NOVARTIS AG
Form 6-K
December 03, 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 November 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 of Form 20-F or Form 40-F.

Form 20-F ý Form 40-F o

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

Enclosures:

1. Novartis files for approval of Zometa® (zoledronic acid) indication for Tumor-Induced Hypercalcemia in Japan
2. Efficacy of calcitonin in treatment of post-menopausal osteoporosis confirmed by European regulatory authority
3. Novartis files marketing applications for Prexige® with health authorities in the USA and the European Union
4. Novartis to transfer marketing and distribution rights of Apligraf back to Organogenesis
5. Novartis launches a new bond transaction
6. Novartis to integrate Ophthalmics Business Unit fully into Pharmaceuticals Division
7. Novartis expands genomics and proteomics state-of-the-art research institute
8.

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- Investor Relations Release -

Novartis files for approval of Zometa® (zoledronic acid) indication for Tumor-Induced Hypercalcemia in Japan

Basel, Switzerland, 29 November 2002 Novartis announced today that it has filed an application with health authorities in Japan for marketing approval of Zometa (zoledronic acid) injection 4 mg for the treatment of tumor-induced hypercalcemia on 31 October 2002. The filing was based on clinical data from studies conducted in Japan. These Japanese data were compared with results of studies in Western countries, such as the U.S. or members of the European Union. The analysis of data collected from Japanese and Western patient groups, who both received 4 mg of Zometa, showed that 10 days after Zometa treatment, the corrected serum calcium concentrations were comparable (84.0% in patients in Japan, 88.4% in patients in Western countries).

"We believe that Zometa will be an important treatment for patients living with cancer and we will work with health authorities in Japan to help facilitate the approval of this filing." said David Epstein, President Novartis Oncology.

About Zometa

Novartis has received marketing clearance for Zometa in the treatment of tumor-induced hypercalcemia (TIH), also known as hypercalcemia of malignancy (HCM), in more than 70 countries throughout the world. Zometa offers patients and healthcare professionals a convenient 15-minute infusion.

More than 55 countries, including the U.S. and European Union, have already granted marketing authorization to Zometa for the prevention of skeletal-related events in-patients with advanced malignancies involving bone. These malignancies include multiple myeloma, prostate cancer, breast cancer, lung cancer, renal cancer and other solid tumors. This is the broadest range of tumor types in which a bisphosphonate has ever demonstrated efficacy. Based on new clinical data demonstrating the longer-term benefit of Zometa for patients with bone metastases from advanced cancers, Novartis has also submitted a supplemental filing with the U.S. Food and Drug Administration (FDA) to include analyses that confirm the long-term efficacy and safety profile of Zometa in all tumor types studied. They also demonstrate in a multiple-event analysis that 4 mg Zometa infused over 15 minutes further lowered the risk of developing skeletal complications in breast cancer patients with bone metastasis in comparison with pamidronate 90 mg infused over two hours.

About TIH

TIH affects more than 10% of all cancer patients and generally occurs late in the course of the disease. TIH occurs when factors made by cancer cells overstimulate cells called osteoclasts, which accelerate the breakdown of bone (resorption) and release excess calcium into the bloodstream. The resulting excessively high calcium levels overload the kidneys' processing capability. Clinical trials in

TIH with patients from Western countries demonstrated a statistically significant difference favoring Zometa in comparison to the previous treatment standard, Aredia, with respect to the proportion of complete responders. TIH is the most common life-threatening metabolic complication associated with cancer

Contraindications and Adverse Events

The Japanese trials in patients with TIH confirmed the safety profile previously found in trials with patients from Western countries. The most commonly reported adverse events were fever and mineral or electrolyte abnormalities.

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; single doses of Zometa should not exceed 4 mg and the duration of infusion should be no less than 15 minutes. Caution is advised when Zometa is administered with other potentially nephrotoxic drugs.

The foregoing release contains forward-looking statements that can be identified by terminology such as "will", or similar expressions, or by discussions regarding potential new indications for Zometa, or regarding potential future sales 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 in any market. Neither can there be any guarantee regarding potential future sales 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 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.

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*.

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- Investor Relations Release -

Efficacy of calcitonin in treatment of post-menopausal osteoporosis confirmed by European regulatory authority

Opinion by CPMP reinforces treatment effect with Miacalcic®(salmon calcitonin)

Basel, 28 November 2002 The European Union's Committee for Propriety Medicinal Products (CPMP) today confirmed the efficacy of calcitonin containing products in the treatment of osteoporosis, following an Article 31 referral.

The Opinion from the CPMP concerns Miacalcic (salmon calcitonin) from Novartis Pharma AG, which is widely used around the world for the treatment of post-menopausal osteoporosis and other bone disorders.

Today's Opinion will harmonize prescribing advice across the European Union. Article 31 Referrals are used to review medicines marketed in the European Union in the light of new data or information related to quality, safety and efficacy.

In formally adopting the Opinion today, the CPMP states that:

Intranasal calcitonin is approved for the treatment of established post-menopausal osteoporosis in order to reduce the risk of vertebral fractures

Injectable calcitonin is approved in the prevention of acute bone loss due to sudden immobilization such as in-patients with recent osteoporotic fractures. It is also approved for Pagets disease and hypercalcaemia of malignancy

The CPMP also states that in the intranasal formulation, a reduction in hip fractures has not been demonstrated and this will be highlighted within the new prescribing information.

"Not only has Miacalcic been shown in studies to increase bone mass and prevent new spinal fractures in post-menopausal osteoporosis, its effectiveness has now been confirmed in a rigorous review by the European regulatory authorities. This extensive analysis by the CPMP provides patients, carers and treating physicians with comprehensive reassurance about the effectiveness of Miacalcic and other calcitonin treatments," said Dr Mathias Hukkelhoven, Novartis global head of regulatory affairs.

Professor John Kanis from the WHO Collaborating Center for Metabolic Bone Diseases, University of Sheffield, United Kingdom, confirmed the importance of the Opinion. He said: "For physicians treating patients with established osteoporosis, it is essential that a broad range of treatment options are available. Different treatments are appropriate for different patients and calcitonin products are valuable because they are effective, easy to use and show a very good safety profile."

Professor Pierre Delmas speaking on behalf of the International Osteoporosis Foundation (IOF) said: "This is excellent news for patients. The number of people with osteoporosis is expected to double over the next 50 years and this represents one of the major health problems of today. In the future it

may become even more important with the aging European population. Although prevention of osteoporosis and lifestyle advice physical mobility, diet, and especially high intake of calcium is important, patients who are at high risk of, or suffer from osteoporotic fractures need effective treatment to reduce the risk of fractures. A variety of drugs inhibiting bone resorption are currently available."

About osteoporosis and calcitonin

Osteoporosis is an increasingly common condition characterized by a reduced amount of bone mass and disruption of bone structure, leading to reduced bone strength and increased risk of fracture[1,2]. It is the most common bone disease that affects humans[3]. Osteoporosis is often referred to as the "silent epidemic' as it progresses without any obvious signs, sometimes for decades, until the person affected suffers a bone fracture. These fractures are usually in the spine, wrist, hip or upper arm. Bone pain which can be very debilitating is the commonest symptom in people with osteoporosis[4]. Osteoporosis increases with age, affecting an estimated one-third of women aged 60 to 70 and two-thirds of women aged 80 or older.

Calcitonin has been used for thirty years in the treatment of osteoporosis and other bone disorders. Calcitonin is a natural polypeptide hormone that causes rapid and reversible inhibition of bone resorption[5]. Calcitonin can be given by injections or by a nasal spray, which is easier for patients to use and is associated with fewer side-effects[5].

About Miacalcic

Miacalcic is registered in 97 countries around the world and it is estimated that it has been administered for over 3 million patient years since it was first launched in 1974 in an injectable form. Miacalcic Nasal Spray received its first approval in 1987. Its first European Union marketing license for post-menopausal osteoporosis was obtained in Portugal in 1987, followed by subsequent approvals in other countries.

With the arrival of new clinical data with Miacalcic Nasal 200IU, a Mutual Recognition Procedure (MRP) was initiated in 1999 with the Republic of Ireland as the Reference Member State. As an outcome of the MRP, seven member states Austria, Belgium, Finland, Germany, Italy, Luxembourg and the UK granted approval for the treatment of post-menopausal osteoporosis in July 2000. Novartis withdrew the MRP application in France, Sweden and The Netherlands.

This press release contains forward-looking statements which can be identified by the use of forward-looking terminology such as "expected to" "in the future it may become", or similar expressions, or by express or implied discussions regarding potential future sales of Miacalcic. 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 and regulatory decisions will result in any increase in Miacalcic sales in any market. Any such results can be affected by, amongst other things, uncertainties relating to competition in general, and to government regulations, 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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- Investor Relations Release -

Novartis files marketing applications for Prexige® with health authorities in the USA and the European Union

Basel, 27 November 2002 Novartis announced today that applications for regulatory approval of a novel COX-2 selective inhibitor, Prexige® (lumiracoxib), have been filed in the USA and the European Union. The applications are based on data from clinical studies in osteoarthritis, rheumatoid arthritis, acute pain and primary dysmenorrhea, involving more than 13 000 adult patients around the world.

The foregoing press release contains forward-looking statements that can be identified by express or implied statements regarding the potential for regulatory approvals to market Prexige based on the applications which have been filed. 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 can be no guarantee that the aforementioned applications for regulatory approval will result in the commercialisation of Prexige in any market. Any such commercialisation can be affected by, amongst other things, uncertainties relating to product development, including the results of the ongoing TARGET clinical trial and other such trials, 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. 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.

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MEDIA RELEASE COMMUNIQUE AUX MEDIAS MEDIENMITTEILUNG

Novartis to transfer marketing and distribution rights of Apligraf back to Organogenesis

New York, 20 November 2002 Novartis announced today it has reached an agreement to transfer the worldwide marketing and distribution rights of Apligraf®, previously licensed to Novartis, back to Organogenesis, which developed the product and remained solely responsible for the manufacture of the product.

Apligraf is a wound care substitute approved by the FDA for treatment for venous leg and diabetic foot ulcers. Deliveries of Apligraf to Novartis have been suspended since 9 September 2002 in advance of the filing of a voluntary petition for reorganization under Chapter 11 of the US Bankruptcy Code by Organogenesis on 25 September 2002.

Under the terms of the agreement, Novartis will market and distribute Apligraf until 17 June 2003 and will transfer marketing and distribution rights back to Organogenesis at the time of consummation of Organogenesis' plan of reorganization. The agreement gives Organogenesis until 31 August 2003 for the consummation of its plan of reorganization. Novartis' ability to resume marketing and distribution of the product is contingent upon Organogenesis' compliance with applicable regulatory requirements. As a consequence of that bankruptcy filing by Organogenesis, the proposed agreement with Novartis is subject to approval by the US bankruptcy court for the District of Massachusetts.

Until the supply of Apligraf resumes, Novartis has also set up a hotline to help answer questions and assist patients and physicians during this transition period. The hotline number is 888-432-5232

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MEDIA RELEASE COMMUNIQUE AUX MEDIAS MEDIENMITTEILUNG

Novartis launches a new bond transaction

Basel, 14 November 2002 Novartis AG announced the launch of a five-year straight bond for an amount of EUR 1 billion (USD 1 006 000 000). The bond was issued through its subsidiary Novartis Securities Investment Ltd., and guaranteed by Novartis AG. The issue was priced at 101.312% and the bonds are expected to be redeemed at their principal amount on 6 December 2007. The bonds will bear interest at the rate of 3.75% per annum payable annually in arrear in each year commencing on 6 December 2002. Application has been made to list the bonds on the Luxembourg Stock Exchange. The issue was rated AAA (stable) by both Standard & Poor's and Moody's.

The proceeds will be used for the refinancing of previous business development activities outside Switzerland.

THE NOVARTIS BONDS OFFERED IN THE OFFERING HAVE NOT BEEN REGISTERED UNDER THE US SECURITIES ACT OF 1933, AS AMENDED, AND MAY NOT BE OFFERED OR SOLD IN THE UNITED STATES ABSENT REGISTRATION OR AN APPLICABLE EXEMPTION FROM REGISTRATION REQUIREMENTS.

THIS PRESS RELEASE SHALL NOT CONSTITUTE AN OFFER TO SELL OR THE SOLICITATION OF AN OFFER TO BUY NOR SHALL THERE BE ANY SALE OF THE BONDS IN ANY JURISDICTION IN WHICH SUCH OFFER, SOLICITATION OR SALE WOULD BE UNLAWFUL.

The foregoing press release contains forward-looking statements that can be identified by terminology such as "are expected", "will bear interest", or similar expressions, or by express or implied statements regarding the success of this bond issue for Novartis or investors. 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 of the success of this bond issue for Novartis or any investors. Any such success or other results, performance or achievements expressed or implied in such statements, can be affected by, amongst other things, uncertainties relating to the bond market, and to uncertainties regarding the success of Novartis' business, including uncertainties relating to product development, government regulation, pharmaceutical production, the ability to obtain or maintain patent or other proprietary intellectual property protection, and competition in general, as well as risk factors discussed in Novartis AG's Form 20-F filed with the Securities and Exchange Commission on 18 March 2002. 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. Stabilisation/FSA

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

Novartis to integrate Ophthalmics Business Unit fully into Pharmaceuticals Division

Efficiency gains and cost savings to result from Business Unit's integration into Pharmaceuticals Division

Basel, 11 November 2002 Novartis announced today that it plans to integrate its Ophthalmics Business Unit fully into the Pharmaceuticals Division. In mid-2003, the Business Unit's global headquarters move from Bülach to Basel. At the same time, the Swiss business will be moved into Novartis Pharma Switzerland in Berne. All employees affected will be offered positions at the new locations; no job reductions are foreseen. The Bülach facility currently employs a staff of about 135.

Luzi von Bidder, Global Head of Novartis Ophthalmics, commented: "Full integration into Pharmaceuticals will shorten and improve the lines of communication. In addition, it will produce efficiency gains and cost savings in the medium term, as our Ophthalmics Business Unit will be able to make greater use of the Pharmaceutical Division's existing central infrastructure and services in Basel."

The Hettlingen production facility is not affected by these transfers but will be separated from the Ophthalmics business unit and managed by Novartis Pharma Technical Operations.

The former ophthalmic pharmaceutical business of CIBA Vision was transferred to Novartis' Pharmaceuticals Division in 2000 where it now forms the Ophthalmics Business unit.

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

Novartis expands genomics and proteomics state-of-the-art research institute

350 researchers in new USD-127-million facility

Basel, 7 November 2002 Novartis announced today the dedication of the expanded Genomics Institute of the Novartis Research Foundation (GNF), a new state-of-the-art research facility that focuses on ground-breaking research and innovative experimentation in neuro-degenerative and metabolic diseases and cancer in San Diego, California.

GNF was founded in 1999 and is funded through the Novartis Research Foundation as a research center focused on genomics and proteomics. GNF is well known for its excellence in developing advanced technologies, ranging from cellular genomics and proteomics to combinatorial chemistry and structural biology.

The contemporary 410 000 square-foot building was built at a cost of USD 127 million. It houses over 350 researchers and engineers who are transforming experimental science. In addition to its unparalleled internal resources, the Institute is located close to the Scripps Research Institute, the University of California, San Diego (UCSD), the Salk Institute, and the Burnham Institute, providing GNF scientists with access to a wide range of seminars and academic collaborators.

According to Dr. Daniel Vasella, Chairman and CEO of Novartis, "The Genomics Institute of the Novartis Research Foundation is an important part of our research activities. We have announced our intention to invest in discovery efforts to maintain our lead in innovation. GNF is helping us to develop therapeutic approaches that will ease patients' suffering and cure disease."

A spectrum of technologies will allow scientists to study thousands of genes/proteins each day, accelerating the discovery process and dramatically enhancing the insights that can be obtained. These discoveries are being translated into treatments for a host of human disorders including neuro-degenerative and metabolic diseases and cancer.

"Building this facility with Dr. Vasella and Novartis has been a unique opportunity for both GNF and Novartis, allowing us as scientists to explore avenues of research that would otherwise be unavailable to us. The success of our efforts and the spin-offs they have yielded testify to the vision and innovation Novartis embraces," said Dr. Peter Schultz, Director of GNF.

Since its foundation in 1999, GNF has launched three very successful, independent start-up companies in the San Diego area, Syrrx, Phenomix, and Kalypsys. These three companies were simultaneously developed as the Institute's world class facility was being finished.

GNF is funded through the Novartis Research Foundation as a research center with freedom to conduct independent research. Scientists at GNF pursue ground-breaking research and publish high impact papers that represent fundamental advances in their fields. The Novartis Research Foundation is an independent research foundation, established by Novartis AG.

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- Investor Relations Release -

Myfortic® the new immunosuppressant from Novartis receives first major approval in Switzerland

Basel, 6 November 2002 Novartis announced today that the Swiss Agency for Therapeutic Products, Swissmedic, has granted marketing authorization for its medicine Myfortic® (mycophenolate sodium), thus making Switzerland the first major country in the world to approve the

product. Myfortic is used in transplantation medicine for the prevention of organ rejection.

Myfortic is a specially designed formulation of the sodium salt of mycophenolic acid (MPA), a key immunosuppressant used in Neoral®-based combination therapies in transplantation. Adjunctive therapy with agents containing MPA is standard in over 70% of new renal transplant patients (which are estimated to be around 40 000 per year worldwide). Unfortunately, dose modifications and discontinuations (e.g. due to GI side effects) are seen with mycophenolate mofetil (MMF), the only MPA formulation currently on the market for transplantation. Frequent changes in MPA dosage are associated with poorer outcomes, such as higher incidence of graft loss, in the transplant recipient.[1]

Myfortic is an advanced, enteric-coated tablet containing MPA sodium developed to help protect the upper GI tract from known side-effects of MPA. Improvement in GI tolerability may lead to fewer dose reductions or discontinuations. Two major pivotal clinical studies involving 748 patients worldwide have demonstrated that enteric-coated Myfortic is a highly potent and well tolerated immunosuppressant for new renal transplant patients and also that transplant patients already taking other MPA drugs can be safely switched to Myfortic. The trend towards fewer dose reductions due to GI intolerability and less serious infections, points to Myfortic being a valuable addition to the immunosuppressive regimens available to the transplant physician.[2,3]

Anthony Rosenberg, Global Head of the Transplantation Business Unit at Novartis Pharma AG commented: "This is extremely good news for transplant patients because Myfortic offers the efficacy of MPA with the additional potential for reduction in some of the unpleasant side effects that can considerably reduce quality of life and ultimately, may prohibit effective post-transplant care. Myfortic will be a valuable contribution to the portfolio of Novartis transplantation treatments from which tens of thousands of patients currently benefit."

The Transplantation and Immunology Team is committed to developing a new and innovative range of therapeutic products for the prophylaxis of organ rejection in order to provide the most extensive choice of drugs to the transplant community and to maintain Novartis' role as global market leader in this field of medicine.

This release contains certain "forward-looking statements", relating to the Company's business, which can be identified by the use of forward-looking terminology such as "may lead to", "points to", "will be", or similar expressions, or by discussions regarding the potential development or commercialization of new products. Such statements include descriptions of Novartis' transplantation products either on the market or under development by the Company. Such statements reflect the

current views of the Company with respect to future events and are subject to certain risks, uncertainties and assumptions. Many factors could cause the actual results to be materially different from any future results, performances or achievements that may be expressed or implied by such forward-looking statements. There are no guarantees that any new products will be developed or commercialised in any market. Any such development or commercialisation can be affected by, among other things, uncertainties relating to the product development and clinical trials, 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.

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[1]Pelletier RP et al., Mycophenolate Mofetil Dose Reduction Influences Clinical Outcome Following Kidney Transplantation, Abstract ATC, Washington, USA, 28. April 1. Mai 2002

[2]De Mattos A et al., Enteric-Coated Mycophenolate Sodium is therapeutically equivalent to Mycophenolate Mofetil in De Novo Transplant Patients., Abstract ICTS, Miami, USA, 25.-30. August 2002

[3]Neumayer H-H et al., Maintenance Renal Transplant Patients can be Safely Switched from Mycophenolate Mofetil to Enteric-Coated Mycophenolate Sodium, Abstract ICTS, Miami, USA, 25.-30. August 2002

NOTES TO EDITORS

1. Acute graft rejection occurs days to months post-transplantation. It is an immune response in which lymphocytes (a type of white blood cell) are key mediators.

2. Myfortic is a highly specific inhibitor of T- and B-lymphocyte proliferation and is effective in the prevention of acute graft rejection. Myfortic is a potent, selective, non-competitive, reversible inhibitor of inosine monophosphate dehydrogenase (IMPDH) upon which active lymphocytes are dependent for their proliferation.

3. The enteric-coating of Myfortic is resistant to the acid environment of the stomach and remains undissolved until it reaches the alkaline environment of the small intestine. Myfortic is thus specifically delivered to the small intestine.

4. In contrast to mycophenolate mofetil, which is a pro-drug requiring conversion to active MPA, Myfortic contains the active component of MPA.

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

Long-term data submitted to EMEA shows efficacy and safety of Zometa® for broad range of advanced cancers involving bone

Data confirms significant clinical benefit of 15-minute Zometa infusion; breast cancer patients had lower risk of bone complications on Zometa versus pamidronate

Basel, Switzerland, 5 November 2002 Novartis announced today that it has submitted a marketing authorization application with the European Agency for the Evaluation of Medicinal Products (EMEA) which includes final analysis of data that demonstrates the long-term benefit and safety of Zometa® (zoledronic acid) for patients with advanced cancers that have spread to the bone.

Zometa was granted market authorization by the EMEA in July 2002 for the prevention of skeletal related events (SREs) in patients with advanced malignancies involving bone. The solid tumors studied included prostate, breast, lung, renal and colorectal cancer. This indication is based on data from three large pivotal trials of more than 3000 patients that evaluated the drug for a treatment period of approximately one year.

The data now submitted to EMEA confirm the longer-term (approximately two years) benefits of Zometa. These benefits include a decrease in number of patients experiencing complications, delay in initial onset of bone complications and reduced risk of developing complications. The multiple event analysis strongly demonstrates that breast cancer patients with metastases to bone treated with Zometa 4 mg in a 15-minute infusion have a lower risk of developing skeletal complications than women treated with pamidronate 90 mg infused over two hours. These complications include among others, pathologic fractures, a need for radiation or surgery to bone, spinal cord compression, and hypercalcemia.

"These data clearly demonstrate that patients with bone complications of advanced cancer benefit from Zometa over an extended period of time," said David Epstein, President, Novartis Oncology.

These data were part of a supplemental new drug application (sNDA) submitted on October 16, 2002, to the US Food and Drug Administration (FDA).

Contraindications and adverse events

In clinical trials in patients with bone metastases and hypercalcemia of malignancy, Zometa had a safety profile similar to other intravenous bisphosphonates. The most commonly reported adverse events included flu-like syndrome (fever, arthralgias, myalgias, skeletal pain), fatigue, gastrointestinal reactions, anemia, weakness, cough, dyspnea and edema. Zometa should not be used during pregnancy. Zometa is contraindicated 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.

The foregoing release contains express or implied forward-looking statements regarding potential new or expanded indications for Zometa, or regarding potential future sales 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 or expanded indications in any market. Neither can there be any guarantee regarding potential future sales 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 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.

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*.

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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

New Zealand Pharmaceutical Management Agency announces funding for Glivec® for all phases of CML and for GIST

Basel, 5 November 2002 Novartis announces that the Board of the Pharmaceutical Management Agency (PHARMAC) of New Zealand has agreed to fund Glivec® (imatinib)* for the treatment of all phases of Philadelphia-chromosome positive chronic myeloid leukemia (CML) and for certain forms of gastrointestinal stromal tumor (GIST).

The announcement by PHARMAC was made at a press conference in Wellington, New Zealand.

The agency will fund Glivec immediately for patients with Philadelphia chromosome-positive CML in the blast crisis, accelerated phase, or in chronic phase whose treatment with interferon-alpha therapy has been unsuccessful. These indications are already approved by the Ministry of Health in New Zealand. Funding for first-line treatment in newly diagnosed CML patients will begin as soon as the Ministry of Health has approved this indication, which is currently under review.

The agency also will fund Glivec for the treatment of Kit (CD-117) positive unresectable and/or metastatic gastrointestinal stromal tumors (GISTs), a second indication for the drug that has recently been approved by the Ministry of Health.

Andrew Moore, managing director of Novartis New Zealand, said the current funding decision recognizes the outstanding benefits of Glivec in CML when administered to patients as early as possible after diagnosis. "As a result, PHARMAC has taken a forward-looking view and approved Glivec for funding in first-line use in CML pending approval by the Ministry of Health," Moore said.

"For the New Zealanders with CML and with GIST, this announcement is a major development as it means that everyone who could potentially benefit from treatment with Glivec will have the opportunity," said Moore.

Moore acknowledged the hard work done by PHARMAC to bring a funding agreement to fruition. "Novartis and PHARMAC both knew that Glivec represented a huge leap forward in the fight against these types of cancer."

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

Contraindications and Adverse Events

In the first-line study (IRIS), the safety profile with Glivec was similar to that of previous Phase II studies in other CML patients. Most adverse events were of mild to moderate grade. The most frequently reported drug-related adverse events with Glivec were nausea, vomiting, diarrhea, oedema and muscle cramps. In the two arms, 2% of Glivec patients compared with 6% of IFN/Ara-C patients discontinued from the study due to adverse events. Additionally, 0.7% of the Glivec patients compared with 23% of the IFN/Ara-C patients crossed over to the control arm due to intolerance to therapy.

The majority of patients treated with Glivec in the Phase II CML clinical trials, upon which the initial approval was based, also experienced adverse events at some time. Most events were of mild to moderate grade, and the drug was discontinued for adverse events 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 dyspnoea, as well as neutropenia and thrombocytopenia.

Glivec is often associated with oedema and occasionally serious fluid retention, GI irritation and severe hepatotoxicity. Because follow-up of most patients treated with Glivec is relatively short, there are no long-term safety data on Glivec treatment.

In the GIST trial that was the basis for GIST approval, drug was discontinued for adverse events in six patients (8%). In this clinical trial, the most common adverse events were edema, nausea, diarrhea, abdominal pain, muscle cramps, fatigue and rash. In this trial, seven patients (5%) were reported to have gastrointestinal bleeds and/or intratumoral bleeds. Gastrointestinal tumor sites may have been the source of GI bleeds.

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.

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MEDIA RELEASE COMMUNIQUE AUX MEDIAS MEDIENMITTEILUNG

FDA committee recommends approval for Clozaril® to treat suicidal behavior

Drug could be first ever with indication

East Hanover, NJ, 4 November 2002 Novartis Pharmaceuticals Corporation announced today that the US Food and Drug Administration (FDA) Psychopharmacologic Drugs Advisory Committee voted to recommend that the FDA approve the use of Clozaril® (clozapine) for the treatment of emergent suicidal behavior in patients with schizophrenia or schizoaffective disorder. FDA reviewers will consider the panel's suggestion before making a final decision. If the new indication is granted, it will mark the first time that any medication has been approved for use in treating suicidal behavior.

Novartis filed a supplemental New Drug Application (sNDA) in March 2002, for the indication based upon data from the International Suicide Prevention Trial (InterSePT), the first study ever to prospectively evaluate a medication in reducing the risk of suicidal behavior.

Dr. Daniel Vasella, Chairman and Chief Executive Officer of Novartis AG commented, "Current estimates suggest that at least two million Americans suffer from schizophrenia, about ten percent of whom will actually die as a result of suicide. The data from our InterSePT study demonstrated that Clozaril reduced the risk of suicide attempts and hospitalizations to prevent suicide among individuals suffering from schizophrenia or schizoaffective disorder by 26% compared to Zyprexa*(olanzapine). I am most gratified that our drug Clozaril, has the potential to provide a life saving benefit to those schizophrenia patients who are most in need."

Suicidal behavior embodies symptoms ranging from suicidal thoughts, to suicidal plans and actual suicide attempts. InterSePT was a multi-center, randomized study initiated in 1998 to compare the efficacy of two antipsychotic compounds, Clozaril and Zyprexa* one of the world's most widely prescribed antipsychotic medications, in reducing the risk of suicidal behavior among patients with schizophrenia or schizoaffective disorder. In addition to reduced suicide attempts and hospitalizations to prevent suicide, patients treated with Clozaril also required fewer concomitant psychotropic medications. The safety profile observed in the study was consistent with the well-known characteristics of Clozaril.

"Today's FDA Advisory Committee recommendation is an important milestone because the risk of suicide and suicidal behavior in schizophrenia is enormous," said Dr. John M. Kane, Vice President for Behavioral Health Services at the North Shore Long Island Jewish Health System, and a lead investigator in the study. "Approximately half of all patients with schizophrenia will attempt suicide during their lifetime. The consequences of that are staggering. When the data suggested that Clozaril might offer hope to these most vulnerable of patients, it was heartening that Novartis moved quickly to conduct this study despite the fact that many other companies would have considered Clozaril a mature product."

According to the National Institute of Mental Health (NIMH), 29,199 Americans committed suicide during 1999. While no reliable data exists on the number of attempted suicides each year, researchers believe that there are between 8 and 25 attempts for each completed suicide. A study by Palmer et al, published in Clinical Neuropharmacology in 1995 estimated that each suicide attempt results in at least $33,000 in direct and indirect costs.

"Overall, this study demonstrated that Clozaril is superior to Zyprexa* for the prevention of suicide attempts in patients with schizophrenia and schizoaffective disorder who are at high risk for suicide," Dr. Kane said. "Wider use of Clozaril in this population could very well help to save many

lives each year. I think that InterSePT will fundamentally change the care that suicidal patients with psychosis receive in the future."

James McNulty, president of the Board of Directors of the National Alliance for the Mentally Ill (NAMI), welcomed the news about the panel vote, "The human toll of suicide in schizophrenia is unacceptable," he notes. "Very often the caregivers for people with schizophrenia are parents or other family members who expend tremendous emotional and financial resources on their care. To lose a beloved family member to suicide creates a void in the fabric of family life that can never be repaired."

Since being introduced in the United States in 1990, Clozaril has established a unique role in the treatment of patients with refractory schizophrenia, and serves as a standard of comparison for the efficacy of most other antipsychotic medications. The compound is classified as an atypical antipsychotic because its profile of binding to certain dopamine receptors and its effects on various dopamine mediated behaviors, differs from those exhibited by older or "typical" antipsychotic drugs. In particular, Clozaril is recognized for a unique binding profile which is associated with a particularly low propensity for movement disorders (extrapyramidal side effects) seen with the typical antipsychotic medications.

Clozaril is currently indicated for the treatment of severely ill schizophrenic patients who fail to respond adequately to standard antipsychotic drug therapies. For complete prescribing information, please call Harry Rohme at 973 781-5151 or, refer to the Clozaril package insert at: *http://www.pharma.us.novartis.com/product/pi/pdf/clozaril.pdf*.

Clozaril use is associated with a substantial risk of seizure affecting 1% to 2% of patients at low doses (below 300 mg/day), 3% to 4% at moderate doses (300 mg/day to 600 mg/day), and 5% at high doses (600 mg/day to 900 mg/day). In clinical trials, Clozaril was associated with a 1% to 2% incidence of agranulocytosis, a potentially fatal blood disorder, which, if caught early, can be reversed. Mandatory weekly white blood cell counts and weekly drug dispensing provide an efficient means of determining developing agranulocytosis. Analysis of post-marketing safety databases suggests that Clozaril is associated with an increased risk of fatal myocarditis, especially during, but not limited to, the first month of therapy. Orthostatic hypotension may occur in some patients, especially during the initial phases of treatment, and can, in rare cases (approximate incidence of $^{1}/_{3}$,000), be accompanied by collapse and/or cardiac arrest.

This release contains certain "forward-looking statements," relating to the Company's business, which can be identified by the use of forward-looking terminology such as "if," "would," "will," or similar expressions, or by discussions of strategy, plans or intentions. Such statements include descriptions of the potential benefit of Clozaril as evidenced by initial clinical trial results. Those statements reflect the current views of the Company with respect to future events and are subject to certain risks, uncertainties and assumptions. Many factors could cause the actual results, performance or achievements of the Company to be materially different from any future results, performances or achievements that may be expressed or implied by such forward-looking statements.

There are no guarantees that the aforementioned clinical trial will result in the commercialization of Clozaril to reduce suicidal behavior in any market. Any such commercialization can be affected by, among other things, uncertainties relating to regulatory actions, delays in or government regulation generally, 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.

Novartis Pharmaceuticals Corporation researches, develops, manufactures and markets leading innovative prescription drugs used to treat a number of diseases and conditions, including central nervous system disorders, organ transplantation, cardiovascular diseases, dermatological diseases, respiratory disorders, cancer and arthritis. The company's mission is to improve people's lives by pioneering novel healthcare solutions.

Located in East Hanover, New Jersey, Novartis Pharmaceuticals Corporation is an affiliate of Novartis AG (NYSE: NVS), 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 74,000 people and operate in over 140 countries around the world.

For further information about Novartis Pharmaceuticals Corporation please consult *www.pharma.us.novartis.com*. For further information about Novartis AG, please consult *www.novartis.com*.

* Zyprexa is a trademark of Eli Lilly and Company

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- Investor Relations Release -

Novartis sells US marketing rights of Foradil® Aerolizer® for respiratory disease to Schering-Plough

Basel and Kenilworth New Jersey, 1 November 2002 Novartis (NYSE:NVS) and Schering-Plough Corporation (NYSE: SGP) today announced an agreement under which Schering-Plough licenses exclusive US distribution and marketing rights to Novartis' Foradil® Aerolizer® (formoterol fumarate inhalation powder), a selective, long-acting beta$_2$-agonist indicated for the maintenance treatment of asthma, chronic obstructive pulmonary disease (COPD), and acute prevention of exercise-induced bronchospasm.

Under terms of the agreement, Novartis receives an upfront license payment and could receive additional payments upon the achievement of certain milestones. In addition, Schering-Plough will pay Novartis a royalty on its net sales of Foradil Aerolizer. Financial terms of the agreement are not being disclosed.

"Our strategy focuses our resources on key growth drivers, yet seeks to maximize our return on our full portfolio of products," said Lawrence Perlow, senior vice president for Novartis Pharmaceuticals Corporation. "Schering-Plough is well positioned to establish Foradil with the broader primary care community, a clear expansion from the specialty communities in which we have been promoting Foradil. This allows us to continue our strong growth emphasis on our major primary care products. Novartis remains fully committed to bringing its other Respiratory Care products through development and to physicians and patients."

"Schering-Plough has a significant presence in the US respiratory market, based on leading products, an experienced sales force and a strong relationship with physicians who prescribe our allergy and asthma medications," said Richard W. Zahn, president of Schering Laboratories. "Foradil Aerolizer promises to be an important addition to our respiratory product line and reflects our continued commitment to this therapy area," he said.

Novartis will continue to market Foradil Aerolizer outside the US where it has broad acceptance among specialists and general practitioners. In recent years, Novartis has made significant investments in a global respiratory research program and embraced a long-term commitment to this therapeutic area.

About Foradil Aerolizer

Foradil capsules are administered via a device called the Aerolizer Inhaler, a delivery system that provides patients and caregivers dosing confirmation that the full dose of medication has been taken. Many patients are concerned that they are not able to confirm that they have taken the full dose of medication with traditional metered-dose inhalers. In contrast, the Aerolizer Inhaler emits a whirring sound when it is activated and can be visually inspected to confirm that a full dose has been dispensed.

In addition the Aerolizer Inhaler eliminates the need for hand-breath co-ordination associated with traditional metered-dose inhalers.

Foradil Aerolizer is indicated for long-term, twice-daily (morning and evening) administration in the maintenance treatment of bronchoconstriction in-patients with asthma or chronic obstructive pulmonary disease, including chronic bronchitis and emphysema. It works by relaxing the muscles that tighten the airways in the lungs. In two randomized, multi-center, parallel-group, double-blind trials totaling 1,634 patients with COPD, twice-daily dosing of Foradil Aerolizer was shown to provide onset of bronchodilation, within five minutes, that lasted for at least 12 hours. Results also showed that Foradil Aerolizer resulted in significantly greater post-dose bronchodilation compared to placebo.

The information in this press release includes certain "forward-looking" information relating to Foradil Aerolizer and its importance to Schering-Plough. The reader of this release should understand that the extent that Foradil Aerolizer will be prescribed will be determined by market forces, and that the market viability of Foradil Aerolizer is subject to substantial risks and uncertainties. In addition, the forward-looking statements may also be adversely affected by general market and business factors, competitive product development, product availability, the extent of market acceptance of new products, current and future branded, generic or over-the-counter competition, federal and state regulations and legislation, the regulatory process for new products and indications, manufacturing issues, trade buying patterns, patent positions, litigation and investigations. For further details and a discussion of these and other risks and uncertainties, see Schering-Plough's Securities and Exchange Commission filings, including its 2001 annual report on Form 10-K and subsequent quarterly reports on Form 10-Q and current reports on Form 8-K.

This release contains certain "forward-looking statements," relating to the Company's business, which can be identified by the use of forward-looking terminology such as "could," "promises," "confident," "will," "help" or similar expressions, or by discussions of strategy, plans or intentions. Such statements include descriptions of the potential benefit of Foradil Aerolizer as evidenced by clinical trial results. Those statements reflect the current views of the Company with respect to future events and are subject to certain risks, uncertainties and assumptions. Many factors could cause the actual results, performance or achievements of the Company to be materially different from any future results, performances or achievements that may be expressed or implied by such forward-looking statements. There are no guarantees that the aforementioned licensing agreement will result in increased sales for Foradil Aerolizer in any market. Any such sales can be affected by, among other things, uncertainties relating to regulatory actions, delays in or government regulation generally, 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.

Schering-Plough is a research-based company engaged in the discovery, development, manufacturing and marketing of pharmaceutical products worldwide.

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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: December 3, 2002

By: /s/ MALCOLM B. CHEETHAM

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

QuickLinks