

NOVARTIS AG  
Form 6-K  
August 05, 2002

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# 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 July 2002

## NOVARTIS AG

(Name of Registrant)

Lichtstrasse 35  
4056 Basel  
Switzerland

(Address of Principal Executive Offices)

Indicate by check mark whether the registrant files or will file annual reports under cover Form 20-F or Form 40-F.

Form 20-F ☒ Form 40-F ☐

Indicate by check mark whether the registrant by furnishing the information contained in this Form is also thereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934.

Yes ☐ No ☒

Enclosures:

1. Elidel® (pimecrolimus), the new non-steroid cream from Novartis, relieves the misery of eczema flares in babies to adults (July 2, 2002).
2. Novartis Generics to open new global headquarters in Vienna (July 1, 2002).
3. New study confirms fungal infection of the foot is a risk factor for bacterial tissue infection of the leg (July 1, 2002).
4. Novartis submits marketing applications globally for Glivec® for first-line use in chronic myeloid leukemia (July 1, 2002).

**Novartis International AG**

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**MEDIA RELEASE   COMMUNIQUE AUX MEDIAS   MEDIENMITTEILUNG**

**Elidel® (pimecrolimus), the new non-steroid cream from Novartis, relieves the misery of eczema flares in babies to adults**

*New data presented at World Congress of Dermatology, Paris, France*

Basel, Switzerland, 2 July 2002 Physicians will soon be able to help babies as young as 3 months of age reduce<sup>1,2,3,4</sup> the misery of flares of atopic eczema with the newly approved non-steroid cream, Elidel® (pimecrolimus). Elidel is expected to be launched later this summer in Denmark, the first European country in which the cream is approved for patients aged 3 months and above. Other European countries are evaluating the cream under the Mutual Recognition Procedure. Elidel was recently approved in Mexico, Venezuela, Columbia and New Zealand for patients aged 3 months and above, and is already available in the USA for patients aged 2 years and older.

Data from randomized double blind controlled studies presented this week at the World Congress of Dermatology in Paris, France, showed that Elidel, when applied at the first signs and symptoms of the itching skin disease, could prevent severe flares in all age groups. Professor Thomas Luger, Professor of Dermatology at the University of Muenster, Germany, said: "Since topical corticosteroids were introduced 50 years ago for atopic eczema, physicians have been waiting for an alternative approach that is suitable for babies and sensitive skin such as the face, and gives extended periods of control without the side effects associated with the long-term use of corticosteroids, such as skin thinning."

Two studies involving a total of 961 infants and children<sup>1,2,4</sup> showed that over a year, Elidel prevented severe flares in 57% of infants aged 3 to 23 months, and in 51% of children aged 2 to 17 years. This compared with just 28% of infants and 28% of children who used a conventional treatment of emollients for dry skin and topical corticosteroids as rescue treatment for flares. Elidel was consistently effective across all degrees of severity. A meta-analysis of the two studies showed an absolute reduction in the risk of flares of 27% (severe), 30% (moderate) and 29% (mild).<sup>4</sup>

Elidel was also shown to be steroid sparing, with 64% of infants and 57% of children not using any topical corticosteroids over a year for their eczema. This compared with 35% and 32% respectively in the conventional treatment groups.

A study involving 192 adult patients showed Elidel significantly delayed the onset of flares. The median time to first flare was 144 days in the Elidel arm compared with 26 days in the control group which used emollients and, whenever the patient desired, topical corticosteroids.<sup>3</sup> In total, 45% of patients in the Elidel group had no unacceptable flares of eczema during the 24-week study compared with just 19% of those in the control group. Corticosteroid use was also significantly reduced in this study with 49% of adults treated with Elidel able to avoid steroids entirely compared with 22% of those in the control group.

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"We now have a strong body of long-term evidence showing that this new non-steroid treatment approach can be used to help patients of all ages to avoid, for long periods of time, the despair often associated with eczema flares. I am sure physicians, whether they are treating adults who have lived with the condition for many years, or children or young babies whose eczema commonly occurs on the face and for whom there are currently few treatment options, will welcome this new therapy," added Professor Luger.

Interim data from a 6-month open label study involving patients aged 3 months and above showed that more than 80% patients rated Elidel as excellent or very good with regard to its non-sticky feel, ease of use and suitability for sensitive facial skin. More than 80% of patients or caregivers in the interim analysis said they would definitely or most likely recommend Elidel to someone else with atopic eczema.<sup>5</sup>

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To date, almost 5 000 patients have been treated with Elidel in clinical trials. The incidence of adverse events has been low, the most common reported side effect being a mild-to-moderate temporary feeling of warmth or burning on the skin where the cream was applied. This occurred in 8% of children aged two to 17 years and in 10% of adults.

### About Elidel

Discovered by the Novartis Research Institute in Vienna, Austria, Elidel contains the active ingredient pimecrolimus, which is derived from ascomycin, a natural substance produced by the fungus *Streptomyces hygroscopicus* var. *ascomyceticus*. Pimecrolimus selectively blocks the production and release of cytokines from T-cells in the skin. It is these cytokines which trigger processes leading to the inflammation, redness and itching associated with eczema.

This press release contains forward-looking statements which can be identified by the use of forward-looking terminology such as "will soon be able", "is expected", "are evaluating", "could prevent" or similar expressions, or by discussions regarding the potential launch of Elidel in new markets, or regarding potential new indications for Elidel. Such forward looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results to be materially different from any future results, performance or achievements expressed or implied by such statements. There are no guarantees that the aforementioned data, clinical trials and regulatory approvals will result in new indications for Elidel in any market, or that Elidel cream will be commercialized in any additional market. Any such results can be affected by, amongst other things, uncertainties relating to the 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 Novartis AG's Form 20-F filed with the US Securities and Exchange Commission. Any of these and other factors can cause the actual results to differ materially from the expected or predicted results.

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 72,600 people and operate in over 140 countries around the world. For further information please consult <http://www.novartis.com>.

1.  
Kapp et al. Pimecrolimus (SDZ ASM 981) Cream: A New Treatment Strategy for the Long-term Management of Atopic Dermatitis in Infants. *Abstract accepted for presentation at the World Congress of Dermatology, Paris, France, 1 July to 5 July, 2002.*
2.  
Wahn et al. Efficacy and safety of pimecrolimus cream in the long-term management of atopic dermatitis in children. *Pediatrics 2002* (in press).
3.  
Meurer et al. Pimecrolimus (SCA ASM 981) Cream improves disease control and quality of life in the long-term management of atopic dermatitis in adults. *Abstract accepted for presentation at the World Congress of Dermatology, Paris, France, 1 July to 5 July, 2002.*
4.  
De Prost et al. Prevention of atopic dermatitis flare by pimecrolimus (SDZ ASM 981): A meta-analysis of children and infant studies. *Abstract accepted for presentation at the World Congress of Dermatology, Paris, France, 1 July to 5 July, 2002.*
5.  
Data on file, Novartis Pharma AG, Basel, Switzerland.

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**MEDIA RELEASE   COMMUNIQUE AUX MEDIAS   MEDIENMITTEILUNG**

## **Novartis Generics to open new global headquarters in Vienna**

*Austria remains location of choice for global management team*

Kundl, 1 July 2002 Novartis Generics, a world leader in off-patent pharmaceuticals, today unveiled plans to relocate the management of its global operations from Kundl in Tyrol to the Austrian capital, Vienna. The transfer will begin next quarter and is expected to be complete by the beginning of 2004.

In recent years, Novartis Generics has achieved outstanding growth, with sales jumping a record 26% to CHF 2433 million in 2001. This success and ambitious goals for the coming years have accentuated the need to find an international location with the appropriate infrastructure and business environment.

Christian Seiwald, Head of Novartis Generics, commented: "Of the five locations we evaluated in Europe and the US, Vienna ultimately emerged as the favorite. Its international attractiveness and growing importance as a pharmaceutical and biotech center were influential factors in our decision. It is good news for Austria and underscores the country's position as an international business location."

Mr. Seiwald emphasised the tremendous contribution made by the Kundl staff to developing the global business. He said that the Kundl and Schaffhausen production centers will not be affected by this decision and will remain in Tyrol, as will the Industrial Business Unit and certain other functions.

Novartis Generics comprises a number of companies that produce high-quality generics (off-patent drugs) 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 Sector employs a total of 7,230 people, and achieved sales of CHF 2.4 billion in 2001. Starting in the fourth quarter of the current year, Novartis Generics' headquarters will be progressively relocated from Kundl to Vienna, with the move scheduled to be completed by the end of 2004.

Biochemie GmbH, the largest single company within the Novartis Generics Sector, is a global pharmaceutical and biotechnology enterprise, and one of the leading manufacturers of beta-lactam antibiotics (e.g. penicillins and cephalosporins). In 2001, total sales of EUR 880 million were achieved, with 2,291 employees. Finished pharmaceuticals and active ingredients produced by Biochemie are used in more than 120 countries. Biochemie is Austria's largest pharmaceutical manufacturer and exporter, with exports accounting for 98% of sales in 2001. For further information please consult [www.biochemie.com](http://www.biochemie.com).

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### **MEDIA RELEASE    COMMUNIQUE AUX MEDIAS    MEDIENMITTEILUNG**

## **New study confirms fungal infection of the foot is a risk factor for bacterial tissue infection of the leg**

*Bacterial cellulitis of the leg strongly associated with onychomycosis and tinea pedis*

Basle, 1 July 2002 The results of a just completed multicentre case-control study show that toenail onychomycosis (fungal nail infection) and tinea pedis (athlete's foot) are significant risk factors for developing bacterial cellulitis of the leg, a potentially serious infection of the skin and surrounding soft tissues. The study confirms the clinical observation of a connection between fungal foot infections and bacterial cellulitis. Onychomycosis and tinea pedis can result in breaks in the skin, which constitute a portal of entry for the causative pathogens of bacterial cellulitis of the leg. These results were presented yesterday at an opening symposium of the 20<sup>th</sup> World Congress of Dermatology in Paris.

"The study findings provide epidemiological evidence that patients with foot dermatomycoses – widespread fungal infections that occur in healthy populations – can be at greater risk for bacterial cellulitis of the leg, a serious infection that requires urgent treatment, close monitoring, and often hospitalization," said Professor Jean-Claude Roujeau of the Hôpital Henri Mondor in Creteil, France, who presented the study results at the Novartis satellite symposium. "These results underscore the potential risks of mycotic foot infections and the need for physicians to actively identify and cure these infections."

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The study found that bacterial cellulitis of the leg was significantly associated with positive fungal cultures for onychomycosis and tinea pedis infections, collectively known as foot dermatomycosis, were obtained from 42.5% of bacterial cellulitis patients and 24.1% from control patients without bacterial cellulitis.

Onychomycosis in particular was found in 32.2% of patients with bacterial cellulitis and in 18.4% of controls, meaning that onychomycosis is almost twice as likely to be found in a patient with bacterial cellulitis than in an individual without cellulitis.<sup>1</sup>

The prevalence of tinea pedis interdigitalis, one specific type of athlete's foot, was also higher in patients with bacterial cellulitis of the leg than in controls (29.6% and 13.3% respectively).

This case-control study recruited 243 cases of patients with bacterial cellulitis of the leg and 467 controls (patients who were admitted to the hospital with an acute condition not related to a fungal skin infection). Patients were enrolled during the period March through December 2001 at a total of 30 centres in four countries: Austria, France, Germany, and Iceland.

"These study results show the clear documentation of the relationship between onychomycosis, tinea pedis, and bacterial cellulitis," said Thomas Ebeling, CEO of Novartis Pharma. "We believe these findings will provide an additional important reason for physicians to identify and cure fungal infections of the foot, thereby eliminating these specific risk factors for bacterial cellulitis of the leg."

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Lamisil® Tablets are a prescription medication for the treatment of fungal nail infection (onychomycosis) and fungal skin infections. Lamisil is produced and marketed by Novartis Pharma AG and is a treatment of choice for the cure of fungal nail infection. It is a very effective antifungal agent that provides high cure rates and low relapse rates, with a short duration of treatment in fungal nail infection.

Bacterial cellulitis is an infection of the skin and surrounding soft tissues.<sup>2</sup> It occurs when bacteria enter through a breach in the skin. Seemingly benign at the outset, the initial primary symptom is inflammation of the skin and underlying tissues, as indicated by pain, swelling, redness, warmth and possibly fever. However bacterial cellulitis can spread uncontrolled into deeper tissues or through the lymphatic or circulatory systems.<sup>2</sup> Untreated, it can lead to serious complications such as necrotizing fasciitis (severe involvement of the deep tissues, leading to cell death) or deep vein thrombosis (blood clots in the veins). In such cases, the condition can become life threatening.

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1. Chronic foot dermatomycosis (tinea pedis and/or onychomycosis) is a risk factor for bacterial cellulitis of the leg: A case-control study. Poster presented at the 20<sup>th</sup> World Congress of Dermatology, Paris, 2002.
  2. Curtis DL. Cellulitis. eMedicine Journal, January 11 2002, Volume 3, Number 1 <http://www.emedicine.com/EMERG/topic88.htm>
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**MEDIA RELEASE   COMMUNIQUE AUX MEDIAS   MEDIENMITTEILUNG**

**Novartis submits marketing applications globally for Glivec® for first-line use in chronic myeloid leukemia**

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*Data demonstrate Glivec shows significantly greater cytogenetic response rate and delayed time to progression to more advanced stages of CML compared to interferon/chemotherapy combination*

Basel, Switzerland, 1 July 2002 Novartis has simultaneously submitted marketing applications with health authorities in the European Union and the United States, seeking marketing authorization for Glivec® (imatinib)\* for the first-line treatment of patients with newly diagnosed Philadelphia chromosome-positive chronic myeloid leukemia (CML). In Switzerland, Glivec has already been granted an accelerated approval process for this indication and a complete dossier will be submitted within the next month.

The filings are based on data from the International Randomized Study of Interferon vs. Glivec (IRIS), which were presented in May 2002 at the annual meeting of the American Society of Clinical Oncology (ASCO) and in June 2002 at the European Haematology Association (EHA). The data demonstrate that in the first-line treatment of newly diagnosed CML patients, Glivec achieved an 83% major cytogenetic response rate, compared to 20% for the combination of interferon-alpha and cytarabine arabinoside (IFN/Ara-C), a form of chemotherapy. Also in the IRIS study, Glivec significantly delayed the time to progression to the more advanced stages of CML compared with IFN/Ara-C. In addition, data presented at EHA also show that Glivec provides newly diagnosed CML patients a significantly better quality of life (QoL) than IFN/Ara-C.

"The first line data show that earlier treatment with Glivec significantly increases the likelihood of achieving a major cytogenetic response a major goal of CML treatment and delays the time to progression to the more advanced stages of CML. Based on these results, Novartis worked quickly to file marketing applications around the world, and we will work closely and diligently with health authorities to facilitate their review," said David Epstein, President, Novartis Oncology.

### Filing Data

IRIS is an open-label Phase III trial that enrolled 1,106 patients in 177 centres across 16 countries. There were two arms to the study: the patients in one arm received Glivec at 400 mg/day by mouth, those in the other arm received IFN by subcutaneous injection at a target dose of 5 MIU/M<sup>2</sup>/day with Ara-C 20 mg/M<sup>2</sup>/day by subcutaneous injection for 10 days each month. At time of analysis, the median follow-up was approximately 14 months. The results showed that patients taking Glivec had a probability of achieving major (Ph<35%) and complete (Ph=0%) cytogenetic responses of 83% and 68% at 12 months, respectively, compared with patients in the IFN/Ara-C arm, for whom the estimated rates of experiencing major and complete cytogenetic responses were 20% and 7%, respectively. The complete haematologic response rates were 94% for the Glivec arm and 55% for the IFN/Ara-C arm.

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In the study, patients taking Glivec had an improved overall progression-free survival compared to those taking IFN/Ara-C. The estimated rate of progression-free survival at 12 months was 97.2% in the Glivec arm as compared with 80.3% in the patients randomized to IFN/Ara-C (P<0.001). Progression was defined as progression to accelerated phase or blast crisis, rapid increase in white blood cell count, loss of either complete haematologic response or major cytogenetic response, or death during treatment. In particular, the estimated probability of being free of progression to accelerated phase or blast crisis at 12 months was also significantly higher in the Glivec arm (98.5%) as compared to the IFN/Ara-C (or control) arm (93.1%), regardless of crossover.

The safety profile with Glivec was similar to that of previous Phase II studies in other CML patients. The most frequent adverse events with Glivec were mild to moderate superficial oedemas, muscle cramps, skin rash and nausea. The most frequent adverse events with IFN/Ara-C were nausea, fatigue, headache and diarrhoea. In the Glivec arm, only 2% and 0.7% of patients discontinued from the study or crossed over to the control arm for safety reasons, respectively. In contrast, in the IFN/Ara-C arm, 6% and 23% of patients discontinued from the study or crossed over for safety reasons, respectively.

The filings come just over one year following the initial approval of Glivec by the U.S. Food and Drug Administration (FDA) for the treatment of patients with Philadelphia chromosome-positive (Ph+) CML in the blast crisis, accelerated phase or in chronic phase after failure of interferon-alpha therapy, on 10 May 2001. Glivec has been approved for this CML indication in more than 65 countries. In addition, in February 2002, just nine months following the initial CML approval, Glivec received FDA approval for the treatment of patients with Kit (CD 117) positive unresectable (inoperable) and/or metastatic malignant gastrointestinal stromal tumours (GISTs). This indication has also been recently approved in the European Union and in Switzerland.

The foregoing release contains forward-looking statements that can be identified by terminology such as "will," "probability" and "significantly increases the likelihood" or similar expressions, or by discussions regarding potential new indications for existing products. 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 are no guarantees that any of the potential products or potential new indications will be commercialized in any market. Any such commercialization can be affected by, among other things, additional analysis of data; new data; unexpected clinical trial results; unexpected regulatory actions or delays or

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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.

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Additional information can be found at [www.novartisoncology.com](http://www.novartisoncology.com) and at [www.novartisoncologyvpo.com](http://www.novartisoncologyvpo.com).

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### SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: July 31, 2002

NOVARTIS AG

By: /s/ MALCOLM B. CHEETHAM

Name: Malcolm B. Cheetham

Title: *Head Group Financial Reporting and  
Accounting*

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