, Elidel was used as soon as the first signs and symptoms appear, to prevent the condition worsening, enabling steroids to be reserved for short-term treatment if the disease is severe. Elidel is a skin-selective inflammatory cytokine inhibitor and works by selectively targeting T-cells in the skin, stopping them producing the cytokines which cause the inflammation, redness and itching associated with atopic eczema (also known as atopic dermatitis).

This press release contains certain forward-looking statements, relating to the Company's business, which can be identified by the use of forward-looking terminology such as "would like," "build on," "new treatments" or similar expressions, or by discussions of strategy, plans or intentions. Such statements include descriptions of the potential benefit of Elidel (pimecrolimus) Cream 1% as evidenced by clinical trial results and FDA approval. Those statements reflect the current views of the Company with respect to future events and are subject to certain risks, uncertainties and assumptions. Many factors could cause the actual results, performance or achievements of the Company to be materially different from any future results, performances or achievements that may be expressed or implied by such forward-looking statements. There are no guarantees that the aforementioned events will result in the commercial success of Elidel (pimecrolimus) Cream 1% in any market. Any such commercial success can be affected by, among other things, uncertainties relating to product development, adverse results in clinical trials, regulatory actions or delays or government regulation generally, the 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.

Page 9 of total 24 pages



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

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 10 of total 24 pages

(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

---

FDA approves Novartis drug Zometa(R) for the treatment of cancer-related bone complications

First bisphosphonate proven effective for the treatment of bone metastases in patients with prostate cancer, lung cancer and other solid tumors; Zometa is approved for second indication in six months

Basel, 22 February 2002 - The US Food and Drug Administration (FDA) today approved the Novartis drug Zometa(R) (zoledronic acid) for the treatment of patients with multiple myeloma and patients with documented bone metastases from solid tumors, in conjunction with standard antineoplastic therapy. These solid tumors include prostate cancer, lung cancer, breast cancer and other solid tumor types. In prostate cancer, patients should have progressed after treatment with at least one hormonal therapy. The trials that led to the approval of Zometa mark the first time any bisphosphonate has demonstrated efficacy in treating bone complications in patients with prostate cancer, lung cancer and other solid tumors. Further, Zometa offers patients, nurses and clinicians a convenient 4 mg, 15-minute infusion time.

"At Novartis we are committed to developing innovative and practical new treatments for patients with cancer," said David Epstein, President, Novartis Oncology. "With this approval, Zometa offers to physicians and patients a new, broadly effective and convenient treatment for the debilitating bone

complications of cancer."

Novartis submitted the new drug application (NDA) for the use of Zometa in the bone metastases indication to the FDA on 22 August 2001 and on 23 October 2001 the NDA received a priority review designation. Submission to the EMEA in the European Union was made on 30 July 2001.

#### Clinical data

The approval for Zometa is based on data from three large international clinical trials evaluating more than 3,000 patients with prostate cancer, lung cancer and other solid tumors, breast cancer and multiple myeloma. This is the largest set of clinical trials ever conducted to evaluate the efficacy and tolerability of a bisphosphonate in treating the complications associated with cancerous bone lesions.

Page 11 of total 24 pages

Clinical trials demonstrated that zoledronic acid decreases the skeletal complications of patients with multiple myeloma and of patients with metastases from solid tumors. In two placebo-controlled clinical studies in patients with bone metastases from prostate cancer or from other solid tumors, both the number of patients with skeletal events and the time to first skeletal related event were decreased relative to placebo.

Breast cancer, lung cancer, prostate cancer, and many other types of solid tumors often spread (metastasize) to bones, while multiple myeloma is a type of cancer that starts in bones. These cancerous bone lesions can cause a variety of complications that seriously affect a patient's life, such as pain, fractures, and/or a need for surgery or radiation therapy.

"Advanced cancers commonly spread to bone and cause a variety of complications that can significantly impact a patient's day-to-day activities," said Matthew Smith, MD, Ph.D., Assistant Professor of Medicine, Harvard Medical School, Massachusetts General Hospital. "There is an unmet clinical need to address these complications, especially in patients with prostate cancer, which makes Zometa an important addition to the current standard treatments for men with advanced prostate cancer."

#### About Zometa

Zometa is a new generation intravenous (IV) bisphosphonate. Novartis initially received marketing clearance for Zometa in the treatment of hypercalcemia of malignancy (HCM), also known as tumor-induced hypercalcemia (TIH), in the European Union and more than 60 countries, including the United States, Switzerland, Brazil, Canada and Australia.

#### Contraindications and adverse events

Zometa, and other bisphosphonates, have been associated with reports of renal insufficiency. Patients should have serum creatinine assessed prior to receiving each dose of Zometa. Caution is advised when Zometa is administered with other potentially nephrotoxic drugs. Doses of Zometa should not exceed 4 mg and the duration of infusion should be no less than 15 minutes.

In clinical trials in patients with bone metastases, Zometa was generally well tolerated, with a safety profile similar to other bisphosphonates. The most commonly reported adverse events included flu-like syndrome (fever, arthralgias, myalgias, skeletal pain), fatigue, gastrointestinal reactions, anemia, weakness, cough, dyspnoea and edema. Occasionally, patients experienced electrolyte and mineral disturbances, such as low serum phosphate, calcium, magnesium and potassium. Zometa should not be used during pregnancy. Zometa is contraindicated

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

in patients with clinically significant hypersensitivity to zoledronic acid or other bisphosphonates, or any of the excipients in the formulation of Zometa.

This release contains certain forward-looking statements relating to the Company's business, which can be identified by the use of forward-looking terminology such as "mark the first time," "offers," "innovative," "new treatments," "important addition," and "significantly impact" or similar expressions, or by discussions of strategy, plans or intentions. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results with Zometa to be materially different from any future results, performance or achievements expressed or implied by such statements. Some of these are uncertainties relating to unexpected regulatory delays, further clinical trial results regarding efficacy or safety of Zometa, government regulation or competition in general, as well as factors discussed in the Company's Form 20F filed with the 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.

Page 12 of total 24 pages

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 13 of total 24 pages

(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

---

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

Novartis breakthrough drug Glivec(R) receives positive opinion from CPMP for treatment of a rare, life-threatening GI cancer; moves closer to EU approval

Glivec - discovered and developed by Novartis - offers unprecedented efficacy in inoperable gastrointestinal stromal tumors (GISTs)

Basel, 22 February 2002 - Novartis announced today that it has received a positive opinion from the Committee for Proprietary Medicinal Products (CPMP) for the novel agent Glivec(R) (imatinib)<sup>1</sup> in the treatment of adult patients with Kit (CD 117) positive unresectable (inoperable) and/or metastatic malignant gastrointestinal stromal tumors (GISTs). Prior to the development of Glivec, patients with GISTs had no effective treatment options beyond surgery. The European Union (EU) Commission usually grants approval of products four months after a CPMP positive opinion. Glivec was designated orphan drug status in November 2001.

Glivec was approved in the EU on 7 November 2001 for its initial indication for the treatment of Philadelphia chromosome (bcr-abl) positive chronic myeloid leukemia (CML) in chronic phase after failure of interferon-alpha therapy, or in accelerated phase or blast crisis.

"Novartis is extremely gratified that Glivec, which has already benefited thousands of patients worldwide with CML, is now one step closer to becoming readily available in the European Union to patients with GISTs," said David Epstein, President, Novartis Oncology.

GISTs are the most common malignant form of sarcoma that arise in the gastrointestinal tract. Worldwide, there are approximately 12,000 new cases each year. The incidence is highest in people 30-60 years of age. Historically, GISTs have been very difficult to treat due to their high levels of resistance to treatment with traditional chemotherapy and radiation therapy. For patients with metastatic or unresectable disease, GISTs had represented an incurable malignancy with a median survival of approximately 10 to 12 months. Until now, surgery has been the only effective treatment option, resulting essentially in palliation of the disease.

-----  
1 Outside the US: Glivec(R) (imatinib); in the US: Gleevec<sup>TM</sup> (imatinib mesylate)

Page 14 of total 24 pages

### About Glivec and GISTs

The CPMP positive opinion for the GIST indication is supported by data from an open-label, multinational study conducted in 147 patients with unresectable or metastatic malignant GISTs. Patients were randomized to receive either 400 mg or 600 mg of Glivec daily for up to 24 months. The overall response rate was 40%, based on confirmed partial responses at the time of the data cut-off for the submission.

Glivec, a signal transduction inhibitor, is one of the first cancer drugs to be developed using rational drug design, based on an understanding of how some cancer cells work. Glivec targets the activity of certain enzymes called tyrosine kinases that play an important role within certain cancer cells. The activity of one of these tyrosine kinases, known as c-kit, is thought to drive the growth and division of most GISTs.

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

Glivec to date

The US Food and Drug Administration (FDA) was the first to approve Glivec for the GIST indication, for which it was designated as an Orphan Drug, on 1 February 2002. Novartis also has submitted a supplemental filing application for Glivec to health authorities in Switzerland for the GIST indication. To date, Novartis has received marketing clearance for Glivec for the CML indication in the European Union and more than 60 countries, including the United States, Switzerland and Japan. In the treatment of CML, it is designated as an Orphan Drug in the United States, European Union and Japan.

Contraindications and adverse events

Although the majority of patients had adverse events reported at least once during the trial, most events were mild to moderate in severity. In the GIST trial, drug was discontinued for adverse events in six patients (8%) in both dose levels studied. In this clinical trial, the most common adverse events were edema, nausea, diarrhea, abdominal pain, muscle cramps, fatigue and rash. In this trial, seven patients (5%) were reported to have gastrointestinal bleeds and/or intratumoural bleeds. Gastrointestinal tumor sites may have been the source of GI bleeds. Glivec is contraindicated in patients with known hypersensitivity. Women of childbearing potential should be advised to avoid becoming pregnant while taking Glivec.

The foregoing release contains forward-looking statements that can be identified by terminology such as "moves closer," "usually grants approval," "until now," "one step closer to becoming readily available," or similar expressions. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results with Glivec to be materially different from any future results, performance or achievements expressed or implied by such statements. In particular, management's ability to ensure satisfaction of the FDA's further requirements is not guaranteed and management's expectations regarding further commercialization of Glivec could be affected by, among other things, additional analysis of data; new data; unexpected clinical trial results for Glivec in the IRIS trial or other Glivec clinical trials; 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; 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 materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those anticipated, believed, estimated or expected.

Page 15 of total 24 pages

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 16 of total 24 pages

## 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>

---

### Investor Relations Release

---

Novartis Venture Fund extends its strategic and geographic reach

Integration of the Novartis BioVenture Fund strengthens its position in the USA

Basel, 21 February 2002 - In its fifth year, the Novartis Venture Fund extended its role as an important partner for start-up companies in Switzerland and other countries, as illustrated in the Activity Report published today. To date, the Fund has been involved in the establishment of 107 companies and, in 2001, a further step in its development was taken with the extension of its strategic and geographic reach. In this strategy, new companies are also to be supported with venture capital beyond the start-up phase. With the integration of the Novartis BioVenture Fund, which is most active in the USA, the Novartis Venture Fund is further extending its field of operations in the important US market.

"With the recent integration of the US-focused Novartis BioVenture Fund, we have further strengthened the position of the Novartis Venture Fund", said Daniel Vasella, Chairman and CEO of Novartis. "And in so doing, we are reinforcing the commitment that we made five years ago - to foster entrepreneurship, to create new jobs and to promote innovative discoveries."

With the addition of the BioVenture Fund, the Novartis Venture Fund now has three pillars of activity: the Spin-off Fund will continue to support Novartis employees who want to set up in business with an innovative idea, while the Start-up Fund supports young companies emerging from the universities. Thanks to the successful business operations of some portfolio companies, the Venture Fund has now seen the first substantial return on its capital. This has allowed the Fund to continue its activities on the same scale as before. Since the inception of the Fund in 1996, 94 new companies have been established and 1350 jobs created, with a total financial support of CHF 126 million.

As its third pillar, the BioVenture Fund, that was recently integrated into the Novartis Venture Fund, increases not only its geographic reach but also its financial muscle. The BioVenture Fund is endowed with USD 100 million and has invested in 13 biotechnology companies, mostly in the USA, whose activities are contributing to the treatment of diseases and helping to speed up the discovery and development of medicines.

As part of the new strategy, a growing share of investments will flow into existing companies which are dependent on additional capital as they continue to develop their technologies. For example, the Spin-off and Start-up Fund last year invested a total of CHF 30 million, of which CHF 18 million went into new companies and CHF 12 million into existing ones.

Page 17 of total 24 pages

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

"Despite the current recessionary trends in the world today, the Life Sciences continue to offer unique opportunities for start-up companies," says Francois L'Eplattenier, Chairman of the Board of the Novartis Venture Fund. "The winners of tomorrow will be those who best manage collaborations and intelligently capitalize on synergies with the growing number of smart and diversified niche players."

The Novartis Venture Fund is built on the belief that economic growth and the creation of new jobs can be achieved in the long run if new entrepreneurial initiatives develop and promising ideas become a business reality. With an initial venture capital of CHF 100 million and USD 100 million, the Novartis Venture Fund supports new and innovative business projects in forward-looking areas, especially in the field of Life Sciences and new technologies. Further information can be found on the internet at <http://www.venturefund.novartis.com>.

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>.

# # #

The Activity Report of the Novartis Venture Fund, which summarizes the activities of the Fund and presents some examples of newly established companies, can be ordered from the following address.

Dr. Rudolf Gygax  
rudolf.gygax@group.novartis.com  
Portfolio- and Business-Manager  
Novartis International AG  
WSJ-200.225  
CH-4002 Basel

Email:

Page 18 of total 24 pages

(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>

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

Dainippon licenses new potential Anxiety treatment to Novartis

Basel, Switzerland and Osaka, Japan, 12 February 2002 - Novartis Pharma AG and Dainippon Pharmaceutical Co., Ltd. today announced a license agreement related

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

to AC-5216, a pre-clinical compound for the treatment of Anxiety.

The number of patients afflicted by one or more of the various Anxiety disorders, such as Generalized Anxiety Disorder (GAD), Social Anxiety Disorder (SAD) and Panic Disorder is estimated to be some 90 million patients worldwide and anti-anxiety treatments represent a growing market currently worth about CHF 8 billion a year.

Under terms of the agreement, Novartis acquires exclusive rights to develop and commercialize the compound worldwide excluding Japan and certain Asian countries where Dainippon possesses exclusive rights to develop and commercialize the compound. Development will be closely co-ordinated between the companies to allow for optimal registration and approval around the world.

The mitochondrial benzodiazepine receptor ligand AC-5216 belongs to a novel class of compounds with a mechanism of action distinct from both Benzodiazepines and Selective Serotonin Re-Uptake Inhibitors (SSRIs). In non-clinical studies, mitochondrial benzodiazepine receptor ligands have demonstrated a fast onset of action without the side effects typical of benzodiazepines such as sedation, muscle relaxation, potentiation of the effects of alcohol, and addiction.

Novartis plans to start phase I trials after completion of certain preparatory activities.

The foregoing press release contains forward-looking statements that can be identified by terminology such as "plan", "have demonstrated", "estimated", "growing" 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 commercialisation of any product in any market. Any such commercialisation can be affected by, among other things, uncertainties associated with the development and 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 materialise, or should underlying assumptions prove incorrect, actual results may vary materially from those described herein as anticipated, believed, estimated or expected.

Page 19 of total 24 pages

Dainippon Pharmaceutical was founded in 1897 as one of the pioneers of the modern Japanese pharmaceutical industry, strives to contribute to the modern world economy through its research and businesses in pharmaceuticals, animal health, food additives, industrial chemicals and research instrumentation. Dainippon's group consolidated revenues for the year ended March 31, 2001 were 158 billion Japanese Yen (USD 1,281 million). Headquartered in Osaka, Japan, Dainippon Pharmaceutical's current pharmaceutical R&D is focused on its fields of expertise in vascular diseases, psycho-neurological diseases, immuno-inflammatory diseases and infectious diseases. For further information please consult <http://www.dainippon-pharm.co.jp/>.

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



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

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 20 of total 24 pages

(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: <a href="http://www.novartis.com">http://www.novartis.com</a>
-----------------	--------------------	---

---

### Investor Relations Release

---

FDA approves Novartis drug Glivec(R) for a life-threatening GI cancer

Glivec - discovered and developed by Novartis - is approved for second indication in nine months, to treat gastrointestinal stromal tumors (GISTs); unprecedented efficacy in an inoperable solid tumor

Basel, 1 February 2002 - The US Food and Drug Administration today approved the Novartis drug Glivec(R) (imatinib)<sup>2</sup> for the treatment of patients with Kit (CD 117) positive unresectable (inoperable) and/or metastatic malignant gastrointestinal stromal tumors (GISTs). The effectiveness of Glivec in GIST is based on the objective response rate. There are no controlled clinical trials demonstrating a clinical benefit, such as improvement in disease-related symptoms or increased survival. Prior to the availability of Glivec, patients had no effective treatment options beyond surgery.

Glivec was approved in the US on 10 May 2001 for its initial indication as a treatment for a specific type of leukemia.

According to Dr. Daniel Vasella, Chairman and CEO of Novartis, "Glivec has already made a major difference in the lives of patients with chronic myeloid leukemia and we're extremely gratified to now make this drug available to patients with GIST." Dr. Vasella continued, "Novartis - along with our colleagues in academia and government - continues to study Glivec and investigate other cancers in which it may help patients - either alone or in combination with other therapies."

GISTs are the most common malignant form of sarcoma that arise in the

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

gastrointestinal tract. Historically, they have been very difficult to treat due to their high levels of resistance to treatment with traditional chemotherapy and radiation therapy. For patients with metastatic or unresectable disease, GISTs had represented an incurable malignancy with a median survival of approximately 10 to 12 months. Until now, surgery has been the only effective treatment option, resulting essentially in palliation of the disease. The limited prevalence of GIST has resulted in the FDA designating Glivec as an Orphan Drug for this indication.

-----  
2 In the US: Gleevec(TM) (imatinib mesylate); outside the US: Glivec(R) (imatinib)

Page 21 of total 24 pages

### About Glivec and GISTs

The FDA approval for the GIST indication is supported by data from an open-label, multinational study conducted in 147 patients with unresectable or metastatic malignant GISTs. Patients were randomized to receive either 400 mg or 600 mg of Glivec daily for up to 24 months. The overall response rate was 38% (400 mg = 33%; 600 mg = 43%), based on confirmed partial responses at the time of the data cut-off for the submission.

Glivec, a signal transduction inhibitor, is one of the first cancer drugs to be developed using rational drug design, based on an understanding of how some cancer cells work. Glivec targets the activity of certain enzymes called tyrosine kinases that play an important role within certain cancer cells. The activity of one of these tyrosine kinases, known as c-kit, is thought to drive the growth and division of most GISTs.

Novartis also has submitted a supplemental filing application for Glivec to health authorities in the European Union and in Switzerland for the GIST indication.

### Glivec To Date

Glivec received US FDA approval for the chronic myeloid leukemia indication (CML) on 10 May 2001 for the treatment of patients in the blast crisis, accelerated phase, or in chronic phase after failure of interferon-alpha therapy. The effectiveness of Glivec in CML is based on overall hematologic and cytogenetic response rates. As yet, there are no controlled trials demonstrating a clinical benefit such as improvement in disease related symptoms or increased survival. For CML, Glivec is currently approved for marketing in the European Union and in more than 60 countries, including Japan, Switzerland and Australia. In the treatment of CML, it is designated as an Orphan Drug in the United States, European Union and Japan.

### Contraindications and Adverse Events

Although the majority of patients had adverse events reported at least once during the trial, most events were mild to moderate in severity. In the GIST trial, drug was discontinued for adverse events in six patients (8%) in both dose levels studied. In this clinical trial, the most common adverse events were edema, nausea, diarrhea, abdominal pain, muscle cramps, fatigue and rash. In this trial, seven patients (5%) were reported to have gastrointestinal bleeds and/or intratumoural bleeds. Gastrointestinal tumor sites may have been the source of GI bleeds. Glivec is contraindicated in patients with known hypersensitivity. Women of childbearing potential should be advised to avoid becoming pregnant while taking Glivec.

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

The foregoing release contains forward-looking statements that can be identified by terminology such as "major difference," "continues to study," "other cancers," "encouraging results," "most major advance" and "is supported by," or similar expressions. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results with Glivec to be materially different from any future results, performance or achievements expressed or implied by such statements. In particular, management's ability to ensure satisfaction of the FDA's further requirements is not guaranteed and management's expectations regarding commercialization of Glivec could be affected by, among other things, additional analysis of data; new data; unexpected clinical trial results; 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; 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 materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those anticipated, believed, estimated or expected.

Page 22 of total 24 pages

Novartis AG (NYSE: NVS) is a world leader in healthcare with core businesses in pharmaceuticals, consumer health, generics, eye-care, and animal health. In 2000, the Novartis Group's ongoing businesses achieved collective sales of CHF 29.1 billion (USD 17.2 billion) and a net income of CHF 6.5 billion (USD 3.9 billion). The Group invested approximately CHF 4.0 billion (USD 2.4 billion) in R&D. Novartis AG is headquartered in Basel, Switzerland. Novartis Group companies employ about 70,000 people and operate in over 140 countries around the world. For further information please consult <http://www.novartis.com>.

# # #

Page 23 of total 24 pages

### 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 5, 2002

By: /s/ RAYMUND BREU  
-----

Name: Raymund Breu  
Title: Chief Financial Officer

Page 24 of total 24 pages