

NOVARTIS AG  
Form 6-K  
September 05, 2002

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**SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**FORM 6-K**

**REPORT OF FOREIGN PRIVATE ISSUER**

**PURSUANT TO RULE 13a-16 or 15d-16 OF  
THE SECURITIES EXCHANGE ACT OF 1934**

**Report on Form 6-K for the month of August 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  / Form 40-F  /

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

Yes  / No  /

Enclosures:

1. Visudyne approved in Europe for occult subfoveal choroidal neovascularisation secondary to age-related macular degeneration (August 28, 2002)
2. Novartis and Orion submit application to U.S. food and drug administration for approval of a new product for Parkinson's Disease (August 26, 2002)
3. CIBA VISION to market mini Glaucomat Shunt (August 22, 2002)
4. FDA grants priority review for Glivec® marketing application for first-line use in early chronic myeloid leukemia (August 22, 2002)
5. Letter published in Lancet today re-confirms levodopa as 'gold standard' therapy for Parkinson's Disease (August 19, 2002)

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6. Novartis' new non-steroid eczema cream, Elidel®: 13 European countries agree to grant a marketing authorization (August 19, 2002)
  7. New England Journal of Medicine features reports using Novartis drug Glivec® in two life-threatening conditions (August 15, 2002)
  8. Novartis to invest CHF 380 million in Diovan® production expansion (August 15, 2002)
  9. FDA approves blood pressure treatment Diovan® for heart failure (August 15, 2002)
  10. New non-steroid cream, Elidel® (pimecrolimus), significantly modifies course of atopic eczema in infants (August 13, 2002)
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11. NICE recommends funding for Glivec® in England and Wales for treatment of patients with chronic myeloid leukemia (August 12, 2002)
  12. New study published in Circulation finds Diovan® (valsartan) more effective than amlodipine in reducing microalbuminuria in type 2 diabetic patients. Positive effects are independent of blood-pressure-lowering (August 6, 2002)
  13. Novartis files for new indication for Lescol® for secondary prevention of cardiovascular events in angioplasty patients (August 5, 2002)
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### - Investor Relations Release -

#### **Visudyne approved in Europe for occult subfoveal choroidal neovascularisation secondary to age-related macular degeneration**

*Indication extension can now provide help to two-thirds of all wet age-related macular degeneration (AMD) patients in Europe*

Basel, 28 August 2002 Novartis and QLT announced today that Visudyne® (verteporfin) therapy has been granted marketing authorization by the European Commission for the treatment of occult subfoveal choroidal neovascularisation (CNV) secondary to age-related macular degeneration (AMD). AMD is the leading cause of blindness among people over the age of 50.

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This European approval includes patients with subfoveal occult wet AMD with evidence of recent or ongoing disease progression. Occult and classic are terms used to describe different patterns of CNV leakage as seen on fluorescein angiography. Together, the occult and predominantly classic forms of the disease account for approximately two-thirds of all wet AMD cases at diagnosis. Although only 15% of AMD patients suffer from the wet form of the disease, this type is more aggressive and accounts for approximately 90% of severe vision loss in people over 50. Approximately 500 000 new cases of the wet form of AMD occur each year worldwide and this estimate is expected to grow dramatically as the population ages.

"The European Commission's approval of Visudyne for occult wet AMD is a great step forward," said Luzi von Bidder, Head of Novartis Ophthalmics. "We are delighted that Visudyne therapy will now help even more in the management of AMD patients and reduces the risk of older people with wet AMD from going blind."

"This is another major milestone and endorsement for Visudyne, representing a benefit to a large group of patients in need of treatment," said Paul Hastings, President and CEO of QLT Inc. "Our next steps will be to secure reimbursement for occult AMD to ensure that no patients will be deprived from treatment for financial reasons."

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Visudyne therapy is a relatively painless two-step procedure. Following intravenous administration, Visudyne is activated by a non-thermal laser light. This process is known as photodynamic therapy. Visudyne selectively targets abnormal blood vessels on the retina, resulting in a reduction in their growth, without affecting normal/healthy blood vessels. This in turn stops the leakage associated with AMD.

AMD and its associated vision loss have been shown to decrease patient quality of life significantly. Every day tasks such as driving and walking can be severely affected. Awareness of the condition and treatment in the early stages of the disease are essential in order to help patients take the necessary steps to visit their physician and begin therapy to halt progression of AMD. Through its unique mode of action, Visudyne provides the chance to preserve vision long term.

The foregoing press release contains forward-looking statements, that can be identified by terminology such as "biggest market expansion opportunity", "will now help" by discussions regarding potential new indications for existing products. Such forward-looking statements involve known and unknown risks, uncertainties and other factors, which may cause the actual results and assumptions to be materially different from any future results, performance or achievements expressed or implied by such statements. There are no guarantees that any of the potential new indications will be commercialized in any market. Any such commercialization can be affected by, among other things, uncertainty regarding the market size of the occult wet AMD population in Europe and other risks associated with the development and commercialization of the treatment, including uncertainties relating to manufacturing, clinical trials, registration, pricing and reimbursement; patient and physician demand for the treatment; competition; any uncertainty regarding patents and proprietary rights; outcome of litigation claims, product liability claims and insurance; government regulation; anti-take-over provisions; dependence on corporate relationships; volatility of share prices; QLT Inc.'s rapid growth, its history of operating losses and uncertainty of future profitability, its access to capital; and additional information and other factors as described in detail in QLT Inc.'s Annual Information Form on Form 10-K and recent and forthcoming quarterly reports on Form 10Q, and Novartis AG's Form 20-F, and other filings with the US Securities and Exchange Commission and, for QLT, Canadian Securities Regulatory authorities.

QLT Inc. (NASDAQ: QLTI; TSE: QLT) is a global biopharmaceutical company dedicated to the discovery, development, and commercialization of innovative therapies to treat cancer, eye diseases and immune disorders. Combining expertise in ophthalmology, oncology and photodynamic therapy, QLT has commercialized two products to date, including Visudyne therapy which is the largest selling ophthalmology product ever launched. For more information, visit our web site at [www.qltinc.com](http://www.qltinc.com).

Novartis AG (NYSE: NVS) is a world leader in healthcare with core businesses in pharmaceuticals, consumer health, generics, eye-care, and animal health. In 2001, the Group's businesses achieved sales of CHF 32.0 billion (USD 19.1 billion) and a net income of CHF 7.0 billion (USD 4.2 billion). The Group invested approximately CHF 4.2 billion (USD 2.5 billion) in R&D. Headquartered in Basel, Switzerland, Novartis Group companies employ about 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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**MEDIA RELEASE      MEDIA RELEASE      MEDIA RELEASE**

**NOVARTIS AND ORION SUBMIT APPLICATION TO U.S. FOOD AND DRUG ADMINISTRATION FOR APPROVAL OF A NEW PRODUCT FOR PARKINSON'S DISEASE**

*Combination Product Contains Widely Used Parkinson's Therapies*

East Hanover, NJ, August 26, 2002 Novartis Pharmaceuticals Corporation and Orion Pharma announced today the filing of a New Drug Application with the U.S. Food and Drug Administration to market the first triple combination product for the treatment of Parkinson's Disease. This new product combines levodopa, carbidopa and entacapone. Levodopa is already available in combination with carbidopa and is the standard therapy for Parkinson's disease. Entacapone, available as Comtan in the US, is the leading COMT-inhibitor, a class of drugs designed to enhance the benefits of levodopa therapy.

"This is an important development for the treatment of Parkinson's Disease because a combination of these three agents in one tablet should allow a more convenient dosing regimen and will certainly simplify treatment," said Abraham Lieberman, MD, Professor of Neurology, University of Miami and National Medical Director, National Parkinson's Foundation.

Levodopa is the most commonly used Parkinson's therapy. At some point in their treatment, almost all patients will rely on levodopa, which is widely accepted as the most effective agent currently available. In the US, levodopa is almost always administered with carbidopa.

Entacapone, the third component of the new combination, is available in the US as Comtan. It is used to enhance levodopa/carbidopa therapy and is indicated for patients with idiopathic Parkinson's Disease who experience signs and symptoms of end-of-dose "wearing off". It belongs to a therapeutic class called COMT- inhibitors, which reduce the breakdown of levodopa allowing it to remain therapeutically available for longer periods between doses. This results in a greater and more sustained availability of levodopa to reach the brain where it is converted into dopamine. Greater and more consistent exposure to levodopa allows patients to stay active longer between doses and reduces some of the burdensome signs and symptoms of Parkinson's Disease.

"Since its introduction in the US in 1999, Comtan combined with levodopa has helped thousands of patients remain more active despite their disease," said Jean Hubble, MD, Medical Director at Novartis. "The new product should make it easier for patients to get the most from their levodopa treatment, which in turn may allow more patients to benefit from improved motor function and performance of activities of daily living."

This is also an important milestone for Orion Pharma, according to Dr. Risto Miettunen, President of Orion Pharma. "The development of both entacapone and this new triple combination therapy with Novartis will expand Orion's role within the US market."

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Entacapone combined with levodopa/carbidopa has been shown to be well tolerated. In clinical studies, among more than 1,400 people with Parkinson's Disease, the most commonly reported adverse events were unwanted or uncontrolled movements (sometimes called dyskinesias) and loss of muscular activity. These side effects were related to levodopa/carbidopa therapy and were generally mild to moderate in nature.

Pursuant to a licensing agreement between Orion Corporation and Novartis Pharma AG, Novartis Pharmaceuticals Corporation markets entacapone under the name Comtan in the United States. For full prescribing information, visit <http://www.Comtan.com>.

**Forward-looking Statement**

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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 "This new product combines", "should allow", "will certainly simplify treatment", "will rely on", "this results in", "should make it easier", "may allow more patients" and "will expand Orion's role" or similar expressions, or by discussions of strategy, plans or intentions. Such forward looking statements 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. Commercialization can be affected by, amongst other things, uncertainties relating to 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 the Company's Form 20F 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 as anticipated, believed, estimated or expected.

Located in East Hanover, New Jersey, Novartis Pharmaceuticals Corporation is an affiliate of Novartis AG. Novartis AG (NYSE: NVS) is a world leader in healthcare with core businesses in pharmaceuticals, consumer health, generics, eye-care, and animal health. In 2001, the Novartis Group's ongoing businesses achieved collective 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. Novartis AG is 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>.

Orion Pharma is a research and development-orientated pharmaceutical division of the Orion Group. The Orion Group (HEX:ORI) is one of the leading companies in the healthcare sector in the Nordic area of Europe. The 2001 net sales of the Group were EUR 970.8 million. The Orion Group employs around 5,371 people. Pharmaceutical R&D at Orion Pharma produce new innovative drugs in four core therapy areas: CNS therapies, cardiology and critical care, hormonal therapies, and respiratory therapies. Entacapone, a COMT enzyme inhibitor, is Orion Pharma's patented molecule discovery, which Orion Pharma developed through multinational clinical trials. Entacapone is available globally as Comtess and Comtan. For further information please consult <http://www.orion.fi> or <http://www.orionpharma.com>

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**CIBA VISION TO MARKET MINI GLAUCOMA SHUNT**

*Device is a revolutionary new alternative for reducing intraocular pressure*

**ATLANTA, AUGUST 22, 2002** CIBA Vision announced today it has signed a licensing and distribution agreement with Optonol Ltd. for the exclusive rights to market a miniature glaucoma shunt in the United States and Canada. The Ex-PRESS mini glaucoma shunt is an innovative, minimally invasive approach for the surgical treatment of glaucoma where medical and conventional surgical treatments have failed.

The Ex-PRESS mini glaucoma shunt is a 400-micron diameter tube made from implantable stainless steel that is less than 3 mm long, and comes loaded on a specially designed disposable inserter. The device reduces intraocular pressure (IOP) by diverting excess aqueous humor from the anterior chamber to a subconjunctival bleb. The Ex-PRESS shunt has advantages over conventional filtering surgery in that it is minimally invasive. Its "miniature" size requires a very small incision in the conjunctiva. In addition, the Ex-PRESS procedure can typically be completed in less than five minutes.

Implantation of the Ex-PRESS requires minimal manipulation, potentially reducing trauma to delicate eye tissues. No iridectomy is required and it is implanted at the limbus without scleral dissection and cauterization.

"I have performed the procedure in more than 100 eyes," said Prof. Isabelle Riss, from The University of Bordeaux in France. "I have found the procedure easy to perform and the post-operative results show an immediate and sustained reduction of intraocular pressure. The results have been excellent."

Clinical studies have shown that this device provides an easy and effective surgical procedure that can be performed under topical anesthesia, and can reduce reliance on glaucoma medications, according to Ira Yaron, CEO of Optonol.

In a multi-center study evaluating the safety and efficacy of the Ex-PRESS R-50 mini glaucoma shunt, researchers found the device effective in reducing intraocular pressure. The success rate of the Ex-PRESS in lowering IOP to less than 21 mm Hg was 88 percent after one year without intra-operative usage of antimetabolites. This represented a 40 percent IOP reduction. The overall average number of glaucoma medications dropped significantly from 1.65 to .38 at one year.

"The beauty of the procedure is its simplicity and effectiveness," said Robin Terrell, president of CIBA Vision's Surgical business. "The Ex-PRESS shunt is minimally invasive when compared to current surgical procedures for glaucoma. This latest strategic alliance shows CIBA Vision's ongoing commitment to providing ophthalmologists new and effective technologies."

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The Ex-PRESS mini glaucoma shunt has received the CE Mark and has been marketed by Optonol in Europe for more than a year, with over 1,000 patients treated. The product received U.S. Food and Drug Administration (FDA) marketing clearance in March 2002 and it is expected to be available from CIBA Vision in the U.S. in September 2002 and in Canada in 2003.

A training course on the device must be completed prior to performing the surgical procedure. CIBA Vision will offer training and certification programs.

Optonol Ltd. is a high-tech engineering company based in Israel and Switzerland that specializes in innovative miniaturized medical devices.

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 Surgical products globally include the pre-rolled CV232 SRE square-round edge intraocular lens; PRL and Vivarte, phakic refractive lenses; UniVisc and Ophthalin brand viscoelastics; the TearSaver punctum plug product line and the Tear Film Analyzer for the treatment of dry eye. CIBA Vision products are available in more than 70 countries. Some products are not available in the U.S. For more information, visit the CIBA Vision web site at [www.cibavision.com](http://www.cibavision.com).

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CIBA Vision is the eye care unit 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 73,937 people and operate in more than 140 countries around the world. For further information, please consult [www.novartis.com](http://www.novartis.com).

\*Device images available upon request.

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### - Investor Relations Release -

#### **FDA grants priority review for Glivec® marketing application for first-line use in early chronic myeloid leukemia**

*Agency to give decision before the end of year*

Basel, 22 August 2002 Novartis announces that Glivec® (imatinib®) has been granted priority review by the US Food and Drug Administration (FDA) for use as a first-line treatment for newly diagnosed patients with Philadelphia-chromosome positive chronic myeloid leukemia (CML) in the chronic phase, the earliest stage of the disease. It is presently approved for the treatment in the later stages of the disease or in chronic phase after interferon-alpha therapy failure, where it is providing valuable treatment for patients suffering from CML. The FDA also granted priority review to an application by Novartis to provide dosing information for Glivec in pediatric patients with CML. The FDA grants priority reviews to products for a serious or life-threatening disease, which may offer a significant improvement, compared to existing therapies. In Switzerland, Glivec has already been granted an accelerated approval process for this indication.

Both applications, submitted in June 2002, were accepted for filing by the FDA. The priority review establishes an action date no later than six months after the filing date.

"We are pleased that the FDA recognizes the importance of Glivec in the treatment of CML patients in the earliest stage of the disease," said David Epstein, President Novartis Oncology. "Data indicate that the earlier CML patients are treated with Glivec, the more likely they are to achieve a positive response. Therefore, making Glivec available as first-line treatment for newly diagnosed patients in the chronic phase would be an important step forward for patients with CML."

#### **Filing Data**

The first-line CML filing was based on data from the International Randomized Study of Interferon vs. STI571 (IRIS), which were presented in May 2002 at the annual meeting of the American Society of Clinical Oncology (ASCO) and in June 2002 at the European Hematology Association (EHA). The data demonstrate that in the first-line treatment of newly diagnosed CML patients, Glivec achieved an 83% major cytogenetic response rate, compared with 20% for

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\* In the US: Gleevec (imatinib mesylate)

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the combination of interferon-alpha and cytarabine arabinoside (IFN/Ara-C), a form of chemotherapy. Also in the IRIS study, Glivec significantly delayed the time to progression to the more advanced stages of CML compared with IFN/Ara-C. In addition, data presented at EHA also show that Glivec provides newly diagnosed CML patients a significantly better quality of life (QoL) than IFN/Ara-C.

Novartis has also submitted marketing applications with health authorities in the European Union, seeking marketing authorization for Glivec for the first-line treatment of patients with Philadelphia chromosome-positive CML in the chronic phase.

Glivec was initially approved in the US in May 2001 for the treatment of patients with Philadelphia chromosome-positive (Ph+) CML in the blast crisis, accelerated phase or in chronic phase after failure of interferon-alpha therapy. In February 2002, just nine months following the initial CML approval, Glivec received FDA approval for the treatment of patients with Kit (CD 117) positive unresectable (inoperable) and/or metastatic malignant gastrointestinal stromal tumors (GISTs). The GIST indication also has been recently approved in Switzerland and the EU.

### **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, edema and muscle cramps. In the two arms, 2% of Glivec patients compared to 6% of IFN/Ara-C patients discontinued from the study due to adverse events. Additionally, 0.7% of the Glivec patients compared to 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, experienced adverse events at some time. Most events are 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 edema 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.

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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The foregoing release contains forward-looking statements that can be identified by terminology such as "application," "to give," "demonstrate," "may offer," "would be," "significant improvement," or similar expressions, or by discussions regarding potential new indications for Glivec, or regarding the long-term impact of a patient's use of 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 that Glivec will be approved for any additional indications in any market. Neither can there be any guarantee regarding the long-term impact of a patient's use of Glivec. In addition, management's ability to ensure satisfaction of the health authorities' further requirements is not guaranteed and management's expectations regarding commercialization of 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; 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 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 please consult <http://www.novartis.com>.



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

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**MEDIA RELEASE    COMMUNIQUE AUX MEDIAS    MEDIENMITTEILUNG**

**Letter published in Lancet today re-confirms levodopa as 'gold standard' therapy for Parkinson's Disease**

*Use of entacapone with levodopa significantly enhances symptom control*

Basel, 19 August 2002 Since the late 1960's levodopa has remained the most widely used treatment for Parkinson's disease. While originally hailed as a 'miracle' drug, questions have been raised over the past decade about the long-term effects of levodopa. In a letter to the Lancet published today, three leading neurologists pointed out that associated motor complications are not so much an inherent problem of levodopa itself, but occur as a result of the method of administration. If administered correctly, not only are the side-effects minimal but levodopa may have neuro-protective properties. Professor Agid, head of neurology at the Hospital de la Salpetriere, Paris, France remarked 'Levodopa is absolutely the most effective treatment used in the management of Parkinson's disease and should remain the gold standard'.

Professor Yves Agid, along with Professor Mizuno, Juntendo University, Japan and Professor Warren Olanow, Mount Sinai School of Medicine, New York, USA, recently co-chaired an International Levodopa Consensus Meeting in Zurs, Austria. The meeting concluded that levodopa, which will be required by all patients at some stage in their disease, remains the most effective anti-parkinsonian treatment.

The group of 28 internationally renowned experts concluded that the problems associated with levodopa are not caused by the medication itself, but the mode of delivery by which levodopa is given and the natural progression of the disease. Levodopa has a relatively short half-life, which means that the dopamine receptor is stimulated in an on/off, pulsatile manner. Recent studies<sup>1,2</sup> indicate that a more effective way of delivering levodopa in a sustained, continuous manner is in combination with a COMT-inhibitor (such as entacapone). It is believed that this produces significantly fewer motor complications, which can have a dramatic improvement on function for Parkinson's disease patients.

The Zurs meeting is the second such meeting chaired by Professor Agid. In 1998 a similar consensus meeting was held in Paris to discuss when and how levodopa should be prescribed. One of the themes of the 1998 meeting was to establish whether levodopa was neurotoxic. At this time, the panel concluded there was no evidence that levodopa caused nerve-cell death. Over the past three years however, new evidence has emerged that levodopa may possess neuroprotective properties. This new evidence led to a second consensus meeting being held.

The most recent meeting, concluded that levodopa deservedly remains unchallenged as the 'gold standard' therapy for the treatment of Parkinson's disease. Professor Agid, commented 'Levodopa provides benefit throughout the course of the disease and is the only medication that has been shown to have an effect on quality of life'. Life expectancy has also improved with the widespread use of levodopa.

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This release contains certain forward-looking statements relating to the Company's business and to potential future sales or approvals of levodopa and/or entacapone. 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

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be no guarantee of any future commercialization or approvals of levodopa or entacapone in any market. Any such commercialization or approvals can be affected by, among other things, unexpected regulatory delays, further clinical trial results regarding efficacy or safety of these products, government regulation or competition in general, as well as factors discussed in the Company's Form 20F 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 as anticipated, believed, estimated or expected.

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Orion Pharma is a research and development-orientated pharmaceutical division of the Orion Group. The Orion Group (HEX: ORI) is one of the leading companies in the healthcare sector in the Nordic area of Europe. The 2001 net sales of the Group were EUR 970.8 million. The Orion Group employs around 5,371 people. Pharmaceutical R&D at Orion Pharma produce new innovative drugs in four core therapy areas: CNS therapies, cardiology and critical care, hormonal therapies, and respiratory therapies. Entacapone, a COMT enzyme inhibitor, is Orion Pharma's patented molecule discovery, which Orion Pharma developed through multinational clinical trials. Entacapone is available globally as Comtess and Comtan. For further information please consult <http://www.orionpharma.com>

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### References

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- Investor Relations Release -

### Novartis' new non-steroid eczema cream, Elidel®: 13 European countries agree to grant a marketing authorization

Basel, 19 August 2002 Novartis announced today that 13 European countries have agreed to approve its new non-steroid cream, Elidel® (pimecrolimus), the first therapeutic agent proven to prevent flare progression in the itching skin condition, atopic eczema. As one of the first new eczema treatments in half a century, Elidel will be indicated in patients aged 2 years and over with mild-to-moderate disease, for the

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short-term treatment of signs and symptoms and intermittent long-term treatment for the prevention of the progression of flares. All 13 countries involved in the Mutual Recognition Procedure (Austria, Belgium, Finland, France, Germany, Greece, Iceland, Italy, Luxembourg, Portugal, Spain, UK and Denmark) are expected to issue a marketing authorization later this year.

"Elidel is another breakthrough product from Novartis" said Thomas Ebeling, Chief Executive Officer of Novartis Pharma AG in Basel. "It brings a much-needed, steroid-free, first-line treatment for this chronic condition which affects 20% of Western people, most of them children."

Discovered by Novartis scientists at the company's research institute in Vienna, Austria, Elidel has been shown to relieve itch – the most bothersome symptom of eczema – within three days of treatment. When used at the first signs of itching or redness of the skin, Elidel has been shown in one-year studies to prevent progression to severe flares in up to 57% of patients, and to eliminate the need for topical corticosteroid treatment in up to 64% of patients.

"I am sure physicians and patients will welcome the introduction of Elidel, as it will give us the opportunity to control atopic eczema in the long term without the risk of steroid-associated side-effects such as skin thinning," said Professor Thomas Luger, Professor of Dermatology at the University of Munster in Germany. "Many patients, and the parents of young children with eczema, are afraid of using corticosteroids, so I am sure they will look forward to having a steroid-free option. Elidel will be especially useful for eczema on the face because, as a cream, it is readily absorbed and cosmetically acceptable, and also because corticosteroid use is usually restricted on the face and other delicate skin."

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The European countries' decision under the Mutual Recognition Procedure is based on clinical trials involving more than 2000 patients aged from 3 months to adulthood. The incidence of adverse events was low, the most common reported side-effect in the pivotal efficacy studies being a mild-to-moderate temporary feeling of warmth or burning on the skin where the cream was applied. This occurred in fewer than 10% of children and in 10% of adults.

Elidel was approved in Denmark in March this year for the treatment of patients aged 3 months and above; the Danish approval will now be amended in line with this month's mutual agreement. Elidel will be launched in Denmark – the first European market – later this month.

According to Thomas Ebeling, new data from on-going, long-term clinical trials in infants will be available shortly and will be included in further discussions with health authorities regarding approval of Elidel for infants under 2 years of age. In the coming months Novartis will also apply for approval of Elidel in remaining European countries.

Outside Europe, Elidel is approved in the USA – where it was launched in March this year – in Mexico, Venezuela, Colombia, Peru, New Zealand, Brazil and Kuwait.

### **About Elidel**

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 cytokines from T cells in the skin. It is these cytokines that trigger processes leading to the inflammation, redness and itching associated with eczema.

Elidel is the second breakthrough product from Novartis to gain a positive health authority decision within a month in major markets. In late July, the Food and Drug Administration in the USA approved Zelnorm® (tegaserod maleate) for irritable bowel syndrome in women whose primary bowel symptom is constipation.

This press release contains forward-looking statements which can be identified by the use of forward-looking terminology such as "agreed to grant", "will be indicated", "are expected", "will welcome", "will be especially useful", "will be now amended", "will be launched" or similar expressions. 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 approvals will result in the successful commercialization or broadening of approved indication for Elidel in any market. Any such results can be affected by, amongst other things, uncertainties relating to the product development, regulatory actions or delays or government regulation generally, the ability to obtain or maintain patent or other proprietary intellectual property protection and competition in general, as well as factors discussed in Novartis AG's Form 20-F filed with the US Securities and Exchange Commission. Any of these and other factors can cause the actual results to differ materially from the expected or predicted results.

Novartis AG (NYSE: NVS) is a world leader in healthcare with core businesses in pharmaceuticals, consumer health, generics, eye-care, and animal health. In 2001, the Group's businesses achieved sales of CHF 32.0 billion (USD 19.1 billion) and a net income of CHF 7.0 billion (USD 4.2 billion). The Group invested approximately CHF 4.2 billion (USD 2.5 billion) in R&D. Headquartered in Basel, Switzerland, Novartis

Group companies employ about 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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**MEDIA RELEASE    COMMUNIQUE AUX MEDIAS    MEDIENMITTEILUNG**

**New England Journal of Medicine features reports using Novartis drug Glivec® in two life-threatening conditions**

*In separate reports, Glivec provides positive data in refractory GIST patients and in patients with certain types of chronic myeloproliferative disorders (blood diseases)*

Basel, 15 August 2002 Treatment with the Novartis drug Glivec® (imatinib<sup>®</sup>) resulted in a sustained reduction in tumor size (over 50%) in more than half of patients with advanced unresectable or metastatic gastrointestinal stromal tumors (GISTs), according to data from a study published in the 15 August New England Journal of Medicine (*NEJM*). In a separate case study in the same issue, four cases reporting the activity of Glivec in treating certain life-threatening blood diseases suggest the drug may offer a potential treatment for these conditions.

"These impressive positive results in GIST, a form of sarcoma which is highly resistant to any conventional chemotherapy, are very exciting news for these patients, who had essentially no effective treatment options before Glivec," said George D. Demetri, MD, Director of the Center for Sarcoma and Bone Oncology at the Dana-Farber Cancer Institute and Harvard Medical School in Boston, Massachusetts, USA. "These data support the observations that the anticancer responses with Glivec in GIST patients are often durable. It is clear that this treatment can shrink even massive tumors in the majority of patients with this malignancy, by targeting and inhibiting the mutant enzyme which is abnormally active in this tumor type."

**Study Details: GIST**

The GIST study was a Phase II, open-label, randomized, international, multicentre trial that evaluated treatment with Glivec in 147 patients. The GIST patients were randomly assigned to receive either 400 mg (N=73) or 600 mg (N=74) of Glivec once daily. All patients in this study had advanced disease and most had failed other treatments, including surgery, chemotherapy and radiotherapy.

In the *NEJM* report, responses remained durable for more than 46 weeks, and a median duration of response had not yet been reached. The estimated one-year survival rate is 88%. To date, the median survival rate has not been established.

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\* In the US: Gleevec (imatinib mesylate)

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The *NEJM* results provide updated data to those originally submitted to the European Union, the U.S. Food and Drug Administration (FDA) and other global regulatory authorities in 2001 for approval of Glivec in the treatment of Kit positive unresectable and/or metastatic GISTs. Specifically, these approvals were based on data showing a response rate of 38% after a median follow-up of approximately seven months. At a median follow-up of nine months, as reported in the *NEJM*, the confirmed rate of objective responses rose to more than half (54%) of the patients. This is due to the fact that many tumors got smaller over a period of four or more months, delaying the recording of a formal response.

*Following are the comparative statistics:*

| <b>GIST</b>                 | <b>Original Data<br/>(Health Authorities 2001)</b> | <b>Updated Data<br/>(<i>NEJM</i>, August 15, 2002)</b> |
|-----------------------------|--|--|
| Median Follow-Up            | <7 months  | 9 months   |
| Confirmed Partial Response* | 38%  | 54%  |

\* Reduction in tumor size of 50% or greater

"The molecular pathways driving certain cancers, such as GIST, become increasingly clear as we gain clinical experience with Glivec," said David Parkinson, MD, Vice President, Clinical Research, Novartis Oncology. "We hope this maturing understanding will point the way to new approaches to further enhance the benefit of Glivec to GIST patients, and, potentially, to those with other cancers and conditions."

**Study Details: Case Report on Myeloproliferative Disorders**

The *NEJM* reported on Glivec activity in four patients with chronic myeloproliferative disorders involving rearrangements of the platelet derived growth factor receptor beta (PDGFR beta), one of the molecular targets for Glivec. In all four cases, the disease was also characterized by a chromosomal abnormality (translocation) that resulted in exchange of genetic material between chromosomes 5 and 12. The molecular rearrangement resulted in abnormal activation of PDGFR beta.

One of the four patients, a 20-year-old man, had from the age of six suffered a disfiguring skin condition associated with the genetic aberration. The condition included plaques that covered 90% of his body. Previous therapy, which included chemotherapy, steroids and interferon, was ineffective. However, within five days of treatment with 400 mg a day of Glivec, the white cell and eosinophil (normally found in low numbers in healthy individuals) counts had normalized, and the skin lesions dramatically improved.

A second patient with the genetic aberration had not responded to 16 months of hydroxyurea and interferon therapy. His blood counts returned to normal within 12 weeks of starting Glivec. The other two patients, ages 50 and 68, who were previously untreated, had normalized counts within one week of starting Glivec.

**About Glivec**

In countries in which Glivec is approved for GIST, it is indicated for the treatment of patients with Kit (CD 117) positive unresectable (inoperable) and/or metastatic malignant GISTs. In Chronic Myeloid Leukemia (CML), in most countries Glivec is indicated for the treatment of patients with Philadelphia chromosome-positive CML in blast crisis, accelerated phase, or in chronic phase after failure of interferon-alpha therapy. On 28 June 2002, Novartis filed marketing applications in the European Union and the United States for Glivec in the first-line treatment of CML.

**Contraindications and Adverse Events**

Although the majority of patients had adverse events reported at least once during the GIST trial, most events were mild to moderate in severity and included nausea, diarrhea, periorbital oedema, muscle cramps, fatigue, headache and skin rash. Serious (Grades 3-4) adverse events occurred in 21.1% of patients overall. They included low white blood cell counts, tumor hemorrhage and abdominal pain. In the GIST trial, the most common adverse events were oedema, 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.

In the case reports on chronic myeloproliferative disease, the authors did not discuss adverse events in patients except for one, the second patient who had not responded to 16 months of hydroxyurea and interferon therapy, who had none.

The majority of patients treated with Glivec in the Phase II CML clinical trials also experienced adverse events at some time. Most events are 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 dyspnea, as well as neutropenia and thrombocytopenia.

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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.

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 "suggest," "may offer," "potential treatment," "hope," "new approaches", or similar expressions, or by discussions regarding potential new indications for Glivec, or regarding the long-term impact of a patient's use of 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 that Glivec will be approved for any additional indications in any market. Neither can there be any guarantee regarding the long-term impact of a patient's use of Glivec. In particular, management's ability to ensure satisfaction of the health authorities' further requirements is not guaranteed and management's expectations regarding commercialization of 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; 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.

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

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**MEDIA RELEASE    COMMUNIQUE AUX MEDIAS    MEDIENMITTEILUNG**

### **Novartis to invest CHF 380 million in Diovan® production expansion**

*Expansion will boost production by 300 tons per year to cover increasing demand for leading ARB antihypertensive. New building for UK Grimsby site; CHF 60 million to further extend Schweizerhalle unit*

Basel, 15 August 2002 Novartis announced plans today to expand its UK and Swiss production facilities for manufacturing the blockbuster antihypertensive Diovan® (valsartan). The company is to invest approximately CHF 380 million in the project, of which approximately CHF 320 million (GBP 134 million) have been earmarked for the construction and fitting of a new building at Novartis' Grimsby, site in the UK. CHF 60 million will be used to expand the purpose-built unit in Schweizerhalle, near Basel, that was opened in 1999.

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Andreas Rummelt, Head of Technical Operations at Novartis Pharma AG, commented "Our need to expand is due to increasing demand for Diovan and projected future growth based on growing prescription rates, new strengths and combinations, and additional future indications. The current plan ensures business continuity and offers a high degree of flexibility to meet medium and long term demand."

Discovered and developed by Novartis in Switzerland, Diovan is approved for first-line treatment of high blood pressure in more than 80 countries, including the US, and is one of the fastest growing agents among the top 10 branded prescription medications for this condition. An estimated three million patient's worldwide take Diovan for high blood pressure. In 2001 sales of the brand increased 58% to CHF 1 880 million, making it Novartis' best-selling product. Diovan received approval in the US to treat heart failure in patients who are intolerant of angiotensin-converting-enzyme (ACE) inhibitors and has been filed in other major international markets for use in heart failure, the fastest growing cardiovascular disease worldwide.

In the past five years Novartis has invested approximately CHF 1 billion in its pharmaceutical production facilities in the Basel region. The Schweizerhalle Diovan unit, a CHF 160 million project, was inaugurated in 1999 and created 60 jobs.

Established more than fifty years ago, Novartis' Grimsby site is one of the Group's three main production centers for active pharmaceutical ingredients (API's) in Europe and manufactures intermediates and drug substances for a range of products. These include treatments for hypertension, arthritis, epilepsy and cancer. The newest building, B120 is currently being expanded to increase production capacity for a new anti-inflammatory and pain relief drug. This expansion project is due to being completed in 2003.

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The foregoing press release contains forward-looking statements that can be identified by terminology such as "to invest", "will", "increasing demand", "further extend", "earmarked", "projected future growth", "fastest growing", "currently under review for approval", or similar expressions. 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 review will result in the commercialization of any product in any market. Any such commercialization can be affected by, amongst other things, uncertainties relating to product development, including the results of 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 20F 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 as anticipated, believed, estimated or expected.

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**- Investor Relations Release -****FDA approves blood pressure treatment Diovan® for heart failure**

*Indicated for patients who cannot tolerate ACE inhibitors*

Basel, 15 August 2002 The US Food & Drug Administration (FDA) approved a leading high blood pressure medicine Diovan® (valsartan) to treat heart failure in patients who are intolerant of angiotensin-converting-enzyme (ACE) inhibitors, a common type of heart failure therapy. Diovan, an angiotensin II receptor blocker (ARB), is the top prescribed ARB franchise in the US and the first drug in its class to obtain an indication beyond hypertension. Diovan represents a therapeutic advance in the treatment of heart failure as the first major new type of drug to be approved in the US for this life-threatening disease in five years. Heart failure is the fastest growing cardiovascular disease in the world and is characterized by a progressive weakening of the heart muscle until it no longer pumps blood effectively.

"Nearly five million Americans have heart failure and 1,500 new cases are discovered every day. However, many heart failure patients are not adequately treated due to side effects and other issues with available medications. So, mortality from heart failure remains unacceptably high and quality of life is low," said Jay N. Cohn, MD, Professor of Medicine, Cardiovascular Division, University of Minnesota Medical School, and lead investigator of the Valsartan Heart Failure Trial (Val-HeFT) one of the largest studies ever conducted in heart failure. "The availability of Diovan is a critical new development for heart failure patients who desperately need alternative options that not only prolong life and slow the progression of disease, but also help them live successfully with this chronic condition."

The primary basis for the new US indication was Val-HeFT, a study of 5,010 heart failure patients from 16 countries. The overall results of Val-HeFT show Diovan improves heart failure morbidity and slows the progression of disease vs. placebo in patients taking other heart failure therapy prescribed by their physicians. Overall mortality was similar in the Diovan and placebo groups. In Val-HeFT, Diovan provided the greatest benefit in patients who did not take an ACE inhibitor. In these patients, Diovan improved survival by 41%, reduced morbidity (illness) by 49% and cut the risk for hospitalization for heart failure by 57%.

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Treatment guidelines by the American Heart Association and American College of Cardiology already support the use of Diovan in heart failure patients who cannot tolerate ACE inhibitors. While ACE inhibitors have known benefits in heart failure, it is estimated that 24% 54% of patients do not receive these drugs because of intolerance or other reasons.

"Diovan is already relied on by physicians as a trusted and effective medicine to control blood pressure," said Paulo Costa, president and chief executive officer, Novartis Pharmaceuticals Corporation. "Now, US physicians can also prescribe Diovan to improve outcomes and reduce suffering of their heart failure patients. This important new indication reflects our intensive clinical development program for Diovan to help patients across the continuum of cardiovascular disease."

Diovan is supported by the world's largest and most innovative clinical trial programs with an ARB involving over 40 000 patients including over 8 000 with diabetes. Besides the recently completed Val-HeFT study in heart failure patients, trials examining the effects of Diovan beyond its indications for hypertension and heart failure include VALUE (high-risk patients with hypertension), VALIANT (post-myocardial infarction patients), and NAVIGATOR (patients with impaired glucose tolerance also called pre diabetes at high risk for cardiovascular events).

"This regulatory milestone underscores our focus on discovering and bringing innovative treatments to market for patients with significant unmet needs in heart disease, oncology and transplantation," said Thomas Ebeling, CEO, Novartis Pharma AG. "We are committed to realizing the full potential of Diovan and other novel compounds through ongoing world-class research."

Heart failure is caused by many factors, including a heart attack or other injury to the heart, abnormalities in heart valves or muscle walls, clogged arteries, or long-term high blood pressure. Three out of four heart failure patients have a history of high blood pressure. Ironically, progress in treating cardiovascular risk factors and disease is helping more people live longer, which has led to an unfortunate increase in the prevalence of heart failure. Besides being lethal, heart failure causes patients' quality of life to deteriorate, making it difficult for them to do simple, routine activities such as walking or climbing stairs. As the heart stops pumping blood efficiently, fluid seeps into the lungs causing frightening shortness of breath. Patients are so frequently hospitalized for heart failure that it has become the leading cause of hospitalization in Americans over age 65.



Separately, Novartis announced plans today to invest CHF 380 million to expand its UK and Swiss production facilities for manufacturing Diovan to boost production by 300 tons per year to cover increasing demand.

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The foregoing press release contains forward-looking statements that can be identified by express or implied statements regarding the potential for additional sales of Diovan in the US as a result of this new indication, or by discussions of potential additional indications for Diovan. 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 any additional sales of Diovan in the US or elsewhere as a result of this new indication, or that the aforementioned clinical trials will result in the commercialization of any additional indications for Diovan in any market. Any such commercial success or commercialization of additional indications, or other results, performance or achievements expressed or implied in such statements, can be affected by, amongst other things, the fact that treatment guidelines by the American Heart Association and American College of Cardiology already support the use of Diovan in heart failure patients who cannot tolerate ACE inhibitors, competition in general, uncertainties relating to product development, including the results of clinical trials, regulatory actions or delays or government regulation generally, uncertainties relating to pharmaceutical production, and the ability to obtain or maintain patent or other proprietary intellectual property protection, 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 materialize, 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**

**New non-steroid cream, Elidel® (pimecrolimus), significantly modifies course of atopic eczema in infants**

*Study shows Elidel reduces the incidence of eczema flares and improves overall control of disease in babies, compared with conventional therapy*

Basel, 13 August 2002 Treatment of the early symptoms of the itching skin disease, atopic eczema, with the new non-steroid cream Elidel® (pimecrolimus) significantly modifies the disease course in infants by reducing the incidence of flares and improving its overall control, according to a study published today in the August issue of the *Journal of Allergy and Clinical Immunology*. Additionally, the study showed that Elidel is more effective than conventional therapy in the long-term control of pruritus (itching) and the signs of atopic eczema (also known as atopic dermatitis).

"In the past we have had very few options for treating eczema in infants," said the trial's principle investigator, Professor Alexander Kapp, Chairman and Director of the Department of Dermatology and Allergology at the Hannover Medical University, Germany. "Since they were introduced 50 years ago, topical corticosteroids have become the mainstay of eczema treatment, but in infants their use is restricted and they should only be used for short periods because of concerns over side effects such as skin thinning. A steroid-free therapy like Elidel would be a

welcome alternative therapy for this young age group,' said Professor Kapp.

Elidel was launched in its first country, the USA, in February of this year, for patients 2 years of age and above. It will be launched in its first European market Denmark later this month.

#### Study Details

The 12-month, multi-center, double-blind controlled study included 251 infants (3-23 months old). The study compared a long-term Elidel treatment regimen with a current conventional therapy regimen of emollients and moderately potent corticosteroids, assessing the long term safety and efficacy of Elidel. In both treatment groups, emollients were allowed for dry skin. One group of patients applied Elidel while the other group applied the a vehicle cream at the earliest signs or symptoms of the disease. Topical corticosteroids of mid-potency were used by both treatment groups to treat any severe flares.

Results showed that Elidel significantly reduced the flare incidence at both six and 12 months compared with the conventional therapy. The proportion of patients who completed the 12 months trial with no flares was approximately twice as high in the Elidel group compared with the control group (67.6% versus 30.4%, at 6 months; 56.9% versus 28.3%).

The study also demonstrated that treatment with Elidel has a steroid-sparing effect. In the Elidel treatment group, 64% of infants did not use any corticosteroids over 12 months, compared with 35% for the control group.

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

#### About Elidel

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

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**MEDIA RELEASE COMMUNIQUE AUX MEDIAS MEDIENMITTEILUNG**

**NICE recommends funding for Glivec® in England and Wales for treatment of patients with chronic myeloid leukemia**

Basel, 12 August, 2002 Novartis is pleased to announce the recommendation for use of its oral cancer drug Glivec® (imatinib) by NICE The National Institute for Clinical Excellence. With this announcement, patients in England and Wales with Philadelphia chromosome-positive chronic myeloid leukemia (CML) in the blast crisis, accelerated phase or in chronic phase, who have been unsuccessfully treated with interferon-alpha therapy, will now have access to Glivec therapy. Glivec is a molecularly targeted treatment for certain forms of CML, one of the four most common types of leukemia.

"Novartis commends NICE for its decision to make Glivec available for CML patients in England and Wales," said David Epstein, President, Novartis Oncology. "The decision is an important milestone which will allow this innovative drug to help patients battling this life-threatening disease. This most recent decision by the NICE authorities adds to the growing number of government authorities that recognize the value and unprecedented efficacy of Glivec and are reimbursing it thus making it available to patients in their country."

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 the United Kingdom, the incidence of CML is 1 - 1.5 per 100 000 of the population, with around 800 new patients diagnosed each year.

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.

**GLIVEC an innovative CML treatment**

Glivec is one of the first oncology drugs that validate rational drug design based on an understanding of how some cancer cells work. It is a signal transduction inhibitor, which interferes with the pathways that signal the growth of tumor cells. Glivec works by inhibiting an abnormally activated enzyme that is coded for by the Philadelphia chromosome (Ph+), the genetic abnormality that characterizes CML in most patients.

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<sup>1</sup> In the US: Gleevec (imatinib mesylate); outside the US: Glivec® (imatinib)

Glivec was approved in the UK on 8 November 2001. In the UK and in most countries where Glivec is approved, it is indicated for the treatment of patients with Philadelphia chromosome-positive CML in blast crisis, accelerated phase, or in chronic phase after failure of interferon-alpha therapy. The effectiveness of Glivec is based on overall haematologic and cytogenetic response rates. Novartis has received marketing clearance for Glivec for the CML indication worldwide. On 28 June 2002, Novartis filed marketing applications in the European Union and the United States for Glivec in the first-line treatment of CML. The data in these applications were from the first ever head-to-head study of Glivec and demonstrated that it is nearly three times more effective in achieving a cytogenetic response in the first-line treatment of newly diagnosed chronic myeloid leukemia (CML) patients than the combination of interferon-alpha and cytarabine arabinoside, a form of chemotherapy (IFN/Ara-C). Cytogenetic response, regarded as the ultimate goal of CML treatment, is the disappearance or reduction of the number of cells containing the Philadelphia chromosome.

**Glivec in GIST a rare GI tumor**

On 31 May 2002, Novartis announced that the European Commission had approved Glivec for the treatment of patients with c-Kit (CD 117) positive unresectable (inoperable) and/or metastatic malignant gastrointestinal stromal tumors (GISTs). The effectiveness of Glivec is based on objective response rates. Glivec also is approved for the GIST indication in the United States and Switzerland. Prior to the availability of Glivec, patients with GIST had relatively few treatment options beyond surgery.

## Contraindications and adverse events

In CML patients, the majority of patients treated with Glivec experience adverse events at some time. Most events are of mild to moderate grade, but in the Phase II clinical trials for the CML submission, 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, diarrhoea, haemorrhage, muscle cramps, skin rash, fatigue, headache, dyspepsia and dyspnoea, as well as neutropenia and thrombocytopenia.

Although the majority of patients in the GIST trial had adverse events reported at least once during the trial, most events were mild to moderate in severity. The most common adverse events were oedema, nausea, diarrhoea, abdominal pain, muscle cramps, fatigue and rash. Serious (Grades 3-4) adverse events occurred in 21.1% of patients overall. They included low white blood cell counts, tumor haemorrhage and abdominal pain. In this trial, seven patients (5%) were reported to have gastrointestinal bleeds and/or intratumoural 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. Glivec is often associated with oedema 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.

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The foregoing release contains forward-looking statements that can be identified by terminology such as "milestone," "will allow," "adds to the growing number", "improve," or similar expressions. 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. In particular, management's ability to ensure satisfaction of the health authorities' further requirements is not guaranteed and management's expectations regarding further commercialization of 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; 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 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 please consult <http://www.novartis.com>.

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

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**MEDIA RELEASE    COMMUNIQUE AUX MEDIAS    MEDIENMITTEILUNG**

**New study published in *Circulation* finds Diovan® (valsartan) more effective than amlodipine in reducing microalbuminuria in type 2 diabetic patients**  
**Positive effects are independent of blood-pressure-lowering**

Basel, 6 August 2002 A new study published today in *Circulation* shows that for the same level of blood pressure control, Diovan® (valsartan), the angiotensin II receptor blocker (ARB), is more effective than the calcium channel blocker amlodipine in reducing microalbuminuria ( $p < 0.001$ ), an early sign of diabetic kidney disease.<sup>1</sup> The results of the study, the Microalbuminuria Reduction with Valsartan (MARVAL) trial, suggest that Diovan lowers microalbuminuria through effects that are independent of blood-pressure-lowering.<sup>1</sup> The lead author of the article was Giancarlo Viberti, MD, MARVAL investigator, from the Department of Diabetes, Endocrinology & Internal Medicine, GKT School of Medicine, Guy's Hospital, King's College, London.

"MARVAL has important implications for type 2 diabetic patients in light of growing evidence that reduction of microalbuminuria, independent of blood pressure lowering, confers added renal and cardioprotection," said Professor Viberti<sup>1</sup>.

Current treatment guidelines from prestigious medical organizations including the American Diabetes Association (ADA)<sup>2</sup> and National Kidney Foundation (NKF)<sup>3</sup> already recommend ARBs such as Diovan as the initial agents of choice in hypertensive type 2 diabetes patients with microalbuminuria.

Microalbuminuria results when deteriorating kidneys allow protein to pass into the urine. Microalbuminuria is a major risk factor for progressive kidney disease as well as heart disease. Left untreated, microalbuminuria may progress to end-stage renal disease (ESRD), resulting in the need for dialysis or transplantation. Up to 40% of people with type 2 diabetes develop ESRD<sup>4</sup> and the annual cost of treating ESRD in the US alone is \$14.5 billion.<sup>5</sup> Heart disease remains the leading cause of death in diabetic patients<sup>6</sup> and studies show risk for death from cardiovascular disease doubles in type 2 diabetes patients who have microalbuminuria.<sup>7</sup>

MARVAL was a multi-centre, double-blind, randomised, parallel study in patients aged 35-75 with type 2 diabetes and microalbuminuria with normal or high blood pressure. As part of the study, both treatment groups had blood pressure controlled to the same level. Patients were randomised to receive valsartan 80 mg once-daily or amlodipine 5 mg once-daily over 24 weeks. The target blood pressure for all patients was 135/85 mmHg, and if necessary, doses of active treatments were doubled at week 4, bendrofluzide (a thiazide diuretic) was added from week 8, and doxazosin (an alpha blocker) was added from week 12 to help patients attain this goal.<sup>1</sup>

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The study was designed to assess the blood-pressure-independent effects of Diovan vs. amlodipine on urinary albumin excretion rates (UAER), a measure of microalbuminuria. At week 24, there was a 44% reduction in UAER with valsartan (56% of baseline) vs. an 8% reduction with amlodipine (92% of baseline), a highly significant effect ( $p < 0.001$ ). Valsartan lowered UAER similarly in both the hypertensive and normotensive subgroups. More patients reversed to normoalbuminuria with valsartan (29.9% vs. 14.5%;  $p = 0.001$ ). Blood pressure reductions were similar between the two treatments (systolic/diastolic 11.2/6.6 mmHg for valsartan, 11.6/6.5 mmHg for amlodipine).<sup>1</sup>

"MARVAL adds to the growing body of evidence that ARBs protect the kidney and offers a compelling new reason for physicians to prescribe Diovan to hypertensive patients with type 2 diabetes," said Francis Plat, MD, Executive Director, Clinical Research and Development, Novartis Pharma AG. "Novartis is conducting several major outcomes trials as well as other Phase IV studies like MARVAL to explore the protective effects of Diovan in diabetes and other diseases across the cardiovascular continuum."

Diovan is supported by the world's largest clinical trial programme with an ARB. These trials include the recently completed Val-HeFT study, which was one of the largest studies ever conducted in heart failure. Other major ongoing trials in the Diovan clinical trial programme are VALUE (high-risk patients with hypertension, including nearly 5000 patients with diabetes), and VALIANT (15 000 post-myocardial infarction patients). Another major study is NAVIGATOR, which will be the largest study ever conducted in patients with impaired glucose tolerance at high risk for cardiovascular events.

Diovan is already approved for first-line treatment of high blood pressure in more than 80 countries, including the US, and is one of the fastest growing agents among the top 10 branded prescription medications for this condition. An estimated three million patients worldwide take Diovan for high blood pressure.

This release contains certain "forward-looking statements", relating to the business of Novartis, which can be identified by the use of forward-looking terminology such as "more effective", "suggest", "offers a compelling new reason", "fastest growing agents" or similar expressions. 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 will result additional regulatory approvals for Diovan or in increased sales of Diovan. Any such commercialization

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can be affected by, amongst other things, uncertainties relating to 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 the Company's Form 20F filed 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.

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**- Investor Relations Release -****Novartis files for new indication for Lescol® for secondary prevention of cardiovascular events in angioplasty patients**

*Approval would benefit nearly two million patients annually*

Basel, 5 August 2002 Novartis today filed for a new indication for both Lescol® (fluvastatin sodium) and Lescol XL® 80 mg extended release tablets for secondary prevention of cardiovascular events in patients who have undergone percutaneous coronary intervention (PCI) procedures such as angioplasty.<sup>2</sup> The filing made with the Food and Drug Administration (FDA) in the U.S will be followed by filings across Europe and with other major health authorities around the world in the next two months. Approved for cholesterol-lowering therapy, Lescol is the first statin to pursue an indication in this patient population. If approved, Lescol could potentially help 1.8 million patients annually who undergo angioplasty procedures world-wide.

"This new filing for Lescol represents an important milestone for Novartis and identifies a new dimension for the role of Lescol as a cardiovascular treatment," said Thomas Ebeling, Chief Executive Officer, Novartis Pharma AG. "We are committed to improving patients' lives through research to broaden indications for existing products and uncover new treatment strategies."

The filings are based on the results of the landmark Lescol Intervention Prevention Study (LIPS), which were published in the *Journal of the American Medical Association (JAMA)* in June 2002. LIPS is the first prospective, randomised, placebo-controlled trial to evaluate the effects of a statin specifically Lescol exclusively in patients who have had a first PCI. These patients represent a population with early-stage coronary heart disease, who are at high risk of a second major adverse cardiac event. While 90% of the 1.8 million patients who undergo PCI have immediate improvement in chest pain (angina), 66% of patients die or have a cardiac event within 10 years after surgery.<sup>2</sup>

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The LIPS findings showed that Lescol 80 mg (40 mg twice daily) significantly reduced major adverse cardiac events by 22% ( $p=0.013$ ), even in patients with normal cholesterol levels. In addition, in certain high-risk patients, the benefits of Lescol were even more profound. Patients with diabetes and multi-vessel disease experienced significant reductions in the risk of a serious cardiac event,<sup>2</sup> as compared with placebo, 47% ( $p=0.041$ ) and 34% ( $p=0.011$ ),<sup>2</sup> respectively. Patients with or without a stent, experienced similar benefits when taking Lescol therapy.<sup>2</sup> Of the patients treated with Lescol, those with unstable angina experienced a greater risk reduction than those with stable angina (28% versus 20%, respectively). Levels of harmful LDL cholesterol were significantly reduced with Lescol to mean levels below 100 mg/dL (2.6 mmol/L) throughout the course of the study.

The risk reduction following Lescol therapy was similar irrespective of baseline cholesterol levels. Because of this, LIPS investigators concluded that statin therapy after coronary intervention procedures such as angioplasty should be based on an overall risk assessment of the patient, and not just absolute cholesterol levels.

"LIPS provides us with the scientific foundation to change the way we treat patients who undergo percutaneous coronary intervention (PCI), such as angioplasty or other similar procedures," commented LIPS principal investigator Patrick Serruys, MD, PhD, Professor of Interventional Cardiology at Erasmus Medical Centre, University Hospital, Rotterdam, The Netherlands.<sup>3</sup> "The study supports early intervention with fluvastatin in post-PCI patients, regardless of cholesterol levels, to help prevent fatal and non fatal cardiac events such as heart attacks and coronary surgery."

LIPS involved 1677 patients recruited from 57 centres in 10 countries (Europe, Canada and Brazil) for four years. The study examined the time to first major adverse cardiac event, following a first PCI. Major adverse cardiac events were defined as cardiac death, nonfatal heart attack, coronary artery bypass grafting or repeat PCI. Patients were randomised to receive either Lescol 80 mg/day (40 mg twice daily) or placebo before hospital discharge after their first PCI coronary surgical procedure.<sup>2</sup>

The data also underscored the excellent safety profile of Lescol: there were no significant elevations of creatine phosphokinase (CPK) above 10x upper limits of normal (ULN) over the three to four years of follow up. Elevated CPK is an indication of muscle breakdown and is a potential side effect of statin therapies. These safety data match those from a recent analysis involving more than 9000 patients of all randomised, controlled clinical trials with Lescol/ Lescol XL® administered as monotherapy, in which the rate of clinically relevant CPK elevations was not significantly different at any Lescol dose than in patients receiving placebo.<sup>3</sup>

Novartis introduced Lescol extended-release, once-daily 80 mg formulation in 2000 (Lescol XL), which has been shown in trials to provide effective lipid management, with reductions of 38% in harmful LDL-cholesterol, up to 31% in triglycerides and increases of up to 21% in

favourable HDL-cholesterol.<sup>4</sup> Until now with the LIPS results, the effect of Lescol and Lescol XL on cardiovascular morbidity and mortality had not been determined. The LIPS results establish that Lescol reduces the risk of major adverse cardiac events in patients at risk for future cardiac events.

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This release contains certain "forward-looking statements", relating to the business of Novartis, which can be identified by the use of forward-looking terminology such as "significantly reduced," "could potentially", "excellent safety profile", "provide effective lipid management" or similar expressions. 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 will result in the commercialization or continued commercialization or broadening of approved indication for Lescol in any market. Any such commercialization can be affected by, amongst other things, uncertainties relating to 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 the Company's Form 20F filed 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.

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- 1 Lescol Draft Prescribing Information. T2001-78. 89011104
- 2 Patrick WJC Serruys, MD, PhD, et al. Fluvastatin for Prevention of Cardiac Events Following Successful First Percutaneous Coronary Intervention. *JAMA*. 2002; 287:3215-3222.
- 3 Benghozi et al. Frequency of creatinine kinase elevation during treatment with fluvastatin. *Am J Card* 2002, Jan 15.
- 4 Ballantyne et al. Efficacy and Tolerability of Fluvastatin Extended-Releases Delivery System: A Pooled Analysis. *Clinical Therapeutics* 2001, No 2, Vol 23, p177-192.

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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 2, 2002

By: /s/ MALCOLM B. CHEETHAM

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

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