NOVARTIS AG
Form 6-K
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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 dated February 2003
(Commission File No. 1-15024)

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: ý Form 40-F: o

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 o No ý

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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.

Yes o No ý

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Investor Relations Release

Novartis' Zometa® receives positive CPMP opinion for label update to include longer-term data in preventing bone complications in a broad range of advanced cancers

CPMP positive on data to expand current indication; data confirm long-term efficacy and safety of Zometa/show breast cancer patients have additional 20% reduced risk of bone complications compared to those treated with Pamidronate; EU approval moves closer

Basel, 25 February 2003 Novartis announced today that it has received a positive opinion from the Committee for Proprietary Medicinal Products (CPMP) to expand the current marketing authorization to include data on long-term use of Zometa® (zoledronic acid) for patients with advanced cancers that have spread to the bone.

Novartis submitted the marketing authorization application for inclusion of these long-term data to the European Agency for the Evaluation of Medicinal Products (EMEA) on 31 October 2002 and anticipates full authorization from the EMEA in Q2 2003. Zometa was granted marketing authorization by the EMEA in July 2002 for the prevention of bone complications in patients with advanced malignancies involving bone. This indication was based on data from three large pivotal trials of more than 3,000 patients that evaluated the drug for a treatment period of approximately one year.

The data submitted to the EMEA confirm the long-term (approximately two years) benefits of Zometa including a decrease in number of patients experiencing bone complications, delay in initial onset of bone complications and reduced risk of developing complications. Bone complications, also known as skeletal related events (SREs), include, among others, pathological fractures, a need for radiation or surgery to bone, spinal cord compression, and hypercalcemia. A multiple event analysis demonstrated that breast cancer patients treated with Zometa 4 mg in a 15-minute infusion had an additional 20% lower risk of developing bone complications after two years of treatment, compared with those treated with pamidronate 90 mg infused over two hours. The multiple event analysis is a rigorous and sensitive statistical analysis that accounts

for the occurrence of SREs over the entire course of treatment.

Zometa is the first intravenous bisphosphonate to demonstrate efficacy in treating bone complications across a broad range of tumor types such as breast, prostate, renal cell and lung cancers, as well as multiple myeloma.

Contraindications and adverse events

In clinical trials in patients with bone metastases, Zometa had a safety profile similar to other intravenous bisphosphonates. The most commonly reported adverse events in bone metastases clinical

trials, regardless of causality with Zometa, included flu-like syndrome (fever, arthralgias, myalgias, skeletal pain), fatigue, gastrointestinal reactions, anaemia, weakness, cough, dyspnoea and oedema.

Zometa is contraindicated during pregnancy, in breast-feeding women and in patients with clinically significant hypersensitivity to zoledronic acid or other bisphosphonates, or any of the excipients in the formulation of Zometa. 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. Due to the risk of clinically significant deterioration in renal function, single doses of Zometa should not exceed 4 mg and the duration of infusion should be no less than 15 minutes. Since safety and pharmacokinetic data are limited in patients with severe renal impairment, Zometa is not recommended in patients with bone metastases with severe renal impairment. In the clinical studies, patients with serum creatinine >3.0 mg/dL were excluded.

The foregoing release contains forward-looking statements that can be identified by terminology such as "EU approval moves closer", "anticipates", or similar expressions, or by discussions regarding potential new indications or labeling for Zometa, or regarding the long-term impact of a patient's use of Zometa. 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. There can be no guarantee that Zometa will be approved for any additional indications or labeling in any market. Neither can there be any guarantee regarding the long-term impact of a patient's use of Zometa. In particular, management's ability to ensure satisfaction of the health authorities' further requirements is not guaranteed and management's expectations regarding commercialization of Zometa could be affected by, among other things, additional analysis of Zometa 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 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 Zometa can be found at www.novartisoncology.com or www.zometa.com. Additional media information can be found at www.novartisoncologyvpo.com.

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MEDIA RELEASE COMMUNIQUE AUX MEDIAS MEDIENMITTEILUNG

Elidel cream 1% shown effective treatment with proven safety profile for infant eczema, study reports

Journal of Pediatrics cites Elidel as "promising" new option for infants

Basel, 24 February 2003 A new publication suggests that Elidel® (pimecrolimus) cream 1% is an effective treatment with a proven safety profile for eczema (atopic dermatitis) in infants as young as 3 months, according to a report in the February issue of the *Journal of Pediatrics* (February 2003, 142(2):155-162). The study found that after six weeks, more than twice as many patients treated with Elidel were clear or almost clear of eczema, compared with those treated with the vehicle (Elidel cream base without the active ingredient). In the context of other favorable efficacy and safety results, the authors conclude that Elidel holds promise as a valuable treatment option for the youngest patients.

According to the report, approximately 10% to 15% of children under age 5 in developed countries are estimated to have eczema. Of these 48% to 75% show initial signs and symptoms within the first six months of life. Left untreated, eczema in infants and young children can potentially have serious long-term consequences. Traditional therapy has included liberal use of moisturizers and short-term use of topical corticosteroids. However, corticosteroids have been associated with serious local and systemic side effects, and infants are more susceptible than older children to these adverse effects.

"These data further support Elidel as a promising option for the treatment of eczema in infants," said Professor Roland Kaufmann, Chair of the Department of Dermatology and Venereology of the University Hospital Frankfurt and one of the lead authors of the publication. "Parents and physicians alike have long been concerned about applying steroids to infant skin, particularly to treat a chronic condition like eczema. The potential value of Elidel for this patient population is significant."

Study Details

The randomized, double-blind, vehicle-controlled study enrolled 186 infants, aged three to 23 months. The patients, who had a diagnosis of mild to moderate eczema affecting at least 5% of their total body area, were treated with either Elidel (n=123) or vehicle (n=63) twice daily, approximately 12 hours apart. Unaffected areas or affected skin areas that had cleared were not treated with study medication. The initial, double-blind phase of the study lasted for six weeks, followed by a 20-week open-label phase, during which patients from the vehicle group were permitted to switch to Elidel.

At the end of the six-week double-blind phase, more than twice as many patients in the Elidel (54.5%) group were clear or almost clear of eczema, as compared to those in the vehicle group (23.8%; P<.001). Clinically relevant improvements were observed by investigators as early as the first study return visit on day eight. Efficacy seen during the double-blind phase was maintained throughout the open-label phase. In addition, patients in the vehicle group who transferred to treatment with open-label Elidel achieved similar disease control to those who had received continuous treatment with Elidel.

Application site reactions and skin infections were infrequent (less than 5% of the patients studied) and there were no significant differences between groups in the incidences of these events.

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 bacterium Streptomyces hygroscopicus var. ascomyceticus. Pimecrolimus selectively blocks the production and release of inflammatory 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 "promising new option", "holds promise", "potential value", or similar expressions, or by express or implied statements regarding potential new indications for Elidel, or potential approvals to market Elidel in additional markets. 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 clinical trials will result in any 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.

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MEDIA RELEASE COMMUNIQUE AUX MEDIAS MEDIENMITTEILUNG

New study offers hope for patients with acromegaly, a rare, life-threatening hormonal disorder

Treatment with Sandostatin® LAR® may reverse effects of acromegalic cardiomyopathy in young patients

Basel, 19 February 2003 Cardiovascular disease is the leading cause of death for patients suffering from acromegaly, a rare hormonal disorder which leads to excess growth hormone (GH) secretion. In a study, recently published in *Clinical Endocrinology* (February 2003 Vol. 58, 169-176), Sandostatin® LAR® (octreotide acetate for injectable suspension) was shown to reverse acromegalic cardiomyopathy and related morbidity and mortality in young patients diagnosed with acromegaly. Globally, an estimated 244,000 people suffer from acromegaly.

An insidious disease, which can cause chronic disfiguring and enlargement of internal organs, acromegaly often remains undiagnosed for up to 15 years, and patients are diagnosed only after presenting for comorbid conditions such as hypertension or diabetes. Patients with acromegaly typically have higher glucose, glycosylated hemoglobin, insulin, LDL-cholesterol, and triglyceride levels as a result of their condition. Other complications associated with acromegaly include respiratory diseases, such as upper airway obstructions; and malignancies, such as colon cancer. Cardiac disease is the major cause of morbidity and mortality in patients with acromegaly, affecting approximately 80% of patients with the disease.

Researchers at "Federico II" University in Naples, Italy, set out to evaluate whether young acromegaly patients, with short disease duration, were more likely to experience reversal of their acromegalic cardiomyopathy when treated with Sandostatin LAR than older patients with longer disease duration. Acromegalic cardiomyopathy is a serious condition in which the heart muscle becomes damaged due to excessive growth, and cannot pump blood adequately.[1]

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[1] http://www.merck.com/pubs/mmanual_home/sec3/18.htm

"The study indicates that reversal of acromegalic cardiomyopathy is achievable in young patients provided that an early diagnosis is made and a prompt and effective treatment, such as Sandostatin LAR, is started," said Annamaria Colao, MD, principal investigator of the published

study and member of the faculty of the Department of Molecular and Clinical Endocrinology and Oncology, "Federico II" University, Naples, Italy.

Left ventricular mass (LVM) normalized in 100% of young patients

Patients with acromegaly typically have increased tissue mass in the left ventricle, causing systolic dysfunction and, ultimately, cardiovascular disease. In the open prospective study, 22 patients with active uncomplicated acromegaly (12 women, 10 men, age range 21 57 years) received Sandostatin LAR dosed 20 mg or 30 mg every 28 days, for 12 months. Cardiac structure, by echocardiography, and left ventricular (LV) performance, by equilibrium radionuclide angiography, were investigated before and after treatment.

After 12 months, Sandostatin LAR normalized LVM in 100% of young (10 patients) and 50% of middle-aged patients (12 patients) ($p<0.0001$). The treatment also improved the left ventricular ejection fraction (LVEF) response at peak exercise in 80% of young and 50% of middle-aged patients. Exercise capacity and duration increased only in young patients ($p=0.02$).

Hormone Suppression May Successfully Reverse Cardiovascular Alterations

A second study, published in *Journal of Clinical Endocrinology and Metabolism* (July 2002, Vol. 87, No. 7 3097-3104), found that elevated levels of growth hormone (GH) and insulin growth factor-1 (IGF-1), as well as acromegaly, had a profound impact on cardiovascular risk parameters. The study demonstrated that patients with acromegaly, even in its early stages (<5 years), had increased cardiovascular risk parameters. However, GH/IGF-1 suppression by Sandostatin LAR successfully reversed cardiovascular alterations in approximately two thirds of the patients.

These two studies show that acromegalic patients treated with Sandostatin LAR achieved normalization of elevated hormone levels and reduction of ventricular mass, resulting in a decrease in morbidity and mortality rates among this patient population.

About Sandostatin LAR

Sandostatin LAR (octreotide acetate for injectable suspension), launched in most major countries in 1998 and in the US in 1999, is a convenient, once-monthly injection that reduces and normalizes levels of IGF-1 and growth hormone in the treatment of acromegaly. Sandostatin LAR is indicated for long-term maintenance therapy in acromegalic patients for whom medical therapy is appropriate and who have been shown to respond to and can tolerate Sandostatin (octreotide acetate) injection. In most countries in which it is approved, Sandostatin LAR is also indicated to control symptoms, such as severe diarrhea and flushing, of functional GEP tumors (e.g. metastatic carcinoid tumors and vasoactive intestinal peptide-secreting tumors (VIPomas)) in patients who have responded to and tolerated subcutaneous injections of Sandostatin.

Contraindications and adverse events

In clinical studies of acromegaly, some patients experienced diarrhea, abdominal pain, gas, constipation, nausea, vomiting, pain at injection site, gallstone formation, and high or low blood sugar levels.

The foregoing release contains forward-looking statements that can be identified by terminology such as "offers hope," "may reverse," or similar expressions, or by express or implied discussions regarding potential additional revenues from sales of Sandostatin LAR. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results with Sandostatin LAR to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Sandostatin LAR will achieve any particular level of revenues. In particular, management's expectations regarding commercialization of Sandostatin LAR could be affected by, among other things, additional analysis of Sandostatin LAR 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 Oncology is a business unit within Novartis AG (NYSE: NVS), 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.

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Additional information can be found also at www.sandostatin.com and media materials at www.novartisoncologyvpo.com.

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Media Release Communique Aux Medias Medienmitteilung

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Federal Circuit Court Upholds Lower Court Decision Preventing Sale of PureVision Contact Lenses in the U.S.

Affirms Ruling that Bausch & Lomb Product Infringes Harvey Patent

Atlanta, 12 February 2003 CIBA Vision Corporation, the eye care unit of Novartis AG (NYSE: NVS), announced today that the Court of Appeals for the Federal Circuit (CAFC) upheld the United States District Court for the District of Delaware ruling on June 26, 2002 that Bausch & Lomb's (NYSE: BOL) PureVision contact lenses infringe CIBA Vision's Harvey patent. The ruling by the Court of Appeals today means that Bausch & Lomb cannot resume manufacture or sale of its PureVision contact lenses within the United States at least until 2005, when the Harvey patent expires.

"CIBA Vision and Wesley Jessen have a long history of research and development of innovative products in the contact lens industry including the development of Focus® NIGHT & DAY , Focus® DAILIES®, Focus® DAILIES® Progressives, Focus® DAILIES® Toric, and the entire FreshLook® line of colored lenses," said Scott Meece, CIBA Vision's General Counsel. "The patent system and enforcement of patent rights promote investment in research and development of new products benefiting consumers. We are proud of our intent to continue investing millions each year to bring new technology to our customers eye care professionals and to consumers."

The patent infringement lawsuit, which CIBA Vision's Wesley Jessen subsidiary originally filed on May 3, 2001, claimed that Bausch & Lomb's PureVision product infringes U.S. Patent No. 4,711,943, issued to Thomas Harvey III. On June 26, 2002, the District Court ruled that Bausch & Lomb's PureVision contact lenses infringe the Harvey patent and ordered the company to discontinue the manufacture and sale of the product in the United States. Bausch & Lomb filed its appeal of the order with the CAFC on June 27, 2002.

In addition to this lawsuit filed on behalf of Wesley Jessen, CIBA Vision has had litigation pending against Bausch & Lomb since 1999 for infringement of four U.S. patents that protect its breakthrough Focus NIGHT & DAY technology, which allows up to 30 nights of continuous wear. If CIBA Vision prevails in this U.S. case, Bausch & Lomb's PureVision lenses will remain off the market until at least 2014. CIBA Vision has also initiated litigation against Bausch & Lomb in several other countries.

Intellectual property lawyers at McDermott, Will & Emery represented Wesley Jessen at trial in the lower court, as well as during the appeal before the CAFC.

With worldwide headquarters in Atlanta, CIBA Vision is a global leader in research, development and manufacturing of optical and ophthalmic products and services, including contact lenses, lens care products and ophthalmic surgical products. CIBA Vision products are available in more than 70 countries. For more information, visit the CIBA Vision web site at www.cibavision.com.

CIBA Vision is the eye care unit of Novartis AG (NYSE: NVS), 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

Forward-Looking Statement

The foregoing statement contains forward-looking statements that involve known and unknown risks, uncertainties and 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. The statement references patent litigation filed by CIBA Vision and our views on the nature and likelihood of success of that litigation. The statement reflects the view of the Company as of today. It is impossible to predict with certainty the outcome of patent litigation and the risks presented thereby. Should one or more of these risks or uncertainties materialize, actual results may vary materially from those described herein as anticipated, believed or expected.

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Investor Relations Release

Novartis divests tension headache products in US

Continuation of strategic focus on introducing new medicines and resourcing key growth drivers

Basel, 12 February 2003 Novartis announced today that it has sold the US rights for its Fioricet® and Fiorinal® product lines to Watson Pharmaceuticals, Inc., Corona, California, for USD 178 million. The products are prescription treatments for tension headaches and are based on combinations of popular pain relief compounds. The transaction has been completed following early termination of the waiting period under the Hart-Scott Rodino Antitrust Improvements Act.

The divestiture allows Novartis Pharmaceuticals to focus further on its primary mission of introducing innovative new medicines across several therapeutic areas, in addition to concentrating resources on its key growth-driver products. At the same time, it ensures that patients and physicians will retain their access to a trusted therapy.

Fiorinal and Fioricet are well established, proven brands that were introduced in the US in the 1960s and mid 1980s respectively. The divested products achieved combined sales of approximately USD 60 million in 2002.

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140 countries around the world. For further information please consult http://www.novartis.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.

NOVARTIS AG

Date: March 3, 2003

By: /s/ MALCOLM B. CHEETHAM

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

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