NOVARTIS AG
Form 6-K
March 03, 2005

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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 February 2005
(Commission File No. 1-15024)

Novartis AG

(Name of Registrant)

Lichtstrasse 35
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Switzerland
(Address of Principal Executive Offices)

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

Form 20-F: ý Form 40-F: o

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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.

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Enclosures:

1. Novartis receives 2005 Excellence in Corporate Philanthropy Award (Basel, February 28, 2005)

2. New study shows Elidel® provides sustained control of eczema and improves patients' quality of life (Basel, February 21, 2005)

3. Xolair® significantly reduces asthma attacks and emergency treatment in patients most at risk of asthma-related death (Basel, February 15, 2005)

4. Novartis obtains rights from Otsuka to develop new treatment for dry eye (Basel, February 7, 2005)

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MEDIA RELEASE COMMUNIQUE AUX MEDIAS MEDIENMITTEILUNG

Novartis receives 2005 Excellence in Corporate Philanthropy Award

Honor recognizes outstanding executive commitment, dedication to measurement and innovation in corporate philanthropy

Over 4.25 million patients worldwide benefited from Novartis access to medicines programs valued at USD 570 million in 2004

Basel, February 28, 2005 Novartis was honored today with the 2005 Excellence in Corporate Philanthropy Award from the Committee to Encourage Corporate Philanthropy (CECP) a distinguished recognition of the company's worldwide corporate citizenship activities that benefit millions of patients in need every year.

Novartis is the first European company to win the Excellence Award from CECP, which has presented the honors annually since 2000 to companies demonstrating outstanding executive commitment, dedication to measurement and innovation in corporate philanthropy.

Novartis was recognized for its efforts to increase access to medicines for patients who cannot afford treatment. In 2004, over 4.25 million patients around the world benefited from Novartis programs valued at USD 570 million. These initiatives range from drug donation and research programs to combat neglected diseases like leprosy, tuberculosis and malaria in developing nations to patient assistance programs that help cancer patients receive the most innovative and effective treatments available.

"We are committed to applying our core strengths in discovering, developing, producing and distributing high quality medicines to ensure that patients around the world receive the treatments they need," said Dr. Daniel Vasella, Chairman and CEO of Novartis. "This award recognizes the work of Novartis associates around the globe who every day dedicate their work to provide patients with effective medicines and contribute to facilitate access to medicines for patients regardless of their ability to pay."

The Excellence Award was presented to Dr. Klaus Leisinger, president of the Novartis Foundation for Sustainable Development, by Pfizer CEO Hank McKinnell at a luncheon ceremony in New York.

"Novartis is a corporate citizen that cares about those who do not have the necessary purchasing power to afford the products it offers in the market place," Dr. Leisinger said. "We made the decision that this is the right thing to do. The fact that our efforts have been recognized with this distinguished award gives all of us a sense of pride and satisfaction."

As part of its worldwide corporate citizenship program, Novartis supports access to medicine programs for uninsured and indigent patients suffering from leprosy, malaria, tuberculosis, chronic myeloid leukemia and other diseases.

Since 2000, Novartis has provided free treatment for all leprosy patients in the world through a public-private partnership with the World Health Organization (WHO). As a result, the prevalence of leprosy has been dramatically reduced around the globe. Thanks to comprehensive and effective treatment with donated multi-drug therapy, more than three million leprosy patients have been cured since 2000.

Under a separate five-year agreement with the WHO, Novartis is providing fixed combination tablets to treat 500,000 tuberculosis patients in the world's poorest countries, with a first program being started in Tanzania in 2005.

Novartis also provides Coartem, a novel medicine against malaria, at no profit for public sector use in developing countries where malaria is endemic and the emergence of drug-resistant stains of malaria has rendered existing drugs increasingly ineffective. Since 2002, more than six million treatments have been provided and production capacity will increase exponentially this year in response to changes in malaria treatment policy by more than 20 African nations.

Patient assistance initiatives in more than 70 countries provide the breakthrough cancer therapy Gleevec/Glivec free of charge to more than 10,000 patients who otherwise would not have had access to the drug to treat their life-threatening disease.

And for 25 years, the Novartis Foundation for Sustainable Development has made significant contributions to the health of needy people in the developing world. Since 1986, the Foundation has supported programs to improve access to treatment and dispel the stigma of leprosy and pioneered field-based disability care services for victims of the disease.

About Novartis

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MEDIA RELEASE COMMUNIQUE AUX MEDIAS MEDIENMITTEILUNG

New study shows Elidel® provides sustained control of eczema and improves patients' quality of life

Basel, February 21, 2005 Treatment with Elidel (pimecrolimus) Cream 1% provided sustained control of the symptoms associated with atopic eczema for up to 18 months in both adult and paediatric patients, according to new study results[(1)] announced during the congress of the American Academy of Dermatology in New Orleans, USA.

"Helping patients control symptoms long-term is a key goal in the overall management of eczema," said Dr Richard Langley, Assistant Professor, Director of Research, Division of Dermatology, Dalhousie University, Canada. "This study provides encouraging news because one of the most unsettling aspects of eczema is the unpredictability of the condition. What this study shows is that using Elidel to treat a flare-up at the onset of symptoms such as tingling or itching may enable patients to control flares and better manage their condition long-term."

The objective of the multinational study was to evaluate long-term efficacy and safety of Elidel in paediatric and adult patients with eczema of any severity, who had previously completed a six-month core study demonstrating the effectiveness of Elidel in controlling the acute signs and symptoms of atopic eczema. The extension study included 368 of these patients, who were treated for up to 18 months.

Patients experienced sustained relief of their eczema symptoms (up to 18 months) when treated with Elidel in a naturalistic setting, i.e. in a clinical study that closely replicated real life. In the core study, 79.6% of patients who had used Elidel twice-daily experienced relief from the itching (pruritis) associated with mild to moderate eczema, defined as an improvement in symptoms to absent/mild pruritus. These compelling results were sustained for an additional 18-month period for 75.0% of those completing the extension study. At the end of the core study, improvements in the Investigators' Global Assessment (IGA) score were experienced by 83.8% of patients for the face and 73.7% for the whole body. Again, the results were sustained for an additional 18 months during the extension study (80.3% and 68.9% respectively). In addition, 76.8% of patients rated their disease control as either "complete" or "good" at the end of the extension study.

During the extension phase, Elidel was incorporated into patients' daily treatment as needed. Elidel was applied twice-daily to affected areas beginning at the earliest signs or symptoms of a flare (e.g. tingling or itching), continuing for as long as the flare persisted. If signs or symptoms returned, patients resumed twice-daily treatment to prevent progression. Emollients and topical corticosteroids could be added to the treatment regimen if the treating physician felt this was warranted.

There were no unexpected safety findings. The most common adverse events (occurring in 5% of patients or more) were infections (nasopharyngitis, upper respiratory tract infection, influenza), respiratory disorders, application-site conditions and headache. The overall incidence of viral infections was less than 1%. Treatment-related herpes simplex occurred in 4 patients (1.1%). The incidence of adverse events decreased from the end of the core study to the end of the extension study. Application-site burning, pruritus and impetigo all became less frequent in the extension study.

Impact of atopic eczema on patients' lives

For many patients, the burden of eczema extends beyond the outwardly visible symptoms and can have a severe impact on their overall quality of life. This was demonstrated by results from a multinational survey called ISOLATE (International Study Of Life with ATopic Eczema), presented yesterday by Seth J. Orlow, MD, PhD, of New York University School of Medicine, USA.[(2)] This showed that among US participants in the survey, most patients and caregivers of children with eczema (51% of patients and 63% of caregivers) always or sometimes worried about their next flare-up. The study also revealed that around 75% of patients and caregivers lack confidence in the ability to effectively manage their disease during a flare-up.

"Patients often report that eczema flares influence multiple aspects of their lives, including the ability to sleep or even attend work or school. The stress of eczema also affects caregivers and other family members of children who suffer from eczema," said Dr Orlow. "Eczema is not only a physical disease. It can carry a psychological burden and influence the quality of life of patients and caregivers."

The ISOLATE study involved 2,000 participants from eight countries (i.e. France, Germany, Spain, Mexico, Netherlands, Poland, and UK, as well as the US). Data were presented at the meeting from a sub-analysis of approximately 400 patients and caretakers of patients from the US. Participants underwent in-depth interviews using a comprehensive questionnaire developed in collaboration with national patient groups and physicians. The study was supported by an unrestricted educational grant from Novartis.

The benefits of Elidel for patients' quality of life were demonstrated by a study involving nearly 1,000 participants that was also presented at the meeting.[(3)] This showed that treatment with Elidel was associated with a statistically significant improvement in quality of life at months two and six of treatment compared to baseline, in both adult patients and parents of children with eczema (up to 12 years old). Those parents who had previously reported concerns about corticosteroid use had a significantly greater improvement in quality of life six months after Elidel treatment than did those without such concerns (p=0.006). Assessments were based on the Parent's Index of Quality of Life Atopic Dermatitis (PIQoL-AD), a standard measure used for patients aged 12 and under, and the Quality of Life Index for Atopic Dermatitis (QoLIAD) for those above 18 years.

About eczema and Elidel

Eczema is a broadly-used term to describe patchy, red, dry itchy and scaly skin, which, when severe, can "weep', bleed and/or crust over. This common and often distressing skin condition tends to run in families and almost always begins in childhood, usually during infancy. The term eczema most often refers to "atopic dermatitis', a chronic relapsing inflammatory skin condition related to allergic rhinitis ("hay fever') and asthma.

Elidel has been demonstrated to be an effective treatment for the management of mild to moderate eczema, with a favorable safety profile. It is the only non-steroid prescription cream approved for the short-term and intermittent long-term treatment of mild to moderate eczema in patients as young as two years old, who do not respond well to, or may have side effects from, conventional treatments.

Elidel may be used on all skin surfaces, including delicate areas such as the face, neck and skin folds. The active ingredient is 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. These cytokines in the skin cause the inflammation, redness and itching associated with eczema.

The foregoing release contains certain forward-looking statements that can be identified by terminology such as "key goal," "long-term management," or similar expressions, or by discussions regarding the potential that Elidel will be approved for marketing, or regarding any potential revenues from Elidel. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results with Elidel to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Elidel will be approved for sale in any market. In particular, management's expectations regarding commercialization of Elidel could be affected by, among other things, uncertainties relating to clinical trials; new clinical data; unexpected regulatory actions or delays or government regulation generally; the company's ability to obtain or maintain patent or other proprietary intellectual property protection; competition in general; government, industry and general public pricing pressures; as well as other risks and factors referred to in the Company's current Form 20-F on file with the US Securities and Exchange Commission. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those anticipated, believed, estimated or expected. Novartis is providing the information in this press release as of this date and does not undertake any obligation to update any forward-looking statements contained in this press release as a result of new information, future events or otherwise.

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MEDIA RELEASE COMMUNIQUE AUX MEDIAS MEDIENMITTEILUNG

Xolair® significantly reduces asthma attacks and emergency treatment in patients most at risk of asthma-related death

New research demonstrates efficacy of first humanised antibody for asthma

Basel, February 15, 2005 A new analysis of results from seven clinical studies published today[1] shows that Xolair® (omalizumab) a first-in-class therapy that targets a root cause of allergic disease significantly reduced the number of asthma exacerbations ("attacks") and almost halved the rate of emergency visits. The studies involved more than 4,300 patients with severe persistent asthma, who were inadequately controlled despite receiving the therapy specified in current guidelines.

The summary of data appears in *Allergy*, the peer-reviewed journal of the European Academy of Allergology and Clinical Immunology (EAACI). The same publication contains the first detailed results[2] from one of the trials, INNOVATE, indicating that "omalizumab is an effective add-on therapy for these difficult-to-treat patients who have an important unmet medical need." Results from all seven studies are included in the application submitted to the Committee for Medicinal Products for Human Use (CHMP), which is currently evaluating whether Xolair should be approved for use in EU countries.

Xolair is a monoclonal antibody that is given by subcutaneous injection every two or four weeks, and targets IgE (immunoglobulin E) which triggers the cascade of inflammatory symptoms in patients affected by diseases such as allergic asthma. Its efficacy is demonstrated by the review published in *Allergy*, in which data from seven studies were pooled to determine the effect of Xolair on asthma exacerbations in patients with severe persistent asthma. Xolair was added to current asthma therapy and compared either with placebo (in five double-blind studies), or with current asthma therapy alone (in two open-label studies).

More than 90% of patients across the seven studies met the criteria for severe persistent asthma laid down in the Global Initiative for Asthma (GINA) 2002 guidelines. The review demonstrates that Xolair reduced the rate of asthma exacerbations by 38% vs. control ($p < 0.0001$). Overall, the total number of emergency visits was reduced by 47% in Xolair-treated patients ($p < 0.0001$), including reductions of 61% in emergency room visits ($p = 0.013$) and 52% in hospital admissions ($p = 0.041$).

Xolair was also shown to reduce the need for inhaled corticosteroids, to improve asthma symptoms and lung function, and to improve asthma-related quality of life. The authors of the report, led by the editor of *Allergy*, Prof Jean Bousquet of Hôpital Arnaud de Villeneuve, Montpellier, France, stated: "The decreases in the rates of asthma exacerbations and those requiring emergency care, are highly relevant to the management of patients with severe asthma."

"Severe exacerbations are responsible for the mortality associated with asthma, and contribute heavily to the morbidity and costs of the disease. Indeed, the 5-10% of asthma patients with the most severe form of the disease contribute some 50% of the total costs associated with asthma.[3] Decreasing the rate of exacerbations in patients with severe asthma is likely to be associated with improvements in quality of life and decrease burdens on patients and health care systems, as well as potentially saving lives."

A total of 15 million people worldwide are estimated to suffer from severe persistent asthma[4] and are therefore at high risk of experiencing severe and potentially fatal attacks.[5][6] One in every 250 deaths throughout the world is thought to be due to asthma-related causes,[4] and the total costs associated with asthma are greater than those for tuberculosis and HIV/AIDS combined.[7] With the number of asthma cases predicted to rise by another 100 million by 2025, the human and social burden could increase even further.[4]

Importantly, the data show that response to Xolair was even more pronounced in individuals known to be at greatest risk of asthma-related death. A sub-analysis of three placebo controlled studies[8] showed that Xolair reduced the rate of asthma exacerbations by 55% vs. placebo ($p < 0.0004$) in 254 patients who were defined as high-risk on the basis of an overnight hospitalisation, intensive care unit stay or emergency room visit in the past year, or any prior intubation.

The review published today incorporates results from INNOVATE, a randomised, double-blind, placebo-controlled study in 419 patients aged 12-75 who were inadequately controlled despite treatment with high-dose inhaled corticosteroids and long acting beta2 agonists (i.e. step 4 therapy in the GINA guidelines). Patients were recruited for the 28-week study at 108 centres in Australia, Belgium, Canada, France, Germany, Israel, Italy, Mexico, the Netherlands, New Zealand, South Africa, Spain, UK, and US. The rate of clinically significant asthma exacerbations (i.e. those requiring rescue systemic corticosteroid therapy) was significantly reduced by 26% ($p = 0.043$), when adjusted for an observed imbalance in asthma exacerbation history prior to randomisation into the trial. Without taking this baseline imbalance into account, a similar magnitude of effect was seen (i.e. a 19% reduction) but this did not reach statistical significance. Unadjusted data were used in the pooled analysis.

In the same difficult-to-treat group of patients, Xolair halved the number of severe asthma exacerbations, i.e. those requiring rescue systemic corticosteroid therapy in which lung function was also below 60% of the patient's personal best (49 events with Xolair vs. 100 with placebo, $p = 0.002$). In addition, Xolair significantly reduced the total number of emergency visits for asthma ($p = 0.038$).

The authors of the study, led by Prof Marc Humbert of Hôpital Antoine Beclere, Clamart, France, concluded: "Patients' quality of life was improved, as were symptoms and lung function, and both patients and investigators considered omalizumab an effective treatment. Omalizumab was well-tolerated, with no evidence of clinically significant concerns of treatment. These clinically meaningful benefits demonstrate the usefulness of omalizumab as an add-on therapy for patients with inadequately controlled severe persistent asthma who have a significant unmet medical need despite best available therapy."

An estimated 33,000 patients have been referred for Xolair treatment in the US since it was launched there in July 2003, and Xolair is also approved in Australia, Brazil, Canada, New Zealand and Venezuela. It has been developed under an agreement between Novartis Pharma AG, Genentech, Inc., and Tanox, Inc. Health authorities in the EU are expected to announce their decision on Xolair approval later this year.

The foregoing release contains certain forward-looking statements that can be identified by terminology such as "predicted to rise," "could increase," "are expected to," or similar expressions, or by discussions regarding the potential that Xolair will be approved for marketing, or regarding any potential revenues from Xolair. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results with Xolair to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Xolair will be approved for sale in any market. In particular, management's expectations regarding commercialization of Xolair could be affected by, among other things, uncertainties relating to clinical trials; new clinical data; unexpected regulatory actions or delays or government regulation generally; the company's ability to obtain or maintain patent or other proprietary intellectual property protection; competition in general; government, industry and general public pricing pressures; as well as other risks and factors referred to in the Company's current Form 20-F on file with the US Securities and Exchange Commission. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those anticipated, believed, estimated or expected. Novartis is providing the information in this press release as of this date and does not undertake any obligation to update any forward-looking statements contained in this press release as a result of new information, future events or otherwise.

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Investor Relations Release

Novartis obtains rights from Otsuka to develop new treatment for dry eye

Novel mechanism of action expected to enhance tear secretion and increase mucin levels covering conjunctiva and cornea

Over 22 million patients visit ophthalmologists each year seeking treatment for symptoms of dry eye

Basel, February 7, 2005 Novartis announced today that it has in-licensed rebamipide, an investigational treatment for dry eye, from Otsuka Pharmaceutical Company, Ltd. Currently being tested in two Phase III studies in the US, rebamipide is expected to demonstrate a novel mechanism of action to enhance tear secretion and increase the levels of mucin covering the conjunctiva and cornea of the eye.

Dry eye is a condition characterized by a patient's inability to produce enough tears or the appropriate quality of tears to keep the eye healthy and comfortable. There are currently 22 million patients who visit an ophthalmologist worldwide for dry eye symptoms and many more who self-treat or do not treat their condition at all.

"As dry eye can have many causes and affects a large and growing patient population, there is a high unmet medical need and opportunities exist for several new pharmacological treatment approaches," said Flemming Ornskov, MD, President of Novartis Ophthalmics. "We expect rebamipide to provide distinct advantages to patients over currently available products."

Dysfunction in the delicate balance in the tear film may develop from aging, systemic inflammatory diseases, ocular surface diseases, or different medications. Palliative treatments for dry eye include artificial tears, which patients can self-administer four or more times per day. Unlike artificial tears, which simply lubricate the eyes and help maintain moisture[(1)], rebamipide provides a new and unique pharmacologic approach to treatment of dry eye by increasing mucin secretion. It is expected to increase tear quality and may improve corneal health.

"Novartis sees promise in rebamipide's novel ability to treat dry eye," said Ornskov. "With this in-license agreement, we expect to be able to offer general ophthalmologists a well-rounded dry eye product portfolio that we hope will elevate the standard of treatment worldwide."

Under the agreement, Novartis will obtain an exclusive license with the right to sub-license the compound globally, excluding Japan and selected Asian countries. Novartis will pay an upfront fee and annual royalties. The terms of the agreement were not disclosed.

The foregoing press release contains certain forward-looking statements that can be identified by terminology such as "will," "expected to increase," "expect to provide," "may improve," "opportunities exist," "sees promise," "expect to be able," or similar expressions, or by express or implied discussions regarding the potential that rebamipide will be approved for marketing, or regarding any potential revenues from rebamipide. Such forward-looking statements involve known and unknown risks, uncertainties or other factors that may cause the actual results to be materially different from any future results, performance, or achievements expressed or implied by such statements. In particular, management's expectations relating to rebamipide could be affected by, among other things, uncertainties relating to clinical trials; unexpected regulatory actions or delays or government regulation generally; the ability to obtain or maintain patent or other proprietary intellectual property protection; competition in general; government, industry and general public pricing pressures, as well as factors discussed in the Company's Form 20-F filed with the US Securities and Exchange Commission. Novartis is providing the information in this press release as of this date and does not undertake any obligation to update any forward-looking statements contained in this press release as a result of new information, future events or otherwise.

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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.

Novartis AG

Date: March 2, 2005

By: /s/ MALCOLM B. CHEETHAM

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

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