

NOVARTIS AG  
Form 6-K  
February 03, 2003

[QuickLinks](#) -- Click here to rapidly navigate through this document

---

# 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

---

### 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 if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):

Yes: ☐ No: ☒

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: ☐ No: ☒

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 files in Japan for approval of Glivec® for treatment of gastrointestinal cancer (January 30, 2003)
2. Novartis Consumer Health launches over-the-counter Loratadine (January 25, 2003)
3. Novartis to unite its generics businesses under one single global brand: SANDOZ (January 21, 2003)

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

4. License agreement for new multi dose dry powder inhaler Airmax signed (January 17, 2003)
  5. Novartis Venture Fund reports substantial increase in its venture capital to around CHF 300 million (January 16, 2003)
  6. Novartis Ophthalmics granted exclusive rights for development and commercialization of the first pharmaceutical treatment of myopia from Valley Forge Pharmaceuticals Inc.(January 8, 2003)
  7. Glivec® approved in European Union for first-line treatment of adults and children with chronic myeloid leukemia (January 3, 2003)
- 
- 
- 

### 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.ch>

### INVESTOR RELATIONS RELEASE

## Novartis files in Japan for approval of Glivec® for treatment of gastrointestinal cancer

Basel, 30 January 2003 Novartis announced today that its Japanese affiliate has filed an application with health authorities in Japan for marketing approval of Glivec® (imatinib)\* for the treatment of patients with gastrointestinal stromal tumors (GISTs), a life-threatening cancer. This filing is based on clinical data from studies conducted in Japan and Western countries, such as the United States and member states of the European Union where Glivec is already approved for this indication.

"GISTs are very difficult to treat and there are very few options beyond surgery for these patients," said David Epstein, President Novartis Oncology. "We will work closely with the Japanese authorities to facilitate the review and to make Glivec available to appropriate GIST patients in Japan as quickly as possible."

GISTs are the most common malignant form of sarcoma found 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 resistance to available chemotherapy and radiation therapy. For patients with metastatic or unresectable disease, GISTs were an incurable malignancy with a median survival of 20 months and, with local recurrence, a median survival of 9-12 months. Until now, surgery has been the only treatment option, resulting essentially in palliation of the disease.

Glivec is approved in the EU, US, and more than 45 other countries for the treatment of patients with Kit (CD 117)-positive unresectable (inoperable) and/or metastatic malignant GISTs.

Glivec is also indicated for treatment of adult patients with Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) in the EU, US and Japan and a number of other markets. Marketing approval in the EU, Switzerland and other countries includes the treatment of pediatric patients. In addition, Glivec is already approved in over 80 countries for the treatment of adult patients with Ph+ CML in blast crisis,

accelerated phase, or in chronic phase after failure of interferon-alpha therapy.

2

---

The Japanese trials in patients with GIST confirmed the safety profile previously found in trials from other countries. The most common undesirable effects experienced during Glivec treatment in CML and GIST are: headache, nausea, vomiting, diarrhoea, dyspepsia, myalgia, muscle spasm and cramps, joint swelling, dermatitis, eczema, rash, oedema, fluid retention, neutropenia, thrombocytopenia or anaemia. Glivec is contraindicated in patients with known hypersensitivity to imatinib or any of its excipients. 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 or by discussions regarding potential marketing approvals for new indications for Glivec. 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. There can be no guarantee that Glivec will be approved for any additional indications in any market. Neither can there be any guarantee regarding the long-term impact of a patients' use of Glivec. In particular, management's ability to ensure satisfaction of the health authorities' further requirements is not guaranteed and management's expectations regarding commercialization of Glivec could be affected by, among other things, additional analysis of Glivec clinical data; new clinical 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 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 AG (NYSE: NVS) is a world leader in pharmaceuticals and consumer health. In 2002, the Group's businesses achieved sales of CHF 32.4 billion (USD 20.9 billion) and a net income of CHF 7.3 billion (USD 4.7 billion). The Group invested approximately CHF 4.3 billion (USD 2.8 billion) in R&D. Headquartered in Basel, Switzerland, Novartis Group companies employ about 72 900 people and operate in over 140 countries around the world. For further information please consult <http://www.novartis.com>.

# # #

*Additional information on Novartis Oncology and Glivec can be found at [www.novartis oncology.com](http://www.novartis oncology.com) or [www.glivec.com](http://www.glivec.com). Additional media information can be found at [www.novartis oncologyvpo.com](http://www.novartis oncologyvpo.com).*

3

---

**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**

**COMMUNIQUE AUX MEDIAS**

**MEDIENMITTEILUNG**

## **Novartis Consumer Health launches over-the-counter Loratadine**

Basel, 25 January 2003 Having received FDA approval, Novartis Consumer Health announced today that it has launched branded and generic over-the-counter versions of loratadine 10-mg. tablets, the generic equivalent of Claritin®, a leading non-sedating antihistamine. The Novartis affiliate Geneva Pharmaceuticals, Inc. manufactures the product and has launched it as a non-prescription product. In March, the Novartis OTC business unit in the US will follow with the launch of Tavist® Non-Sedating loratadine and private label loratadine both available for consumers, without prescription.

This innovative marketing scenario involving both the Generics and OTC business units distinctively position Novartis to meet the disparate needs of today's retail customer, leveraging the strengths of the two business units. The move of Claritin® from prescription directly to OTC is result of a recent decision by the U.S. Food and Drug Administration.

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

As a result of the Claritin® switch, some managed care plans may significantly increase co-pays or require pre-authorization for the remaining prescription non-sedating antihistamines. Further, patients may have to pay a higher retail price for the OTC version as compared to their co-pay for the branded product.

"We expect the switch of loratadine will allow retailers to better meet consumers' desire for self medication, whether self-directed or driven by the physician. With this dual marketing approach, retailers will not only be able to counsel patients on appropriate antihistamine selection, but will enable patients to take full advantage of the switch with a lower cost alternative to any prescription product in the antihistamine category," said Lynne Millheiser, Senior Vice President, OTC North America.

Geneva has launched loratadine as a non-Rx, behind the pharmacy counter product. This enables pharmacists the opportunity to convert their prescription-based consumers as well as those with existing Claritin® prescription refills. This unique, behind the pharmacy counter marketing approach for a non-Rx drug will provide pharmacists with a time saving method to seamlessly offer prescription patients Geneva's lower cost, over-the-counter, generic version of Claritin®.

Novartis OTC plans to sell its in-aisle private label 10-mg. version of loratadine in 10-, 20-, 30- and ultimately 60-count packages, at prices significantly less than branded Claritin® OTC. Novartis' Tavist Non-Sedating brand of loratadine will be a branded, value-priced alternative to Claritin, available in 10- and 30-count packages.

Claritin® is a registered trademark of Schering Plough Corporation.

4

---

The foregoing release contains forward-looking statements that can be identified by terminology such as "will", "may", "expect" or similar expressions, or by express or implied discussions regarding the issues resulting from the switch of loratadine from Rx to OTC, the cost of loratadine to the patient, Geneva's behind the pharmacy counter marketing approach, or potential revenues from this product. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results, including actual sales of loratadine to be materially different from any future results or performance expressed or implied by such statements. In particular, management's expectations regarding the potential for loratadine could be significantly affected by the approach taken by managed care plans and the response of the patients to the OTC switch of loratadine 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.

Both Geneva Pharmaceuticals, Inc. and Novartis Consumer Health, Inc. are members of the Novartis AG (NYSE: NVS) group of companies, a world leader in healthcare with core businesses in pharmaceuticals, consumer health, generics, eye-care and animal health. Novartis AG (NYSE: NVS) is a world leader in pharmaceuticals and consumer health. In 2002, the Group's businesses achieved sales of CHF 32.4 billion (USD 20.9 billion) and a net income of CHF 7.3 billion (USD 4.7 billion). The Group invested approximately CHF 4.3 billion (USD 2.8 billion) in R&D. Headquartered in Basel, Switzerland, Novartis Group companies employ about 72 900 people and operate in over 140 countries around the world. For further information please consult <http://www.novartis.com>.

# # #

5

---

**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**

**COMMUNIQUE AUX MEDIAS**

**MEDIENMITTEILUNG**

**Novartis to unite its generics businesses under one single global brand: SANDOZ**

## *New name to strengthen recognition as a world-leading generics manufacturer*

Basel/Kundl, 21 January 2002 Novartis today unveiled plans to unite its 14 Generics company brands under a single global umbrella name, "Sandoz", to strengthen recognition and leverage share of voice in the highly competitive marketplace for generics (off-patent medicines). The initiative capitalises on the strong reputation of the Sandoz name, which still commands a high level of awareness and trust among physicians, pharmacists and patients.

Christian Seiwald, CEO of Novartis Generics, explained: "We have achieved outstanding growth in recent years and have made a number of strategic acquisitions to become the second largest generics company in the world. As a result we have operated under an increasing number of different brands without global identity or recognition. Unified international branding sets a milestone in our strategy to strengthen and harmonise our global business. The Sandoz name underscores our reputation for highest quality and innovation, adding more than a century of heritage. We want Sandoz to become the world's clear number-one brand for affordable generic medicines, and active ingredients."

All Novartis Generics companies, including Geneva Pharmaceuticals in the US, Azupharma in Germany, and Biochemie in Austria, the Business Unit's largest single company, will be rebranded with the new name Sandoz. For the time being, Lek will keep its name as agreed between the management of the two companies.

In recent years, Novartis Generics has achieved outstanding growth, with sales jumping a record 26% to CHF 2 433 million in 2001 and a further 24% in the first nine months of 2002. The Business Unit comprises a number of companies that produce high-quality generics and active ingredients for the pharmaceutical and biotechnology industry. Because of its expertise in production and formulation, Novartis Generics can offer a broad range of high-quality pharmaceuticals at competitive prices. The Business Unit employs more than 11 000 people worldwide.

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 and a net income of CHF 7.0 billion. The Group invested approximately CHF 4.2 billion in R&D. Headquartered in Basel, Switzerland, Novartis Group companies employ about 74 000 people and operate in over 140 countries around the world. For further information please consult <http://www.novartis.com>.

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 "to unite", "to strengthen", "plans", "strategy", "will", or similar expressions. Such statements reflect the current plans or views of the Group with respect to future events and are subject to certain risks, uncertainties and assumptions. Management's expectations could be affected by, among other things, competition in general, and other risks and factors referred to in Novartis AG's 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 described herein as anticipated, believed, estimated or expected.

6

---

### **Novartis International AG**

Novartis Communication  
CH-4002 Basel  
Switzerland

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

**MEDIA RELEASE**

**COMMUNIQUE AUX MEDIAS**

**MEDIENMITTEILUNG**

## **License agreement for new multi dose dry powder inhaler Airmax signed**

Basel, 17 January 2003 Novartis announced that its affiliate Novartis Pharma AG has signed a license agreement regarding a new multi dose dry powder inhaler Airmax developed by Ivax Corporation. This agreement covers the use of Airmax Ivax device to deliver Novartis respiratory drugs Foradil® (formoterol) and Miflonide® (budesonide) in Europe and other countries. Ivax will be responsible for filing and marketing approval in Europe and will manufacture the products. Novartis will be the exclusive distributor of the new products in some countries, while IVAX and Novartis may jointly distribute them in others.

"This agreement will enhance the opportunity to make Foradil and Miflonide available in a new device giving wider options to patients in Europe," said Andrew Kay, Head of Global Sales and Marketing, Novartis Pharma.

Foradil® (formoterol) is a beta-2-agonist bronchodilator that has both a rapid onset of action (within 3-5 minutes after inhalation) and a long duration of action for over 12 hours. It is widely used in 87 countries around the world. Miflonide® (budesonide) is a second generation inhaled corticosteroid with a well established efficacy and tolerability.

The foregoing press release contains forward-looking statements which can be identified by terminology such as "will", or similar expressions, or by express or implied statements regarding potential future marketing approvals or sales of an Airmax device to deliver Foradil or Miflonide. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results to be materially different from any future results, performance or achievements expressed or implied by such statement. There can be no guarantee that Airmax will be approved for sale in any market for the delivery of Foradil or Miflonide, or that any particular level of sales will be reached. Management's expectation regarding the commercial potential of Airmax in any market could be affected by, amongst other things, uncertainties relating to product development, regulatory actions or delays or government regulation generally, the ability to obtain or maintain patent or other proprietary intellectual property protection and competition in general, as well as factors discussed in the Company's Form 20-F filed with the 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.

Novartis AG (NYSE: NVS) is a world leader in pharmaceuticals and consumer 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 74 000 people and operate in over 140 countries around the world. For further information please consult <http://www.novartis.com>.

©

2001 Novartis AG, [Legal Disclaimer](#)

7

**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**

**COMMUNIQUE AUX MEDIAS**

**MEDIENMITTEILUNG**

## **Novartis Venture Fund reports substantial increase in its venture capital to around CHF 300 million**

### *Important contribution to the support of new companies in a difficult environment*

Basel, 16 January 2003 Last year, the Novartis Venture Fund boosted its capital endowment by CHF 50 million, thus providing the Fund now with around CHF 300 million. This emerges from the Activity Report published today. In the six years since its foundation, the Novartis Venture Fund has already provided support for 117 company start-ups with loans and equity participation plans. There are currently 68 start-up companies in its portfolio of stocks.

"The activities of the Novartis Venture Fund are becoming increasingly important and making a significant contribution in their support of fledgling companies with innovative, pioneering technologies which meet the needs of patients", said Daniel Vasella, Chairman and CEO of Novartis AG. "I am pleased that about a quarter of companies in the portfolio of the Novartis Venture Fund are active in cancer research, where there is such a high and urgent patient need."

The Novartis Venture Fund is a composite of three separate funds: The Spin-off Fund supports associates of Novartis who want to set up in business with an innovative idea. The Start-up Fund principally supports young companies which are formed from university departments. Over the last six years, the Novartis Venture Fund has supported 96 start-ups through these two funds and helped to create about 1500 jobs in the process. The third fund is the BioVenture Fund, which is focused on companies in the area of biotechnology; this fund is endowed with USD

100 million and has so far provided support for 21 companies.

The year 2002 was a difficult period for many start-up companies. Even those able to boast a good initial performance had difficulty obtaining additional capital to take their technologies further down the road of development. The additional CHF 50 million which the Novartis Venture Fund has received from Novartis will play an important part in providing support in the form of venture capital for young companies wanting to take their development forward. In addition to capital, the Management of the Fund also provides young companies with practical support and advice, for example when they have to draw up financial plans or modify their business plans.

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 a capital endowment of around CHF 300 million, the Novartis Venture Fund supports new and innovative business projects in forward-looking areas, especially in the field of Health Sciences. Further information can be found on the internet at <http://www.venturefund.novartis.com>.

8

---

Novartis AG (NYSE: NVS) is a world leader in pharmaceuticals and consumer 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 74 000 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, can be ordered from the following address.

Dr. Rudolf Gyga  
Email: [rudolf.gygax@group.novartis.com](mailto:rudolf.gygax@group.novartis.com)  
Managing Director  
Novartis International AG  
WSJ-200.225  
CH-4002 Basel

9

---

**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 Ophthalmics granted exclusive rights for development and commercialization of the first pharmaceutical treatment of myopia from Valley Forge Pharmaceuticals Inc.**

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

*Novartis Ophthalmics committed to advancing new therapy for myopia (nearsightedness)*

Basel, Switzerland and Irvine, Calif., USA, 8 January 2003 Novartis Ophthalmics, the eye health unit of Novartis, and Valley Forge Pharmaceuticals, Inc., announced today that they have entered into a licensing agreement for a novel eye medication for the treatment of myopia (nearsightedness). The compound Pirenzepine is currently in Phase II clinical trials. Upon successful completion of Phase III clinical trials and regulatory approvals, Novartis Ophthalmics will market the compound worldwide.

In Phase II clinical trials Pirenzepine has been shown to reduce the progression of the disease by at least 50% in the first 12 months of therapy in children who suffer from myopia.

Financial terms of the transaction were not disclosed.

"This novel compound significantly strengthens our development pipeline by addressing myopia, one of the most important unmet needs in ophthalmics," said Dr. Flemming Ørnkov, Head of Novartis Ophthalmics. "It could set new standards for the treatment of this eye disorder, since there is no pharmacological therapy available today."

Paul A. Lopez, CEO of Valley Forge, commented, "We are very excited about this agreement and securing such a strong partner as Novartis Ophthalmics. The licensing of our lead product, Pirenzepine ophthalmic gel, is an important milestone for Valley Forge Pharmaceuticals, Inc. We look forward to a productive collaboration."

Pirenzepine ophthalmic gel is a completely new therapeutic approach to myopia – a relatively selective muscarinic M1 receptor antagonist administered as an eye gel twice a day, which is expected to reduce the progression of myopia (near-sightedness) by up to 50%.

### About Myopia

Myopia (nearsightedness) is a very common eye disorder, with onset occurring mainly during childhood. It affects approximately 50 million young people (age 5-19 years) in industrialized countries. Severe myopia (myopia higher than 6 diopter) and pathologic myopia (myopia higher than 12 diopter) are associated with an elevated risk of ocular complications later in life. Additionally, lesser degrees of myopia may also represent a risk factor for future ocular disorders.

10

---

The foregoing press release contains forward-looking statements that can be identified by terminology such as "upon successful completion", "could set new standards", "Novartis Ophthalmics will market", "is expected to advance" 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. Such factors include, but are not limited to: risks associated with the development and commercialization of the treatment, including uncertainties relating to manufacturing, clinical trials, registration, pricing and reimbursement; patient and physician demand for the treatment; competition; any uncertainty regarding patents and proprietary rights; product liability claims and insurance; government regulation; dependence on corporate relationships; volatility of share prices as well as factors discussed in the Company's Form 20-F 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.

### Background on Novartis Ophthalmics

With worldwide headquarters in Bulach, Switzerland, Novartis Ophthalmics is a global leader in research, development and manufacturing of leading ophthalmic pharmaceuticals that assist in the treatment of glaucoma, age-related macular degeneration, eye inflammation, ocular allergies and other diseases and disorders of the eye. Novartis Ophthalmics products are available in more than 110 different countries. The North American headquarters are based in Atlanta, Georgia. Novartis Ophthalmics products are made in Switzerland, France and Canada. For further information please consult [www.novartisophthalmics.com](http://www.novartisophthalmics.com) or [www.novartisophthalmics.com/us](http://www.novartisophthalmics.com/us).

### Background on Novartis

Novartis AG (NYSE: NVS) is a world leader in pharmaceuticals and consumer 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 74,000 people and operate in over 140 countries around the world. For further information please consult [www.novartis.com](http://www.novartis.com).



## Background on Valley Forge

Valley Forge Pharmaceuticals Inc, is an early stage ophthalmic pharmaceutical company located in Irvine, California. The Company's key focus is the development of anti-myopia drugs. Valley Forge Pharmaceuticals Inc. has secured an extensive world wide patent estate related to their areas of development and the company will continue to evaluate new and innovative compounds for ophthalmic use. For further information please consult [www.valleyforgepharmaceuticals.com](http://www.valleyforgepharmaceuticals.com).

###

11

### 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.ch>

### INVESTOR RELATIONS RELEASE

## Glivec® approved in European Union for first-line treatment of adults and children with chronic myeloid leukemia

*Novartis drug available immediately for newly diagnosed patients; action marks third indication in Europe in less than 14 months*

Basel, Switzerland, 3 January 2003 Novartis announced today that the European Commission (EC) approved Glivec® (imatinib)\* as a first-line treatment for adult and pediatric patients with Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML), enabling physicians to provide the drug to newly diagnosed patients. This third approval in late December 2002 comes within 14 months of the initial approval of Glivec in the EU and follows a positive opinion from the EU's Committee for Proprietary Medicinal Products (CPMP) received in September 2002.

The EC's approval of Glivec as first-line therapy for adult patients was based on 12-month data from a large head-to-head study comparing Glivec with a combination of interferon-alpha and cytosine arabinoside (IFN/Ara-C), a traditional treatment for CML. In the International Randomized Study of Interferon vs. ST1571 (IRIS), patients treated with Glivec given orally at 400 mg per day were nine times more likely to achieve a complete cytogenetic response, a major goal of CML treatment, compared with those treated with the combination. In addition, Glivec significantly delayed the time to progression to the more advanced stages of CML.

The pediatric approval was based on a Phase I study of children with Ph+ CML who had failed prior IFN therapy. The results of this study indicated similar efficacy and safety as seen in adults.

"The rapid decision of EU health authorities should allow appropriate newly diagnosed CML patients access to Glivec early in the course of their disease, when its potential benefits are greatest," said David Epstein, President, Novartis Oncology. "In addition, these patients are more likely to benefit sooner from an improved quality of life as compared with those on traditional therapies."

### Clinical data

Updated 18-month data from the IRIS study were presented in December 2002 at the annual meeting of the American Society of Hematology (ASH) in Philadelphia, Pennsylvania, and indicated even better results than the 12-month data used to support the approval. The updated 18-month data have not been reviewed by the health authorities.

Following are comparative statistics:

IRIS Study	12-month data submitted to health authorities (28 June 2002)		Updated 18-month data presented at ASH (8 December 2002)	
	Glivec Arm	IFN/Ara-C Arm	Glivec Arm	IFN/Ara-C Arm
Complete* Cytogenetic Response	68%	7%	74%	8%
Major** Cytogenetic Response	83%	20%	85%	22%
Progression-Free Survival	97.2%	80.3%	92.3%	73.6%

\*

no cells detected containing the Ph+ chromosome.

\*\*

detection of less than 35% Ph+ cells remaining.

Based on the 12-month data filed with the health authorities, only 2% and 0.7% of patients in the Glivec arm withdrew from the study or crossed over to the IFN/Ara-C arm for tolerability reasons, respectively. In contrast 6% and 23% of patients, respectively, in the IFN/Ara-C arm withdrew from the study or crossed over for tolerability reasons.

### Glivec

In most countries in which it is approved, Glivec is indicated for the treatment of patients with Ph+ CML in the blast crisis, accelerated phase or in chronic phase after failure of interferon-alpha therapy. In addition, Glivec was approved by the US Food and Drug Administration for first-line treatment of patients with newly diagnosed Ph+ CML one day after the 19 December 2002 EU approval.

Glivec also received EU approval on 24 May 2002 for the treatment of patients with Kit (CD 117)-positive unresectable (inoperable) and/or metastatic malignant gastrointestinal stromal tumors (GISTs).

### Contraindications and adverse events

In the first-line study (IRIS), the safety profile with Glivec at the 12-month follow-up was similar to that of previous Phase II studies in other CML patients with the exception of a lower incidence of myelosuppression. The majority of patients treated with Glivec experienced adverse events at some time. Most events were of mild to moderate grade and treatment was discontinued for adverse events only in 2% of patients in chronic phase, 3% in accelerated phase and 5% in blast crisis. The most common side effects included nausea, fluid retention, vomiting, diarrhea, hemorrhage, muscle cramps, skin rash, fatigue, headache, dyspepsia and dyspnea, as well as neutropenia and thrombocytopenia. Glivec is contraindicated in patients with known hypersensitivity to imatinib or any of its excipients.

The foregoing release contains forward-looking statements that can be identified by expressed or implied discussions regarding potential additional revenues to Novartis as a result of this new indication for Glivec, or regarding the long-term impact of a patient's use of Glivec. 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. There can be no guarantee that the approval described above will result in any additional revenues to Novartis. Neither can there be any guarantee regarding the long-term impact of a patient's use of Glivec. In particular, management's expectations regarding Glivec could be affected by, among other things, additional analysis of Glivec clinical data; new clinical 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 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.

## About Novartis

Novartis AG (NYSE: NVS) is a world leader in pharmaceuticals and consumer 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 74,000 people and operate in over 140 countries around the world. For further information please consult WEB ADDRESS.

# # #

Additional information on Novartis Oncology and Glivec can be found at [www.novartisoncology.com](http://www.novartisoncology.com) or [www.glivec.com](http://www.glivec.com). Additional media information can be found at [www.novartisoncologyvpo.com](http://www.novartisoncologyvpo.com).

14

---

## 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: January 31, 2003

By: /s/ MALCOLM B. CHEETHAM

---

Name: Malcolm B. Cheetham  
Title: Head Group Financial Reporting and Accounting  
15

---

## QuickLinks

[Novartis files in Japan for approval of Glivec® for treatment of gastrointestinal cancer](#)

[Novartis Consumer Health launches over-the-counter Loratadine](#)

[Novartis to unite its generics businesses under one single global brand: SANDOZ](#)

[License agreement for new multi dose dry powder inhaler Airmax signed](#)

[Novartis Venture Fund reports substantial increase in its venture capital to around CHF 300 million](#)

[Novartis Ophthalmics granted exclusive rights for development and commercialization of the first pharmaceutical treatment of myopia from Valley Forge Pharmaceuticals Inc.](#)

[Glivec® approved in European Union for first-line treatment of adults and children with chronic myeloid leukemia](#)

## SIGNATURES