NOVARTIS AG
Form 6-K
September 02, 2003

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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 August 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

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7):

Yes: o No: ý

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. Patients welcome new non-steroid treatment for atopic eczema (29 August 2003)

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Alex Matter to head Novartis Institute for Tropical Diseases (28 August 2003)

3. NICE recommends Glivec® in England and Wales for first-line treatment of chronic myeloid leukemia patients (28 August 2003)

4. Novartis launches generic omeprazole in the US (19 August 2003)

5. FDA issues approvable letter for updated label for Zometa® to include long-term data for broad range of advanced cancers involving bone (18 August 2003)

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**MEDIA RELEASE COMMUNIQUE AUX MEDIAS MEDIENMITTEILUNG**

**Patients welcome new non-steroid treatment for atopic eczema**

*New data show that patients are highly satisfied using Elidel® (pimecrolimus) Cream 1% for early control and prevention of progression to flare*

Basel, 29 August 2003 New clinical evidence suggests that ease of use and patient satisfaction are important factors in achieving patient compliance and continued use of treatments for chronic condition such as atopic eczema. The results of two new studies presented today on the new steroid-free eczema treatment Elidel® (pimecrolimus) Cream 1%, show that it not only prevents progression to flare and controls atopic eczema but is also considered to be easy to use by patients. Participants declared a high intention to continue with the treatment as they found the cream easy to apply and spread and appreciated that Elidel cream is not sticky.

Presenting the Elidel data at the International Symposium on Atopic Dermatitis (ISAD) in Rome, Italy, Dr Richard Langley, Director of Research, Division of Dermatology at Dalhousie University, Nova Scotia, Canada, commented: "Patient compliance and satisfaction are crucial success factors for treating a chronic disease such as atopic eczema. The study results show how much patients appreciate using a new non-steroid cream that is not only efficacious and safe, but also convenient for treating their condition."

These are among the latest results of two important clinical studies with Elidel (pimecrolimus) Cream 1% reported today at this medical meeting. Together, the studies involved more than 1,500 patients with atopic eczema, followed up to six months.

The first study, called NOBEL, was an international open-label clinical tria1[1], designed to reflect "real-life" clinical practice and involved 947 patients from 12 countries worldwide. Results showed that the majority of those who took part in the study said they would willingly incorporate Elidel into their daily skin care routine.

between 69 and 74% of patients rated Elidel as "good" or "excellent" in terms of spreadability, ease of application and rub-in, and the fact that Elidel did not feel sticky

70% would "definitely" or "most likely":

- continue to use Elidel after completion of the study
- recommend Elidel to other eczema sufferers

A similar pattern emerged in the second study[2], called the RAINBOW Study, to which 515 Canadian patients with atopic eczema were recruited:

- more than 92% of patients were satisfied with the cosmetic effects from using Elidel
- 80% of patients continued to use Elidel for more than 28 days
- 78% said they would almost certainly continue to use Elidel once the study had finished
- 78% of those who had used ointments before preferred Elidel

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- 67% said they were worried for a variety of reasons about using steroid creams, especially:
  - skin thinning (77%)
  - becoming immune to steroid effects (52%)
  - other long-term concerns (59%)
- nearly one-third (29%) said these concerns had stopped them from using topical steroids prescribed by a doctor

Leading dermatologist and patient group representative confirm the importance of patient satisfaction with Elidel treatment.

Dr. Langley explained "We know that today patients wait too long before seeing their physician about their atopic eczema, which means that they experience flares that are more severe and last longer, causing significant disruption to their lives. Thus, a treatment that patients are happy to use early on and that can give them more 'flare-free' days will have a considerable positive impact."

Patient group spokesman Thomas Schwennesen, Chairman of the German Atopic Dermatitis Federation, was equally enthusiastic. He said: "All atopic eczema sufferers know how demoralized and helpless you feel when a new flare is about to start and to disrupt you and your family's life. Now there is a new treatment option that patients actually enjoy putting on their skin and feel comfortable using at the earliest signs and symptoms. We have waited for a long time for this breakthrough to bring eczema under control and enable us to lead a more normal life."

**Background**

Atopic eczema (also known as atopic dermatitis) is a chronic inflammatory skin disease that can affect all areas of the body. The main symptom is dry, itchy and inflamed skin that is often poorly controlled with current treatments.

For more than half-a-century, eczema has been managed by using emollients to moisturize skin, with steroid creams to treat flares when they occur. The main drawback of such strategies is that they are essentially short-term measures to treat what is a long-term, chronic skin disorder.

Elidel is a new non-steroid cream for the treatment of atopic eczema and the prevention of flare progression, which frequently occurs with this chronic skin condition. It is an anti-inflammatory cytokine inhibitor that delivers rapid and sustained relief of pruritus (itch) and

inflammation[3].

**About Elidel**

Elidel Cream is a new non-steroid selective inhibitor of inflammatory cytokines, which is licensed for the treatment of atopic dermatitis. 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. Elidel is now approved in 59 countries worldwide and launched in 30.

This release contains certain "forward-looking statements", relating to the Group's business, which can be identified by the use of forward-looking terminology such as "", "", "suggests", "high intention", "would", "recommend", "will", "breakthrough", or similar expressions, or express or implied discussions regarding potential future sales of Elidel. Such statements reflect the current views of the Group with respect to future events and are subject to certain risks, uncertainties and assumptions. There can be no guarantee that the aforementioned clinical trials will result in Elidel reaching any particular sales levels. In particular, management's expectations could be affected by, among other things, 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; increased government pricing

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pressures; 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 described herein as 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 USD 20.9 billion and a net income of USD 4.7 billion. The Group invested approximately USD 2.8 billion in R&D. Headquartered in Basel, Switzerland, Novartis Group companies employ about 78 200 people and operate in over 140 countries around the world. For further information please consult *http://www.novartis.com.*

*Notes to editors:*

I. The International Symposium on Atopic Dermatitis (ISAD) was held in Rome, Italy, August 29-31 2003.

II. The Rainbow study was a multi-centre, single-arm, prospective, open-label (both investigator and subject know they are receiving one active drug) clinical study to assess the safety of Elidel in patients with atopic eczema.

III. The Nobel study was a real-world, quality of life, single-arm clinical study to study the efficacy and safety of Elidel in patients with atopic eczema.

*References*

1. A 6-month open label, multi-national, effectiveness, and safety study of Elidel® (pimecrolimus) Cream (NOBEL study)

2. A Multicentre, single arm prospective, open label study to assess the safety of Elidel® (SDZ ASM 981 pimecrolimus) cream 1% in patients with atopic dermatitis (RAINBOW study)

3. Data on file

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**MEDIA RELEASE COMMUNIQUE AUX MEDIAS MEDIENMITTEILUNG**

**Alex Matter to head Novartis Institute for Tropical Diseases**

Basel, 28 August 2003 Professor Alex Matter, MD, the Novartis scientist who spearheaded the discovery of the breakthrough cancer treatment Glivec®* (imatinib), has been named the inaugural director of the new Novartis Institute for Tropical Diseases (NITD) in Singapore.

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* In the US: Gleevec® (imatinib mesylate)

Dr. Matter retires this month as worldwide Head of Novartis' Oncology Research and also as Head of the Novartis Institute for Biomedical Research in Basel, a post he has held for the past 15 months. In the late 1990s, after more than a decade of research focused on the role of kinases in cancer, Alex Matter led the team that discovered the Bcr-Abl inhibitor Glivec and helped to bring this groundbreaking treatment for chronic myeloid leukemia (CML) to market. As one of the first targeted anti-cancer medicines, Glivec is tailor-made to block the mutant enzyme that causes uncontrolled cell proliferation in CML, without harming healthy surrounding tissue. It represents a new era in the battle against one of the world's biggest killers.

During his distinguished career, Dr. Matter has also led drug discovery programs in the fields of anti-infectives and HIV/AIDS.

"I am really enthusiastic that a scientist of Alex's caliber will lead the NITD", said Professor Paul Herrling, Head of Corporate Research at Novartis and Chairman of the NITD. "His experience and excellence as a drug-discovery scientist greatly enhances the probability that Novartis will soon make new and effective medicines available to those in need. I am looking forward to working with Alex towards the success of NITD".

Novartis and the Singapore government established the Singapore based Institute two years ago. Its staff of approximately 70 scientists will be devoted to the discovery of novel methods of treating and preventing major tropical diseases, focusing initially on dengue fever and drug-resistant tuberculosis. These two diseases afflict over 200 million people worldwide every year. Novartis intends to make treatments discovered at NITD readily available on a non-profit basis in countries where tropical diseases are endemic.

NITD's discovery technology is state-of-the-art and the scope of its activities ranges from target discovery to development of screening technology and compound optimization. The NITD is also a center of excellence that offers teaching and training opportunities for post-doctoral fellows and graduate students in drug-discovery.

Alex Matter joins a strong scientific advisory board made up of Nobel Laureate Professor Sidney Brenner of The Salk Institute in California; Nobel Laureate Professor Rolf Zinkernagel, Head of the Institute of Experimental Immunology at the University in Zurich; Professor Barbara Imperiali of Massachusetts Institute of Technology in Cambridge; Professor Duane Gubler of the Centers for Disease Control (CDC) in Fort Collins, Colorado; and Professor Stefan Kaufmann of the MPI for Infection Biology in Berlin.

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In addition to his career in industry, Dr. Matter has also held academic positions at the University of Geneva, Harvard Medical School, and the National Institute for Medical Research in Mill Hill, UK. Since 1985, he has been an associate professor of the medical faculty at the University of Basel.

Alexander Kamb, Ph.D., the founder of Arcaris Inc., has been named the new Global Head of Oncology Research at the Novartis Institutes for Biomedical Research. Dr. Kamb was a member of the research team at Myriad Genetics Inc. that identified the involvement of the BRCA1 gene in breast cancer.

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**Additional media information can be found at:**

*http://novartis.imagedirector.net/album?album_code=kjh4olrvjqr4*

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**MEDIA RELEASE COMMUNIQUE AUX MEDIAS MEDIENMITTEILUNG**

**NICE recommends Glivec® in England and Wales for first-line treatment of chronic myeloid leukemia patients**

Basel, Switzerland, 28 August 2003 The National Institute for Clinical Excellence (NICE) issued a final recommendation today that the Novartis drug Glivec® (imatinib)* should be used as first-line treatment for patients newly diagnosed with Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) in all phases of the disease.

The decision will allow newly diagnosed Ph+ CML patients in England and Wales to have access to Glivec as their first drug treatment option. Prior to today's decision, Glivec was recommended only for Ph+ CML patients in the blast crisis, accelerated phase or in chronic phase after failure or intolerance of interferon-alpha therapy, a traditional treatment for CML.

For people in chronic phase CML currently receiving interferon-alpha (IFN) as first-line treatment, the choice of whether to change to Glivec should be based upon the response of the disease to current treatment and by the tolerance of the patient to IFN. This decision should be made after informed discussion between the patient and the responsible clinician.

NICE was established on 1 April 1999 as a Special Health Authority for England and Wales. It is part of the National Health Service (NHS) and its role is to promote high clinical standards in the NHS by developing or commissioning guidance on clinical and cost-effectiveness and disseminating guidance to clinicians, patients and commissioners.

Worldwide, CML has an incidence of one-to-two cases per 100 000 population per year and is responsible for 15 to 20% of all adult cases of leukemia. In England and Wales, approximately 2660 people have CML each year. The annual case rates are 1.0 per 100 000 men and 0.8 per 100 000 women, according to NICE.

**About Glivec**

Glivec is indicated for the treatment of newly diagnosed adult and pediatric patients with Ph+ CML in the EU, Switzerland, and a number of other markets. Glivec is approved in the U.S. for newly diagnosed adult patients with Ph+ chronic phase CML and pediatric patients with Ph+ chronic phase CML whose disease has recurred after stem cell transplant or who are resistant to interferon-alpha therapy. In addition, Glivec is already approved in over 80 countries for the treatment of patients with Ph+ CML in blast crisis, accelerated phase, or in chronic phase after failure of interferon-alpha therapy.

Glivec is also approved in the EU, U.S. and more than 70 other countries for the treatment of patients with Kit (CD 117)-positive unresectable (inoperable) and/or metastatic malignant gastrointestinal stromal tumors (GISTs).

**Contraindications and Adverse Events**

In the first-line study (IRIS), the safety profile with Glivec was similar to that of previous Phase II studies in other CML patients. The majority of patients treated with Glivec experienced adverse events

at some time. Most events were of mild to moderate grade and treatment was discontinued for adverse events only in 2% of patients in chronic phase, 3% in accelerated phase and 5% in blast crisis. The most common side effects included nausea, superficial edema, muscle cramps, skin rash, vomiting, diarrhea, hemorrhage, fatigue, headache, joint pain, cough, dizziness, dyspepsia and dyspnea, as well as neutropenia and thrombocytopenia.

The most common undesirable effects experienced during Glivec treatment in GIST are: headache, nausea, vomiting, diarrhea, dyspepsia, myalgia, muscle spasm and cramps, joint swelling, dermatitis, eczema, rash, edema, fluid retention, neutropenia, thrombocytopenia or anemia.

Glivec is contraindicated in patients with known hypersensitivity to imatinib or any of its excipients. Women of childbearing potential should be advised to avoid becoming pregnant while taking Glivec.

The foregoing release contains forward-looking statements that can be identified by terminology such as "recommends," "should be used," "will allow," "should be made," or similar expressions, or by express or implied discussions regarding potential future revenue from Glivec. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results with Glivec to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee regarding revenues from Glivec. In particular, management's ability to ensure satisfaction of the health authorities' further requirements is not guaranteed and management's expectations regarding Glivec could be affected by, among other things, additional analysis of Glivec clinical data; new clinical data; unexpected clinical trial results; unexpected regulatory actions or delays or government regulation generally; the company's ability to obtain or maintain patent or other proprietary intellectual property protection; competition in general; increased government pricing pressures; and other risks and factors referred to in the Company's current Form 20-F on file with the US Securities and Exchange Commission. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those anticipated, believed, estimated or expected.

Novartis AG (NYSE: NVS) is a world leader in pharmaceuticals and consumer health. In 2002, the Group's businesses achieved sales of USD 20.9 billion and a net income of USD 4.7 billion. The Group invested approximately USD 2.8 billion in R&D. Headquartered in Basel, Switzerland, Novartis Group companies employ about 78 200 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 Glivec can be found at *www.novartisoncology.com* or *www.glivec.com*. Additional media information can be found at *www.novartisoncologyvpo.com*.

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**Investor Relations Release**

**Novartis launches generic omeprazole in the US**

Basel, 19 August 2003 Novartis announced today that its generics unit Sandoz is launching a generic form of the anti-ulcer treatment Prilosec® (omeprazole) in the US. Sandoz' generic product is being launched under the Lek label and will be available by prescription in 10 and 20mg dosage strengths.

"We believe there is significant interest in providing physicians and their patients in the US with an attractive high-quality alternative to currently available products", said Christian Seiwald, CEO of Sandoz, which already markets a generic version of omeprazole in Europe.

Sandoz, a Novartis company, is a world leader in generic pharmaceuticals and develops, manufactures and markets these medicines as well as pharmaceutical and biotechnological active ingredients. Altogether, Sandoz employs around 11 500 people worldwide and posted sales of USD 1.8 billion in 2002.

This release contains forward-looking statements that can be identified by forward-looking terminology such as "is launching," "is being launched," "will be available," or similar expressions, or by express or implied discussions regarding potential future revenues from omeprazole. Such 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 omeprazole will reach any particular sales levels. Management's expectations regarding omeprazole could be affected by, among other things, the risks of patent or other litigation with the originator of omeprazole, market place risks that could adversely affect Novartis affiliates' ability to market omeprazole in the US, government pricing pressures, as well as the other factors discussed in Novartis AG's Form 20-F filed with the Securities and Exchange Commission. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those described herein anticipated, believed, estimated or expected.

Prilosec® is a registered trademark of AstraZeneca.

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invested approximately USD 2.8 billion in R&D. Headquartered in Basel, Switzerland, Novartis Group companies employ about 77 200 people and operate in over 140 countries around the world. For further information please consult *http://www.novartis.com*.

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**MEDIA RELEASE COMMUNIQUE AUX MEDIAS MEDIENMITTEILUNG**

**FDA issues approvable letter for updated label for Zometa® to include long-term data for broad range of advanced cancers involving bone**

Basel, 18 August 2003 The US Food and Drug Administration (FDA) has issued an approvable letter, pending future labelling discussions, for the supplemental new drug application (sNDA) of Zometa® (zoledronic acid) for patients with bone metastases from advanced cancers, Novartis announced today.

Novartis submitted the sNDA for the updated labelling to the US FDA on existing approved indications in October 2002. The data upon which the application was filed provides clinicians long-term data (approximately two years) to advance their understanding of the role of Zometa in the treatment of cancer related bone complications. Bone complications, also known as skeletal related events (SREs), include, among

others, bone pain, pathological fractures, a need for radiation or surgery to bone, spinal cord compression, and hypercalcemia.

"Nearly 500 000 patients worldwide have received Zometa to date, making it the most widely used bisphosphonate for the treatment of cancer-related bone complications," said David Epstein, President, Novartis Oncology. "These data of up to 24 months filed with the FDA provide valuable insights on the broad utility and appropriate use of Zometa."

**About Zometa**

Novartis has received marketing authorization for Zometa in more than 60 countries, including the member states of the European Union and the United States, 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. The EU authorities approved early June 2003 the expansion of this marketing authorization to include data on long-term treatment.

Novartis also has received marketing clearance for Zometa in the treatment of tumor-induced hypercalcemia (TIH), also known as hypercalcemia of malignancy (HCM), in more than 80 countries throughout the world. The proven safety and efficacy of this treatment has resulted in nearly 500 000 patients worldwide receiving Zometa to date.

**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, anemia, weakness, cough, dyspnea and edema.

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

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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 "approvable," "long-term," "pending future," or similar expressions, or by discussions regarding the potential approval of an updated label for Zometa, or regarding potential future sales of Zometa. Such forward-looking statements reflect the current views of the company regarding future events, and 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 an updated labelling. Neither can there be any guarantee regarding potential future sales of Zometa. In particular, management's expectations regarding 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; increased government pricing pressures; and other risks and factors referred to in the Company's current Form 20-F on file with the Securities and Exchange Commission of the United States. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those anticipated, believed, estimated or expected.

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Additional information 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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**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: September 1, 2003

By: /s/ MALCOLM B. CHEETHAM

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

QuickLinks