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September 6, 2001

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Securities and Exchange Commission
450 Fifth Street, N.W.
Washington, D.C. 20549

Novartis AG **Current Report on Form 6-K (Commission File No. 1-15024)**

Ladies and Gentlemen:

On behalf of Novartis AG, please find enclosed a copy of a Report on Form 6-K for the month of August 2001, submitted electronically through EDGAR, under the Securities Exchange Act of 1934, as amended.

If the Staff wishes to discuss this matter at any time, please telephone (collect) any of James M. Bartos or the undersigned in our London office at (44-207) 655-5000.

Very truly yours,

Eurydice Goulet
Legal Assistant

Enclosure

cc: New York Stock Exchange (Listed Securities Library)
George Miller (Novartis AG)
James M. Bartos (Shearman & Sterling)

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, 2001

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) Novartis files application with FDA for Zometa® in a broad range of cancer-related bone complications (August 24, 2001)
- (2) Novartis Ophthalmics and QLT announce FDA approval of Visudyne™ as the first drug treatment for pathologic myopia and ocular histoplasmosis (August 23, 2001)
- (3) FDA approves Novartis' Zometa for the treatment of hypercalcemia of malignancy (August 21, 2001)
- (4) Novartis transplantation portfolio and pipeline presented in Istanbul (August 21, 2001)
- (5) Certican™ targets primary causes of chronic organ rejection (August 21, 2001)
- (6) Data confirm new approach to patient management by Neoral® C₂ monitoring improves patient outcomes in maintenance and *de novo* transplant patients (August 21, 2001)

- (7) FTY720, a novel compound with a unique mode of action - A breakthrough in immunosuppression (August 21, 2001)
- (8) Neoral® demonstrates four-fold lower incidence of post-transplant diabetes mellitus (PTDM) compared to tacrolimus in renal transplantation (August 21, 2001)
- (9) Myfortic™ - advanced and improved enteric-coated formulation delivers optimum drug exposure at no safety cost in transplant patients (August 21, 2001)
- (10) Trileptal®, Novartis' oral suspension treatment for epilepsy, completes European Mutual Recognition Procedure (August 20, 2001)
- (11) Novartis reports sustained growth in first half of 2001 (August 16, 2001)
- (12) Pre-Announcement: 2001 first-half results (August 14, 2001)
- (13) Leukemia drug Glivec® may help improve therapy in advanced CML based on research insights (August 3, 2001)
- (14) Novartis agreement with Compugen to speed completion of Novartis human protein database (August 2, 2001)
- (15) Novartis files application with EMEA for Zometa® in cancer-related bone complications (August 2, 2001)
- (16) Novartis files Estradot®, smallest hormone replacement patch, in the European Union (August 2, 2001)

MEDIA RELEASE • COMMUNIQUE AUX MEDIAS • MEDIENMITTEILUNG**Novartis files application with FDA for Zometa® in a broad range of cancer-related bone complications***Based on Clinical Data from Largest Trials Ever in these Indications*

Basel, 24 August 2001 – Novartis announced today that it has submitted an application to the Food and Drug Administration (FDA), seeking marketing authorization for Zometa® (zoledronic acid for injection) in the treatment of bone complications (metastases) associated with a broad range of tumor types. These include prostate and lung cancer, for which no bisphosphonate therapy is currently approved, as well as breast cancer and multiple myeloma. Bone metastases, or the spread of cancerous cells from the original tumor to the bone, can lead to serious complications called skeletal related events (SREs) [e.g., fractures, compression of the spinal cord, severe bone pain and hypercalcemia].

Zometa is a new generation intravenous bisphosphonate that was approved by the FDA just four days ago (20 August 2001) for the treatment of hypercalcemia of malignancy (HCM), the most common life-threatening metabolic complication of cancer. To date, Novartis has received marketing clearances for Zometa in the treatment of HCM in more than 30 countries, including the EU, Switzerland, Brazil, Canada and Australia. Novartis has filed a supplemental application in the EU for the treatment of bone metastases.

Today's submission for FDA review is based on data from three trials evaluating more than 3,000 patients. This is the largest set of clinical trials ever conducted to evaluate the efficacy and tolerability of bisphosphonates in treating bone metastases. The trials evaluated 4mg of Zometa given as a 15-minute infusion every three or four weeks. In the prostate cancer trial, Zometa demonstrated clear efficacy when compared to placebo in the treatment of bone metastases. Over the 15-month evaluation period of this trial, a lower proportion of patients receiving Zometa experienced an SRE compared to those receiving placebo. Further, patients on Zometa had a delay in the onset of the first SRE when compared to placebo. In the trial in lung cancer and other solid tumors (excluding breast and prostate cancer), Zometa had a positive impact on median time to the first SRE when compared to placebo. The results of these two well-controlled clinical trials mark the first time any bisphosphonate has demonstrated efficacy in treating SREs associated with prostate cancer, lung cancer and other solid tumors. In the third trial, in breast cancer and multiple myeloma, Zometa was as effective and well tolerated as Aredia® (pamidronate disodium for injection) – the current standard of treatment – with the added convenience of a 15-minute infusion time versus the 2 to 24 hours for Aredia.

“Bone complications can be extremely debilitating to cancer patients, and seriously impact their day to day activities. Zometa offers these patients an effective treatment with a convenient 15- minute infusion time,” said David Epstein, President, Novartis Oncology. “Novartis is pleased to bring forward another drug that will help make a marked difference in the lives of cancer patients and their families.”

Bone Complications of Metastatic Cancer

Bone metastases/lesions are a common complication in prostate, breast and lung cancer, and multiple myeloma patients, and can have severe debilitating consequences.

Current therapeutic options for complications of bone metastases include: chemotherapy, hormonal therapy, radiotherapy, analgesics for pain management, and surgery. While Aredia is approved for use in breast

cancer patients with bone metastases and multiple myeloma patients with osteolytic lesions; it is not approved for use in bone metastases associated with prostate, lung cancer, and other solid tumors.

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 “seeking,” “bring forward,” “first time,” and “will help,” or similar expressions, or by discussions of strategy, plans or intentions. Such statements include descriptions of Zometa, a new product soon to be introduced by the Company, and anticipated customer demand for Zometa. Such statements reflect the current views of the Company with respect to future events and are subject to certain risks, uncertainties and assumptions. Many factors could cause the actual results, performance or achievements of the Company to be materially different from any future results, performances or achievements that may be expressed or implied by such forward-looking statements. Some of these are uncertainties relating to unexpected regulatory delays, further clinical trial results regarding Zometa's efficacy or safety, 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.

Novartis (NYSE: NVS) is a world leader in healthcare with core businesses in pharmaceuticals, consumer health, generics, eye-care, and animal health. In 2000, the Group's ongoing businesses achieved sales of CHF 29.1 billion (USD 17.2 billion) and a net income of CHF 6.5 billion (USD 3.9 billion). The Group invested approximately CHF 4.0 billion (USD 2.4 billion) in R&D. Headquartered in Basel, Switzerland, Novartis employs about 70,000 people and operates 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.novartisoncology.com

MEDIA RELEASE · COMMUNIQUE AUX MEDIAS · MEDIENMITTEILUNG**Novartis Ophthalmics and QLT announce FDA approval of Visudyne™ as the first drug treatment for pathologic myopia and ocular histoplasmosis***Visudyne improved or stabilized vision in patients with devastating eye conditions*

Basel, 23 August 2001 – Novartis Ophthalmics, the eye health unit of Novartis AG, and QLT Inc. today announced that the United States Food and Drug Administration (FDA) has approved Visudyne™ (verteporfin for injection) therapy for the treatment of predominantly classic subfoveal choroidal neovascularization (CNV) due to pathologic myopia (severe near-sightedness) and presumed ocular histoplasmosis. Visudyne is the only drug treatment approved for these devastating eye conditions.

“The FDA approval is great news,” said Dr. Julia Levy, president and CEO of QLT. “For the first time, patients who would otherwise face a progressive loss of vision now have an effective treatment option. The approval also represents another advance in our efforts to combat serious ocular conditions with Visudyne.”

Dan Myers, president of Novartis Ophthalmics, North America said, “The fact that Visudyne therapy has demonstrated the ability to stabilize and in some cases improve vision in these pathologic myopia and presumed ocular histoplasmosis patients is another remarkable success story for this breakthrough therapy. We’re very pleased to now be able to make Visudyne available to the tens of thousands of patients who

In phase III studies in patients with CNV due to pathologic myopia, Visudyne therapy stabilized or improved vision (as defined by a loss of less than 8 letters on a standard eye chart) in 72% of patients versus 44% on placebo at month 12.

In an open label safety study involving 26 patients with ocular histoplasmosis, visual acuity improved by an average of more than 1 line on a standard eye chart at 12 months (6.7 letters on a standard eye chart) with 28% of patients experiencing a visual acuity improvement of 3 lines (15 letters) or more. Visual acuity decreased by less than 3 lines of vision in 88% of patients during the same time period.

Visudyne was approved in April 2000 in the United States and has since been launched in almost 50 countries for the treatment of predominantly classic CNV caused by age-related macular degeneration (AMD), the leading cause of blindness in people over the age of 50.

CNV due to pathologic myopia

CNV in pathologic myopia is characterized by abnormal blood vessels that grow under the center of the retina as a result of an abnormal elongation of the eye associated with severe near-sightedness or myopia. It generally occurs among people over 30 years of age and can result in a progressive, severe loss of vision. The worldwide incidence of CNV due to pathologic myopia is estimated to be 50,000 new cases per year.

Presumed ocular histoplasmosis

In presumed ocular histoplasmosis, CNV develops from the margin of retinal scars in the back of the eye, which are caused by a fungal infection of the retina. It can lead to severe, irreversible vision loss. The condition is caused by inhaling the fungus *Histoplasma capsulatum* which is found predominantly in the mid-central US. The fungus generally remains in a dormant stage but tends to become more active when a person’s immune system is compromised.

About Visudyne

Visudyne therapy is a two-step procedure that can be performed in a doctor's office. First, the drug is injected intravenously into the patient's arm. A non-thermal laser light is then shone into the patient's eye to activate the drug. Visudyne therapy uses a specially-designed laser that produces the low level, non-thermal 689nm light required to activate the drug. Visudyne is generally well tolerated and has an excellent safety profile. Potential side effects include injection site reactions, headaches, blurring, decreased sharpness and gaps in vision, and in 14 % of patients a substantial decrease in vision with partial recovery in many patients. People should avoid direct sunlight for five days to avoid sunburn. People with porphyria should not be treated.

For more information, visit www.visudyne.com.

The foregoing press release contains forward-looking statements that can be identified by terminology such as "intends," "expected," "potential," "able to make available" or similar expressions. 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. Such factors include, but are not limited to: risks associated with the development and commercialization of the treatment, including uncertainties relating to manufacturing, clinical trials, registration, patient enrollment, 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-takeover 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 any 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, Novartis AG's Form 20-F on file, and other filings with the US Securities and Exchange Commission.

Background on Novartis Ophthalmics and QLT

Novartis Ophthalmics: With worldwide headquarters in Bulach, Switzerland, Novartis Ophthalmics is a global leader in research, development and manufacturing of leading ophthalmic pharmaceuticals that assist in the treatment of glaucoma, age related macular degeneration, eye inflammation, ocular allergies and other diseases and disorders of the eye.

Novartis Ophthalmics products are available in more than 110 different countries. The North American headquarters is based in Atlanta, Georgia. Novartis Ophthalmics has production sites in Switzerland, France and Canada. For more information, visit www.novartisophthalmics.com or www.novartisophthalmics.com/us.

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QLT Inc. (NASDAQ:QLTI; TSE:QLT) is a world leader in photodynamic therapy, a field of medicine utilizing light-activated drugs in the treatment of disease. QLT's innovative science has led to the development and commercialization of breakthrough treatments utilizing this technology for applications in ophthalmology and oncology and is exploring the potential in other diseases. For more information, you are invited to visit QLT's web site at www.qltinc.com.

Visudyne™ is a trademark of Novartis AG

MEDIA RELEASE · COMMUNIQUE AUX MEDIAS · MEDIENMITTEILUNG**FDA approves Novartis' Zometa[®] for the treatment of hypercalcemia of malignancy**

New option to treat life-threatening cancer complication offers improved efficacy and dosing convenience over current treatment standard

Basel, 21 August 2001 — Novartis announced today that it has received marketing approval from the US Food and Drug Administration (FDA) for Zometa[®] 4 mg (zoledronic acid for injection), a new generation intravenous bisphosphonate for the treatment of hypercalcemia of malignancy (HCM). HCM is the most common life-threatening metabolic complication associated with cancer.

Clinical trials have demonstrated a statistically significant difference favoring Zometa when compared with the current treatment standard, Aredia[®] (pamidronate disodium for injection), with respect to the proportion of complete responders. Response was measured by a normalization of corrected serum calcium by day 10. In addition, a 4 mg dose of Zometa offers the convenience of a 15-minute infusion time, as compared with 2 to 24 hours for Aredia.

“We are pleased that the FDA has approved this next generation bisphosphonate as a new treatment option for patients with HCM,” said David Epstein, President, Novartis Oncology. “We remain committed to further exploring potential uses of Zometa in treating other cancer-related skeletal complications.”

About HCM and Zometa

HCM, which is characterized by elevated serum calcium levels, affects more than 10% of all cancer patients and generally occurs late in the course of the disease. HCM occurs when factors made by cancer cells over-stimulate cells called osteoclasts, which accelerate the breakdown of bone (resorption) and release excess calcium into the bloodstream. The resulting excessively high calcium levels overload the kidneys' processing capability. The calcium remains in the blood, leading to potentially life-threatening complications such as dehydration, generalized muscle weakness, fatigue, nausea, vomiting, confusion, coma and even death. HCM appears most frequently in cases of breast cancer, multiple myeloma and non-small-cell lung cancer. It may also occur in head and neck cancer, lymphoma, leukemia, kidney cancer and gastrointestinal cancer.

The clinical data upon which the filing and subsequent approval were based are from two pivotal studies comparing Zometa with Aredia. The two multi-center trials enrolled 287 patients of which 275 met the evaluation criteria. Patients received a single dose of either Zometa 4 mg or Zometa 8 mg and were compared with patients receiving a single dose of Aredia 90 mg. By day 10 of treatment, corrected serum calcium concentrations were normalized in 88% of patients treated with Zometa 4 mg. In comparison, only 70% of patients treated with Aredia 90 mg achieved normalized serum calcium concentrations (p=0.002). The results of this trial were published in the January 2001 issue of the *Journal of Clinical Oncology*.

In the patients taking Zometa, the median duration of complete response (maintaining normalized calcium levels) was 32 days for Zometa 4 mg, and 18 days for Aredia 90 mg. Time to relapse was 30 days for Zometa 4 mg and 17 days for Aredia 90 mg (p<0.05). There was no difference between the outcomes in the 4 mg versus 8 mg dose of the Zometa arm.

To date, Novartis has received marketing clearances for Zometa for the treatment of HCM in more than 30 other countries, including the EU, Switzerland, Brazil, Canada and Australia.

A supplemental application for Zometa in the treatment of bone metastasis will be filed with the FDA shortly.

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 “likely,” “will,” “will be filed,” “support,” or similar expressions, or by discussions of strategy, plans or intentions. Such statements include descriptions of new products expected to be introduced by the Company and anticipated customer demand for such products. Such statements reflect the current views of the Company with respect to future events and are subject to certain risks, uncertainties and assumptions. Many factors could cause the actual results, performance or achievements of the Company to be materially different from any future results, performances or achievements that may be expressed or implied by such forward-looking statements. Some of these are uncertainties relating to unexpected regulatory delays, further clinical trial results regarding Zometa's efficacy or safety, 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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Novartis Transplantation Portfolio and Pipeline

Presented in Istanbul, 21 August 2001

Istanbul, 21 August 2001 – Novartis today holds a press conference during the Transplantation congress “2001 - A Transplant Odyssey”. Below you will find the lead paragraphs of the five press releases being issued at the press conference. The complete versions of all releases as well as background information can be found on the following web site: <http://www.novartis.com>.

1) Neoral[®] demonstrates four-fold lower incidence of post-transplant diabetes mellitus (PTDM) compared to tacrolimus in renal transplantation

Meta-analysis shows important benefits of Neoral-based regimens on long-term health outcomes and costs associated with PTDM

Strong evidence presented today at “2001 – A Transplant Odyssey” suggests that Neoral[®]-based immunosuppressive regimens may lead to a four-fold decrease in the initial development of post-transplant diabetes mellitus (PTDM) in patients within the first year after renal transplantation compared to tacrolimus-based regimens.¹

These findings, which substantiate previous reports of the lower incidence of PTDM with Neoral as compared to tacrolimus are of particular importance given the considerable health and economic impact of PTDM. PTDM is associated with poor long-term graft and patient survival, as well as with other important diseases which affect patients in the long term. Data presented at Istanbul also suggest an incremental annual cost of £ 14,000 (USD 20,000) to treat a renal transplant patient developing PTDM, as compared to a patient not developing diabetes.² This cost is primarily associated with increased use of dialysis services and transplant management.

1. Moore R. Presented at the 2001 A Transplant Odyssey: The Future Is Here Transplantation Congress; Aug 20-23, 2001: Istanbul, Turkey. Abstract #1522.
2. Whitby S, *et al.* Presented at the 2001 A Transplant Odyssey: The Future Is Here Transplantation Congress; Aug 20-23, 2001: Istanbul, Turkey. Abstract #1657.

2) Data confirm new approach to patient management by Neoral[®] C₂ monitoring improves patient outcomes in maintenance and *de novo* transplant patients

New data confirm Neoral[®] C₂ monitoring^{*} is a highly effective patient management technique, significantly enhancing the performance of Neoral (cyclosporin microemulsion) and improving patient outcomes. The data, presented at “2001 – A Transplant Odyssey” meeting in Istanbul, demonstrated clinical benefit in *de novo* (newly transplanted)^{1,3} and maintenance² patients.

Confirming the benefits of patient management by Neoral C₂ monitoring, Dr Paul Keown, from The University of British Columbia, Vancouver and one of the world’s most experienced physicians with C₂ monitoring, stated: “The adoption of C₂ monitoring of Neoral blood levels, as opposed to standard trough

levels, is a simple and highly effective way to enhance both the safety and efficacy of Neoral as cornerstone immunosuppression. We are now beginning to see more and more data which clearly demonstrate the benefits this management technique can have in terms of reduced acute rejection rates and improved patient outcomes, and I would encourage centres to move to this new strategy.”

*** What is C₂ monitoring?**

Neoral C₂ monitoring is the measurement of the cyclosporin level in a patient’s blood two hours (C₂) after the dose instead of the traditional practice of trough level monitoring, when cyclosporin blood levels are measured immediately before the dose (C₀ levels).

1. Levy et al. Presented at the 2001 A Transplant Odyssey: The Future is Here Transplantation Congress; Aug 20-23, 2001: Istanbul, Turkey. Abstract # 1822
2. Levy et al. Presented at the 2001 A Transplant Odyssey: The Future is Here Transplantation Congress; Aug 20-23, 2001: Istanbul, Turkey. Abstract # 1070
3. Keown et al. Presented at the 2001 A Transplant Odyssey: The Future is Here Transplantation Congress; Aug 20-23, 2001: Istanbul, Turkey. Abstract # 1824

3) FTY720, a novel compound with a unique mode of action — a breakthrough in immunosuppression?

Data from early clinical analyses presented today at “2001 – A Transplant Odyssey” meeting in Istanbul suggest FTY720, a novel compound under development for organ transplant immunosuppression, is highly efficacious, well tolerated and exerts its effect in a completely different manner to any other current immunosuppressant^{1,2} — potentially making it a genuine breakthrough in transplant immunotherapy. Treatment with FTY 720 in animal models has shown that the immunity to systemic viral infections remained unimpaired, which may provide a striking advantage compared to classical immunosuppressive agents⁴.

In addition, data revealed FTY720 was associated with a considerably lower rate of biopsy-confirmed acute rejection compared to mycophenolate mofetil (MMF)³. In a Phase II trial (n=208 adult renal transplant recipients aged 18-65 years), FTY720 was shown to be highly efficacious and well tolerated in newly transplanted kidney patients, delivering an acute rejection rate as low as 9.8 percent compared to 17.1 percent achieved by MMF³, both in combination with Neoral® (cyclosporin microemulsion) and corticosteroids.

FTY720 has also been administered concomitantly with CerticanTM (everolimus) in a proof-of-concept clinical trial.

1. Brinkmann V, Pirschewer D, Feng L, Chen S. FTY720: altered lymphocyte traffic results in allograft protection. Transplantation 2001; 72 (in press).
2. Brinkmann V *et al.* Presented at the 2001 A Transplant Odyssey: The Future Is Here Transplantation Congress; Aug 20-23, 2001: Istanbul, Turkey. Abstract #1711.
3. Tedesco Silva H *et al.* Presented at the 2001 A Transplant Odyssey: The Future Is Here Transplantation Congress; Aug 20-23, 2001: Istanbul, Turkey. Abstract # 1612.
4. Pirschewer DD, Ochsenbein AF, Odermatt B, Brinkmann V, Hengartner H, Zinkernagel RM. FTY720 immunosuppression impairs effector T-cell peripheral homing without affecting induction, expansion, and memory. J Immunol 2000; 164: 5761.

4) MyforticTM — advanced and improved enteric-coated formulation delivers optimum drug exposure at no safety cost in transplant patients

First major phase III data presentation on enteric-coated Myfortic from Novartis

New phase III data presented today in Istanbul on MyforticTM (enteric-coated formulation of mycophenolate acid [MPA]) demonstrate the pharmacokinetic benefits of this advanced MPA formulation are two-fold: therapeutic MPA exposure is achieved more rapidly and for a longer duration than with mycophenolate mofetil (MMF). This enhanced absorption is reached at no safety costs, which means that Myfortic broadens the therapeutic index of MPA in the important post-transplant period.

Delegates at “2001 – A Transplant Odyssey” in Istanbul, heard how this broadened therapeutic window points to a great potential for Myfortic to improve efficacy – a finding that has been documented in previous key papers looking at optimal MPA exposure^{1,2}.

Presenting this important phase III data for the first time, Robert Schmouder M.D., Director of Clinical Pharmacology of Novartis Pharma AG, commented: “The potential of Myfortic as an immunosuppressive agent is extremely exciting. The Myfortic formulation advance means physicians should be able to give patients MPA doses that are high enough to deliver exposure associated with important outcome benefits, without putting patients at risk for the well-documented side-effects of higher dose MPA that have been reported with mycophenolate mofetil (MMF) — the current formulation of MPA”.

1. Hale, M.D et al. Clin Pharmacol Ther. 1998; 64:672-683

2. Van Gelder T et al. Transplantation. 1999; 68:261-266

5) Certican™ targets primary causes of chronic organ rejection

New data highlight risk factors for chronic rejection, and show potential for Certican in targeting these factors

New evidence was presented at the “2001 – A Transplant Odyssey” meeting in Istanbul today, which clearly links a number of primary risk factors with chronic rejection¹, the leading cause of graft loss. Concurrently, data were presented which suggest Certican™ (RAD, a Proliferation Signal Inhibitor) to be an effective investigational agent to target a number of these risk factors. Together, these data show a strong emerging promise for the role of Certican in achieving the ultimate goal of transplantation — targeting primary causes of chronic rejection.

A review of the transplant literature on chronic rejection identified a number of risk factors, including the incidence of acute rejection (a finite episode when the body displays evidence of rejection which can be treated)¹, cytomegalovirus (CMV infection)², CNI-induced nephrotoxicity³, and smooth muscle cell proliferation^{4,5}.

1. H. Meier-Kriesche *et al.* Presented at the 2001 A Transplant Odyssey: The Future Is Here Transplantation Congress; Aug 20-23, 2001; Istanbul, Turkey. Abstract #1536.

2. Soderberg – Naucler C *et al* Viral infections and their impact on chronic renal allograft dysfunction. Transplantation 71, SS24 – SS30, No 11, June 15, 2001

3. Furness PN *et al.* Histopathology of chronic renal allograft dysfunction. Transplantation 71, SS31 – SS36, No 11, June 15, 2001

4. Hancock WH *et al* Cytokines adhesion molecules and the pathogenesis of chronic rejection of rat renal allografts. Transplantation 1998; 56: 643

5. Orosz C. Endothelial activations and chronic rejection allograft rejection. Clin. Transplant. 1994; 8: 299

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MEDIA RELEASE • COMMUNIQUE AUX MEDIAS • MEDIENMITTEILUNG**CerticanTM targets primary causes of chronic organ rejection**

New data highlight risk factors for chronic rejection, and show potential for Certican in targeting these factors

Istanbul, Tuesday 21 August 2001 – New evidence was presented at the “2001 Transplant Odyssey” meeting in Istanbul today, which clearly links a number of primary risk factors with chronic rejection¹, the leading cause of graft loss. Concurrently, data were presented which suggest CerticanTM (RAD, a Proliferation Signal Inhibitor) to be an effective investigational agent to target a number of these risk factors. Together, these data show a strong emerging promise for the role of Certican in achieving the ultimate goal of transplantation – targeting primary causes of chronic rejection.

A review of the transplant literature on chronic rejection identified a number of risk factors, including the incidence of acute rejection (a finite episode when the body displays evidence of rejection which can be treated)¹, cytomegalovirus (CMV infection)², CNI-induced nephrotoxicity³, and smooth muscle cell proliferation^{4,5}.

Results of a major analysis of renal transplant patient data (assessing 73,707 primary renal transplants reported from 1988 to 1997 from the United States Renal Data System [USRDS] database) – designed to determine the factors associated with chronic rejection were presented in Istanbul by Dr Meier-Kriesche of University of Michigan, Ann Arbor, USA. This analysis clearly identified acute rejection as the strongest risk factor associated with chronic rejection¹. This causal link between acute and chronic rejection makes clear the potential for Certican to help reduce chronic rejection, given the reported low rates of acute rejection with Certican⁶.

New data presented in Istanbul show acute rejection rates with Certican as low as 3.5% at six months and 8.8% at 12 months, when administered concomitantly with Simulect[®] (basiliximab), reduced-dose Neoral[®] and steroids⁶. In addition, less CNI-induced nephrotoxicity was reported in the reduced dose Neoral arm⁶. In terms of CMV infection – another primary cause of chronic rejection – data were presented showing lower infection rates for Certican (5.2% for 1.5mg and 7.6% for 3.0mg) compared to 19.4% for mycophenolate mofetil (MMF)⁷.

Dr Björn Nashan, from Medizinische Hochschule Hannover, Germany, stated: “Impact on acute rejection rate is clearly an important marker of a drug’s ability to prevent ultimate organ loss. Certican, as well as being highly effective in reducing acute rejection, also demonstrates the ability to positively impact upon other causes of chronic rejection, including CMV infection. In addition, Certican use may allow for a reduction in calcineurin inhibitor (CNI) dosage which leads to reduced CNI nephrotoxicity. What is really exciting about Certican – from a mode of action point of view – is that it has been demonstrated to inhibit smooth muscle proliferation, a key cause of chronic rejection⁸.

As such, Certican is living up to its probable potential as an important new agent to help improve long-term graft survival and patient outcomes.

These new findings for Certican, the Proliferation Signal Inhibitor, – low rates of acute rejection, low incidence of CMV infections and acceptable renal function – combined with good tolerability and an

acceptable side-effect profile, indicate that Certican may fulfill an important promise for Certican in targeting primary causes of chronic rejection and improving patient management.

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Notes to editors

Certican is an investigational new drug developed as a novel Proliferation Signal Inhibitor to be administered concomitantly with Neoral to suppress T-cell proliferation and prolong graft survival. Certican has been studied in more than 3,200 patients and found to be an effective and generally safe immunosuppressive agent. Certican modifies the mechanism associated with vascular rejection and inhibition of growth-factor driven smooth muscle cell proliferation. Certican is being developed to be used with Neoral.

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MEDIA RELEASE · COMMUNIQUE AUX MEDIAS · MEDIENMITTEILUNG**Data confirm new approach to patient management by Neoral[®] C₂ monitoring improves patient outcomes in maintenance and *de novo* transplant patients**

Istanbul, Tuesday 21 August 2001 – New data confirm Neoral[®] C₂ monitoring^{*} is a highly effective patient management technique, significantly enhancing the performance of Neoral (cyclosporin microemulsion) and improving patient outcomes. The data, presented at “2001 A Transplant Odyssey” meeting in Istanbul, demonstrated clinical benefit in *de novo* (newly transplanted)^{1,3} and maintenance² patients.

Confirming the benefits of patient management by Neoral C₂ monitoring, Dr Paul Keown, from The University of British Columbia, Vancouver and one of the world’s most experienced physicians with G monitoring, stated: “The adoption of G monitoring of Neoral blood levels, as opposed to standard trough levels, is a simple and highly effective way to enhance both the safety and efficacy of Neoral as cornerstone immunosuppression. We are now beginning to see more and more data which clearly demonstrate the benefits this management technique can have in terms of reduced acute rejection rates and improved patient outcomes, and I would encourage centres to move to this new strategy.”

Barry D. Kahan, Ph.D., M.D. Professor of Surgery and Director, The Organ Transplantation Center, University of Texas, Houston Medical School added further support for Neoral C₂ monitoring, by speaking of an important emerging understanding that the optimisation of cyclosporin exposure in *maintenance* renal transplant recipients by Neoral C₂ monitoring may reduce the risk of chronic rejection. He commented: “An extensive review of Neoral pharmacokinetics and clinical outcomes in long-term renal transplant recipients suggests a significant correlation between Neoral C₂ levels and incidence of chronic nephropathy. This is a major contribution to supporting the use of Neoral C₂ monitoring in all transplant recipients, irrespective of their time post-transplantation.”

Neoral C₂ monitoring – New patient management technique effective in *de novo* kidney transplant patients...

Results from a Canadian multicenter open-label study in *de novo* renal transplant patients evaluated pharmacokinetic factors contributing to improved patient outcomes in the first month post-transplant³. Full cyclosporin AUC profiles^{**} following Neoral dosing (8-12 mg/kg/day) were obtained at days 3, 7, and 14 post-transplant. Patients achieving G target levels greater than 1.5 µg/mL at day 7 had no acute rejection (AR) by day 14; patients who failed to achieve this C₂ target level had a 58% incidence of AR.

These C₂ findings correlate with those for AUC targets in the study, whereby achievement of AUC₀₋₄ targets at day 7 led to considerable reductions in AR at day 14. This finding substantiates previous data that C₂ is the best surrogate of AUC₀₋₄ and is a more simple patient monitoring technique to help optimise Neoral therapy and patient outcomes.

...Neoral C₂ monitoring effective in maintenance and *de novo* liver transplant patients

Clinical data at 12 months post transplant for 306 *de novo* liver transplant patients were also presented in Istanbul¹. Patients were randomized at transplantation to be managed by either C₂ or C₀ monitoring. Biopsy-proven AR was 20% lower in the C₂ group (26.4%), compared with the C₀ group (33.5%); furthermore, C₂ monitoring reduced the number of patients with histologically moderate or severe AR by 42% (C₂, 13.5% vs. C₀, 23.4%; P=0.02).

Stable maintenance patients were also shown to benefit from Neoral C₂ monitoring in a study of 110 liver transplant patients². Approximately one third of patients at 12 months (or longer) post-transplant, previously managed by C₀ monitoring, were found to have C₂ levels exceeding the recommended target. Subsequent reduction in Neoral doses to achieve the desired C₂ target resulted in statistically significant improvements in renal function and blood pressure. The study concluded that Neoral C₂ monitoring using specified target levels provides a more sensitive measure of drug exposure in the individual patient resulting in improved clinical benefits from cyclosporine immunosuppression, compared to C₀.

Neoral C₂ monitoring for management of cyclosporin blood levels is currently being adopted by many of the world's major transplant centres. Further clinical trials continue to add to the evidence that this patient management technique is superior to traditional monitoring methods, and as time passes, a growing body of experience will develop to help with the practical considerations of performing C₂ monitoring.

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Notes to editors

*** What is C₂ monitoring?**

Neoral C₂ monitoring is the measurement of the cyclosporin level in a patient's blood two hours (C₂) after the dose instead of the traditional practice of trough level monitoring, when cyclosporin blood levels are measured immediately before the dose (C₀ levels).

**** Rationale for patient management by C₂ monitoring**

Studies leading to the establishment of Neoral C₂ patient management identified the early phase of Neoral absorption (i.e. AUC₀₋₄) as the absorption phase of Neoral that should ideally be used to decide dosing levels to improve efficacy and safety compared to C₀. However, taking the many blood levels needed for AUC₀₋₄ monitoring was not feasible and subsequently the single timepoint C₂ was identified as the most precise surrogate for the early phase of Neoral absorption. Studies have since shown C₂ measurements are most closely correlated with acute rejection, and have subsequently been used to establish minimum target levels for C₂ to reduce acute rejection and improve patient outcome.

Neoral is the cornerstone immunosuppressive agent for transplant recipients, offering well-documented excellent outcomes in both the *de novo* and maintenance patient settings. Neoral is a critical-dose drug with a narrow therapeutic index, absorption of which is highly dependent upon formulation. Neoral, used in over 100,000 transplant patients world-wide, is indicated for the prophylaxis of organ rejection in kidney, liver and heart allogeneic transplants in adults and children. Neoral is contraindicated in patients with a hypersensitivity to cyclosporin or any ingredients in the formulation. Only physicians experienced in the management of systemic immunosuppressive therapy for the indicated disease should prescribe Neoral.

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MEDIA RELEASE • COMMUNIQUE AUX MEDIAS • MEDIENMITTEILUNG**FTY720, a novel compound with a unique mode of action —
A breakthrough in immunosuppression?**

Istanbul, Tuesday 21 August 2001 – Data from early clinical analyses presented today at “2001 A Transplant Odyssey” meeting in Istanbul suggest FTY720, a novel compound under development for organ transplant immunosuppression, is highly efficacious, well tolerated and exerts its effect in a completely different manner to any other current immunosuppressant^{1,2} — potentially making it a genuine breakthrough in transplant immunotherapy. Treatment with FTY 720 in animal models has shown that the immunity to systemic viral infections remained unimpaired, which may provide a striking advantage compared to classical immunosuppressive agents⁵.

In addition, data revealed FTY720 was associated with a considerably lower rate of biopsy-confirmed acute rejection compared to mycophenolate mofetil (MMF)³. In a Phase II trial (n=208 adult renal transplant recipients aged 18-65 years), FTY720 was shown to be highly efficacious and well tolerated in newly transplanted kidney patients, delivering an acute rejection rate as low as 9.8 percent compared to 17.1 percent achieved by MMF³, both in combination with Neoral® (cyclosporin microemulsion) and corticosteroids.

FTY720 has also been administered concomitantly with Certican™ (everolimus) in a proof-of-concept clinical trial.

A safety and pharmacokinetics study⁴ of kidney transplant patients who were at least one year post transplant, also found FTY720 to be well tolerated in doses up to 5.0 mg/day for 28 days.

Dr Helio Tedesco-Silva, from Hospital do Rim e Hipertensão, São Paulo, Brazil, commented: “These new data increase our understanding of the highly complex molecular regulation involved in the immune response. The FTY720 research is revealing a compound that appears to work in a completely different way to current immunosuppressants, which could mean that patients in the future would benefit from new therapeutic approaches and drug combinations, which are more effective in preventing acute rejection with improved tolerability.”

FTY720 appears to be unique because, unlike current immunosuppressants with a broad immunosuppressive approach, the compound exerts its remarkable potency in a targeted fashion¹. Current immunosuppressants tend to exert a generalised immunosuppressive effect over the entire body, potentially reducing the body's defence against infections and malignancies. The new data^{1,2} presented in Istanbul by Dr Volker Brinkmann, Novartis Pharma AG, suggest FTY720 activates the cell mobility machinery via a novel class of cell membrane receptors, hereby accelerating their response to homing chemokines *. This leads to a sequestration of lymphocytes to lymphatic organs, thus preventing them from migrating to and reacting with the transplanted organ.

The data presented today open up the possibility of new therapeutic drug combinations, which could deliver better protection against acute as well as chronic rejection and with improved tolerability. In

particular, previously reported data suggest the unique mode of action of FTY720 may be synergistic and complimentary to Neoral.

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Notes to editors

- FTY720 is a novel immunosuppressant with a unique mechanism of action, currently in Phase II clinical trials. In vivo studies of FTY720 demonstrate its ability to prolong allograft survival with remarkable potency. Data show that extrapolated to the transplantation situation, the intact immunity to systemic infection during treatment with FTY720 may provide a striking advantage compared to classical immunosuppressive agents. In preclinical models, FTY720 has been shown to prevent rejection of solid organ grafts and when combined with Neoral. The molecule shows synergy with Neoral and with Certican, suggesting the potential for use in multi-drug combinations.
- *** Chemokines** - naturally occurring proteins involved in the chemotaxis and migration of leukocytes

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MEDIA RELEASE - COMMUNIQUE AUX MEDIAS - MEDIENMITTEILUNG**Neoral[®] demonstrates four-fold lower incidence of post-transplant diabetes mellitus (PTDM) compared to tacrolimus in renal transplantation***Meta-analysis shows important benefits of Neoral-based regimens on long-term health outcomes and costs associated with PTDM*

Istanbul, 21 August 2001 – Strong evidence presented today at “2001 - A Transplant Odyssey” suggests that Neoral[®]-based immunosuppressive regimens may lead to a four-fold decrease in the initial development of post-transplant diabetes mellitus (PTDM) in patients within the first year after renal transplantation compared to tacrolimus-based regimens.¹

These findings, which substantiate previous reports of the lower incidence of PTDM with Neoral as compared to tacrolimus are of particular importance given the considerable health and economic impact of PTDM. PTDM is associated with poor long-term graft and patient survival, as well as with other important diseases which affect patients in the long term. Data presented at Istanbul also suggest an incremental annual cost of £14,000 (USD 20,000) to treat a renal transplant patient developing PTDM, as compared to a patient not developing diabetes.² This cost is primarily associated with increased use of dialysis services and transplant management.

The four-fold increase in the development of PTDM following tacrolimus-based regimens compared to Neoral regimens was presented by Dr Richard Moore Clinical Director of the Renal and Transplant Unit at University Hospital of Wales, Cardiff, UK. He commented: “PTDM is a major consideration for all those involved in transplant management as it is one of the commonest complications after renal transplantation and is associated with an increase in the risk of graft loss and death after transplantation. These data, which show a considerably increased risk in those patients on a tacrolimus-based immunosuppressive regimen are therefore highly important and should be considered as one of the main factors involved in choosing a long-term immunosuppressant therapy tailored to individual need.”

The meta-analysis presented by Dr Moore studied a primary database (n=860) of clinical trials in *de novo* renal transplants. Incidence of PTDM was defined as use of insulin for 30 days or longer in patients who had no history of diabetes prior to transplant. The database showed a 10.1% (55/508) incidence of PTDM within the first year post-transplant in the tacrolimus treated groups compared to just a 2.6% incidence (9/352) in the Neoral groups. (9/352 or 2.6%). At 5 years post transplant, the incidence of PTDM was 41% in the tacrolimus group versus 14.3% in the Neoral group.

Considerable health economic impact of PTDM²

The incremental cost of treating a patient with PTDM was estimated from a health economic model presented by the SchARR group from Sheffield University, UK, James Chilcott of the SchARR

group comments, “Although little direct quantified evidence exists, it is predicted that PTDM will bring with it considerable short and long-term economic consequences which need to be considered when evaluating the comparative risk-benefits of various immunosuppressive regimens and their association with PTDM. The burden of illness of PTDM is currently not fully understood, but should not be underestimated.”

PTDM: A problem also highlighted by the recent WHO Classification of diabetes³

A final set of data presented at the meeting show the considerable problems of PTDM becoming more evident with the new classification of diabetes defined by the WHO. The new WHO classification defines a lower threshold value for normal fasting plasma glucose level (110 mg/dl), which means that patients with values between 110 and 126 mg/dl glucose are considered as having impaired fasting glucose (IFG), and those with values equal or higher than 126 mg/dl as having diabetes. A preliminary study presented by Dr. Piero Marchetti and his group from the University of Pisa, Italy, shows that, according to this new classification, the percentage of tacrolimus-treated renal transplant patients having IFG or PTDM is more than two-fold higher than that of patients treated with Neoral. This finding is of relevance in view of studies showing that PTDM can adversely affect patient survival and function of transplanted organs.

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Notes to editors:

* **Diabetes Mellitus** has been underdiagnosed in the transplantation field, and up to now has been primarily defined only as a requirement for insulin, which highly underestimates the total population exposed to the problem. PTDM is associated with poor long-term graft and patient survival, as well as with other important diseases which affect patients in the long term. Transplant patients are already exposed to a greater risk of cardiovascular disease, and PTDM is an independent factor that further magnifies that risk.

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MEDIA RELEASE • COMMUNIQUE AUX MEDIAS • MEDIENMITTEILUNG**Myfortic™ — advanced and improved enteric-coated formulation delivers optimum drug exposure at no safety cost in transplant patients***First major phase III data presentation on enteric-coated Myfortic from Novartis*

Istanbul, Tuesday 21 August 2001 – New phase III data presented today in Istanbul on Myfortic™ (enteric-coated formulation of mycophenolate acid [MPA]) demonstrate the pharmacokinetic benefits of this advanced MPA formulation are two-fold: therapeutic MPA exposure is achieved more rapidly and for a longer duration than with mycophenolate mofetil (MMF). This enhanced absorption is reached at no safety costs, which means that Myfortic broadens the therapeutic index of MPA in the important post-transplant period.

Delegates at “2001 A Transplant Odyssey” in Istanbul, heard how this broadened therapeutic window points to a great potential for Myfortic to improve efficacy – a finding that has been documented in previous key papers looking at optimal MPA exposure^{1,2 *}.

Presenting this important phase III data for the first time, Robert Schmouder M.D., Director of Clinical Pharmacology of Novartis Pharma AG, commented: “The potential of Myfortic as an immunosuppressive agent is extremely exciting. The Myfortic formulation advance means physicians should be able to give patients MPA doses that are high enough to deliver exposure associated with important outcome benefits, without putting patients at risk for the well-documented side-effects of higher dose MPA that have been reported with mycophenolate mofetil (MMF) — the current formulation of MPA”.

The pharmacokinetic (PK) data presented were from a subset of 51 patients from the pivotal ERLB301 Phase III study³, comparing Myfortic and MMF in kidney transplant patients. Patients were maintained on equimolar MPA dosing: Myfortic 720mg or MMF 1000mg twice daily and had intensive PK sampling of MPA at 14, 90 and 180 days post-transplant. Myfortic was associated with higher systemic MPA exposure (ug*hr/mL) at all three time-points; 29.1, 50.7, and 55.7 when compared to MMF; 23.3, 39.1 and 37.2 respectively. The statistically significant increase in mean MPA exposure associated with Myfortic was 32% (p=0.004). The study showed no increase in side effects compared to MMF.

Dr Schmouder also demonstrated the important benefits Myfortic has on individuals' MPA exposure levels. Within the most critical period after transplantation, 55% of the Myfortic™ group achieved the target therapeutic MPA exposure (AUC > 30 ug*h/mL) at day 14, compared to just 15% of the MMF group. At 90 days, 86% of the Myfortic group had achieved this MPA exposure compared to 76% of the MMF group. At 180 days, 100% of the Myfortic group achieved MPA exposure compared to just 72% of the MMF group.

Looking at the B301 study as a whole, data from 423 newly transplanted renal patients showed therapeutic equivalence, the main study objective, between the two treatment arms: the rate of biopsy-proven acute graft rejection in the first 6 months in the Myfortic group was 20.7% compared to 22.4% in the MMF group. Overall the frequency of adverse events was comparable for both groups, although the frequency of serious infections was slightly lower at 6 months for the Myfortic group (18.3%) as compared to MMF (23.3%, NS). GI intolerance resulted in medication discontinuation in 3.8% of patients in each group, and in dose reductions or temporary interruptions in 9.4% of the Myfortic group compared to 13.8% of the MMF group (NS).

The enhanced exposure of Myfortic has potential to provide improved long-term outcomes with regard to chronic rejection and graft survival.

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*** Editor's notes:**

Optimal target MPA exposure has been studied in the past in two key papers 1,2. The results from these papers, summarized below, are pivotal in the findings and conclusions discussed in this release:

Van Gelder, T et al. Transplantation. 1999; 68:261-266:

	Target MPA Exposure (AUC ¹)		
	Low (16 ug*hr/mL)	Intermediate (32 ug*hr/mL)	High (61 ug*hr/mL)
Biopsy proven acute rejection	27.5%	14.9%	11.5%
Withdrawal due to adverse events	7.8%	23.4%	44.2%
diarrhoea	7.8%	8.5%	19.2%
Abdominal pain	5.9%	8.5%	13.5%
Vomiting	2.0%	6.4%	9.6%

¹ AUC = Area Under Curve

Hale, M.D et al. Clin Pharmacol Ther. 1998; 64:672-683:

	Target MPA Exposure (AUC)		
	Low (16 ug*hr/mL)	Intermediate (32 ug*hr/mL)	High (61 ug*hr/mL)
Acute rejection	31%	13%	11%
Withdrawal rate	12%	23%	48%

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4. Arns W *et al.* Presented at the 2001 A Transplant Odyssey: The Future Is Here Transplantation Congress; Aug 20-23, 2001: Istanbul, Turkey. Abstract #1659

MEDIA RELEASE - COMMUNIQUE AUX MEDIAS - MEDIENMITTEILUNG**Trileptal[®], Novartis' oral suspension treatment for epilepsy, completes European Mutual Recognition Procedure**

Basel, 20 August 2001 – Novartis announced today that the European Mutual Recognition Procedure for its oral suspension formulation of Trileptal[®] (oxcarbazepine) has been completed. The new product will become available as soon as member states have issued licenses and appropriate reimbursement matters have been addressed. Trileptal is indicated for monotherapy and adjunctive therapy in children and adults with partial seizures, with or without secondary generalization.

“Many people, particularly young children, the elderly, and patients who are mentally impaired, often have difficulty swallowing medication in tablet form,” said Thomas Ebeling, CEO of Novartis Pharma. “The oral suspension formulation of Trileptal offers epilepsy patients an easy-to-swallow liquid formulation that provides effective seizure control.”

The oral suspension has a pleasant plum-lemon flavoring and can be mixed in a small glass of water just prior to administration or swallowed directly from the oral syringe provided with each bottle. The medication can be taken with or without food, an additional advantage in terms of ease of administration.

The effectiveness of Trileptal as a first line monotherapy and adjunctive therapy for partial seizures in adults and children has been established in multicenter, randomized, double-blind, controlled trials. Efficacy as monotherapy has been demonstrated in eight well-controlled multicenter trials, using placebo, other antiepileptic drugs (AED) and low doses of Trileptal as comparators, in newly diagnosed patients and in patients poorly controlled on their first AED. Efficacy of Trileptal as adjunctive therapy was evaluated in two multicenter, randomized, double-blind, placebo-controlled trials. In addition, Trileptal has shown to be well-tolerated with over 400,000 patient years of post marketing experience worldwide.

Trileptal has been one of the most dynamically launched CNS drugs ever in the US, as evidenced by its very rapid uptake into the market. The oral suspension was approved by the US Food and Drug Administration (FDA) in May of this year. The tablet formulation completed the European Mutual Recognition Procedure in November 1999 and is currently marketed in over 50 countries, including the US and Europe.

Epilepsy – a Worldwide Phenomenon

More than 50 million people worldwide experience some form of epilepsy. It is the most common form of neurological disorder affecting people of all ages with periods of relatively high incidence in early childhood, adolescence and people over the age of 65. Its symptoms include various forms of recurrent seizures and can occur throughout a patient's lifetime.

The foregoing press release contains forward-looking statements which can be identified by terminology such as, "will be", "can be", 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. 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.

About Novartis

Novartis (NYSE: NVS) is a world leader in healthcare with core businesses in pharmaceuticals, consumer health, generics, eye-care, and animal health. In 2000, the Group's ongoing businesses achieved sales of CHF 29.1 billion (USD 17.2 billion) and a net income of CHF 6.5 billion (USD 3.9 billion). The Group invested approximately CHF 4.0 billion (USD 2.4 billion) in R&D. Headquartered in Basel, Switzerland, Novartis employs about 70,000 people and operates in over 140 countries around the world. For further information please consult <http://www.novartis.com>

MEDIA RELEASE • COMMUNIQUE AUX MEDIAS • MEDIENMITTEILUNG

Novartis reports sustained growth in first half of 2001

- *Group sales up 12% in local currencies (11% in Swiss francs) to CHF 15.5 billion (USD 8.6 billion)*
- *Pharmaceuticals' sales grow 13% in local currencies, 21% in the US, and 9% in the rest of the world*
- *Operating income up 7% to CHF 3.5 billion (USD 1.9 billion) accompanied by increased investments in pharmaceutical launches and key products*
- *Net income climbs 10% in Swiss francs to CHF 3.7 billion (USD 2.1 billion)*
- *On track to achieve record financial targets for full year*

Consolidated key figures from continuing activities

	First half 2001			First half 2000		Change	
	USD m	CHF m	%	CHF m	%	CHF m	%
Sales	8,591	15,464		13,970		1,494	11
Operating income	1,933	3,480		3,266		214	7
in % of sales			22.5		23.4		
Net income	2,072	3,729		3,396		333	10
in % of sales			24.1		24.3		
Number of employees		70,166		66,124		4,042	6
Earnings per share (CHF)		1.44		1.30		0.14	11

Basel, 16 August 2001 – The Novartis Group continued to build on its strong first-quarter performance to post overall first-half sales of CHF 15.5 billion (USD 8.6 billion), an increase of 12% in local currencies or 11% in Swiss francs. Sales growth was driven by Pharmaceuticals and the sustained dynamism of the US business, where Pharmaceuticals' sales climbed 21%.

In the Group's first half report, published today, Daniel Vasella Chairman and CEO commented: "As a result of our focus on healthcare and the good performance of our Pharmaceuticals business, we achieved double-digit growth both in sales and net income. Our increased level of investment in marketing and sales, with the priority on key growth drivers, resulted in a sales growth of 21% in Pharmaceuticals in the US. Furthermore, despite the difficult conditions prevailing in the financial markets, we managed to achieve financial results slightly superior to those of the previous year. I am confident that our pharmaceutical business will post double-digit sales growth in the second half of the year. "

Operating income up 7% to CHF 3.5 billion (USD 1.9 billion)

Overproportional investment in Pharmaceutical Marketing & Distribution to power key growth drivers, new product launches and the expansion of products into new indications and markets had the expected effect of lowering the Group's operating margin. Operating income increased 7% to CHF 3.5 billion (USD 1.9 billion), resulting in an operating margin of 22.5% compared with 23.4% for the same period last year.

Net income rises 10% to CHF 3.7 billion (USD 2.1 billion)

Income from associated companies, primarily Chiron, increased CHF 53 million (USD 29 million) to CHF 77 million (USD 43 million). Despite difficult financial market conditions, net financial income increased CHF 26 million (USD 14 million) to CHF 952 million (USD 529 million), owing in particular to successful fund management and the sale of US dollar bonds.

Strong balance sheet

At 30 June 2001, the strength of the Group's balance sheet was undiminished despite several significant transactions, including the acquisition, as a long-term financial investment, of 20% of the voting rights of Roche Holding AG for CHF 4.8 billion (USD 2.7 billion) in May, and further purchases of Novartis treasury shares under a second trading line for CHF 3.1 billion (USD 1.7 billion).

The Group's equity at 30 June 2001 remained at its 31 December 2000 level of CHF 36.9 billion (USD 20.5 billion). As a result of these and other transactions, net liquidity (marketable securities, cash and cash equivalents, less financial debt) was reduced by CHF 7.1 billion (USD 3.9 billion) to CHF 7.3 billion (USD 4.1 billion). The debt/equity ratio changed from 0.16:1 on 31 December 2000 to 0.21:1 on 30 June 2001.

Free cash flow from continuing activities, excluding amounts related to changes in intangible and financial assets, amounted to CHF 110 million (USD 61 million) in the first six months of 2001, less than the CHF 304 million (USD 169 million) in the prior period, owing to increases in dividends, net current assets and investments in tangible fixed assets.

Personnel

The number of employees increased from 67 653 on 31 December 2000 to 70 166 on 30 June 2001. Pharmaceuticals increased by approximately 1400 as it continued to expand its sales force, which now comprises 16 700 worldwide (of which approximately 5100 are in the US). Generics also increased by more than 1100 principally as a result of acquisitions.

Outlook

The Group expects double-digit sales growth for Pharmaceuticals in 2001, based on the performance of key brands, new product launches and new indications, including *Gleevec/ Glivec*, *Femara* and *Zometa*.

Pharmaceuticals' operating income is expected to rise, although a decline of approximately two percentage points in the operating margin is foreseen as a result of continued investment in order to expand the market share of key growth drivers.

The remaining sectors are expected to develop in line with their first-half performances.

Barring any unforeseen disturbances, full-year Group operating income and net income are expected to exceed last year's level on an ongoing basis.

Sector reviews

Pharmaceuticals

Sales

Pharmaceuticals' sales (+13% in local currencies) were lifted by the strong performances of key Primary Care brands and recently launched products in Oncology and Ophthalmics.

Primary Care

Diovan (+53%; hypertension) is now the fastest growing top-ten antihypertensive in the US. It was filed globally for congestive heart failure, and has received priority review in the US for this indication. Novartis' cardiovascular franchise was further strengthened as *Lotrel* (+47%; hypertension) sustained strong double-digit growth in the US.

Starlix (sales to end of June: CHF 29 million; USD 16 million), the type 2 diabetes treatment, has experienced a gradual increase in prescriptions since its US launch in February and prescribers are becoming more familiar with this new approach to managing postprandial glucose. A large scale multinational study (NAVIGATOR) is to assess and profile potential benefits of both *Diovan* and *Starlix* in the prevention of type 2 diabetes and cardiovascular disease.

Lamisil (+18%; fungal infections) continued to gain segment share, buoyed by a new wave of direct-to-consumer advertising in the US.

Miacalcic (+12%; osteoporosis) continued to post double-digit growth as the osteoporosis segment expands due to demographic changes.

Exelon (+174%; Alzheimer's disease) sales topped CHF 220 million (USD 122 million), with a good performance worldwide, particularly in the US.

Trileptal (+69%; epilepsy) built on its dynamic launch to post total sales of CHF 98 million (USD 54 million).

Foradil (+24%; asthma) achieved sales of CHF 199 million (USD 111 million) and was launched in the US. *Foradil* is also under review by the FDA for approval in the treatment of chronic obstructive pulmonary disease (COPD), an indication that has already gained approval in several European countries.

Elidel (inflammatory skin disease) was filed for regulatory approval in Europe in June, having been filed in the US towards the end of last year.

In June, the FDA issued a 'not-approvable' letter for *Zelnorm/Zelmac* (constipation predominant irritable bowel syndrome) requesting further information. The company is submitting an appeal to the FDA regarding the decision. The application for regulatory approval was withdrawn in Europe. Subsequent to these decisions, Novartis and Bristol Myers Squibb have mutually decided not to pursue the collaboration established to develop and commercialize tegaserod (*Zelmac/Zelnorm*). Novartis recently launched *Zelmac* in its first market, Mexico.

The FDA also requested additional data for the new asthma treatment *Xolair*, and the amended file is currently expected to be submitted towards the end of 2002, or early in 2003.

Mature Products

Of the Mature Products, *Voltaren* (–10%; inflammation) faced continued pressure from generic products in various markets; however, the sales decline was modest and lower than in the comparative period of 2000.

Oncology

The Novartis Oncology business experienced dynamic growth fuelled by solid performances of *Sandostatin* (+31%; acromegaly) and Novartis' leading bisphosphonate *Aredia* (+28%; cancer complications). *Zometa* (hypercalcemia of malignancy), the more potent successor compound to *Aredia*, got off to a solid start in Europe after its introduction in Germany in May, and has now been approved in 19 countries. US approval is pending.

Sandoglobulin sales (CHF 101 million; USD 56 million; –31%) contracted, especially in the US (–39%), as the manufacturer continues to reduce supply.

Gleevec/Glivec gained US approval for chronic myeloid leukemia within two and a half months of filing, making this the fastest time to market of any cancer treatment. The drug was distributed to patients within just 24 hours of US approval. It is now approved in some twenty countries and posted sales of CHF 58 million (USD 32 million) by the end of June.

Launched in *February* in Europe and the US as first-line therapy for advanced postmenopausal breast cancer, *Femara* achieved sales growth of 64%. Due to its proven superiority over tamoxifen, it has won category leadership in France, Spain, Belgium, Mexico, Switzerland and Australia.

Ophthalmics

Visudyne (+254%; a form of wet age-related macular degeneration) sales reached CHF 178 million (USD 99 million), benefiting from European reimbursement gained earlier in the year and boosted by additional revenues from the pathologic myopia indication approved in Europe in January.

Transplantation

Expanding sales of *Neoral* in Japan contributed to supporting overall sales of the gold-standard immunosuppressant *Sandimmun/Neoral* (–8%). Despite increased generic competition, the erosion of US sales (–25%) is broadly in line with the index for other critical dose drugs. This again reflects the fact that many physicians prefer to maintain patients who are stable and doing well on *Neoral*, as rejection episodes impair long-term outcome.

Strengthened US pharmaceuticals operation

The US (+21%) reported continued strong growth, particularly from *Diovan* (+40%) and *Lotrel* (+47%), despite intense competition. *Femara* (+144%), boosted by its new indication, and *Visudyne* (+241%) were other important contributors to US pharmaceutical sales, which now make up 41% of Pharmaceuticals' total revenues.

Operating income

Investments in Marketing & Distribution increased overproportionally as a result of field force expansion, in particular in the US, and the intensified promotional activities associated with product launches and growth drivers. Research & Development investments reached CHF 1.7 billion (USD 0.9 billion) or 17% of sales, increasing in absolute terms from CHF 1.6 billion. Overall, the operating margin eased down 1.6 percentage points as predicted.

Generics

Sales

Overall sales in Generics grew 12% worldwide in local currencies despite a 2% decline in the US. Sales growth was lifted 16 percentage points by recent acquisitions. The industrial generics business

posted a solid performance and benefited from a partial recovery of certain anti-infective prices. The active ingredients business performed well particularly in Japan and Western Europe.

With the Sector's market presence strengthened through recent acquisitions in Europe, the US and Latin America, the retail business reported strong sales growth. In the key US market, price pressures and increased competition impacted sales growth, whilst in Europe, sales were lifted by significant expansion of the product portfolio, including the launch in Germany of Azupharma's macrolid antibiotic, Roxithromycin.

Operating income

Generics' operating margin declined 8.6 percentage points to 12.6% as a result of restructuring costs in the US, additional costs for the integration of recent acquisitions, increased investments for new product launches and continued price pressures in the retail business. Operating income was CHF 141 million (USD 78 million) and is expected to benefit in the second half from the recent restructuring at Geneva Pharmaceuticals and expected new product launches. Whilst Marketing & Distribution expenses increased substantially, Research & Development investments were maintained at 7% of sales.

Consumer Health

Sales

Sales of over-the-counter medicines (**OTC**) rose 4% in local currencies with the key brands *Voltaren Emulgel* (topical pain), *Lamisil Cream* (antifungal), *Triaminic* (pediatric cold remedy) and *Nicotinell/Habitrol* (smoking cessation) continuing to perform well. *Maalox Max* (antacid plus anti-gas) was launched in April and has begun to counter inroads made by competitor products (H₂ receptor antagonists). Overall, growth was achieved despite the weak cough and cold season and the withdrawal of products containing phenylpropanolamine (PPA). A new PPA-free formulation of *Tavist* (allergy, sinus, headache) was launched in April. *Lamisil Cream* was successfully introduced in the OTC markets of Germany and the UK.

The growth in **Medical Nutrition** (+6%) reflected good results in Europe and Latin America. The US performance was less robust due to a decline in the tube feeding business. On the other hand, the dysphagia (swallowing difficulty) and wound care products posted strong sales.

In **Health & Functional Nutrition** (+3%), Gerber increased its share of the US baby/toddler food segment to more than 75%, despite strong competition. The Gerber food line was launched in South Africa, and Gerber Baby Care closed the gap on the segment leader.

Operating income

Operating income was maintained at CHF 385 million (USD 214 million) resulting in an operating margin of 11.7% compared with 12.2% in the prior period. The decline was due to one-time costs associated with the transfer of *Ovaltine* production from the UK to Switzerland. As a percentage of sales, investments in Marketing & Distribution and Research & Development were maintained at last year's level. Research & Development investment focused mainly on OTC development projects.

CIBA Vision

Sales

A significant boost came from sales generated by Wesley Jessen products, which added 43 percentage points to the underlying growth. The lens business achieved strong sales growth, driven by the Wesley Jessen line of contact lenses acquired in October 2000, as well as by *Focus DAILIES* and *Focus NIGHT & DAY*. The decline in sales of conventional lens products reflected the continued market trend towards disposable products such as *Focus DAILIES*. The lens care business, which is also

affected by this trend, reported diminishing sales, while Refractive Surgery showed strong growth resulting from the re-launch of the *MemoryLens*.

Overall, the US and Europe performed well, whilst growth in Japan was constrained by the availability of *Focus DAILIES*.

In the first half, CIBA Vision launched *FreshLook ColorBlends Toric* lenses, the world's first disposable cosmetic toric lenses and SOLO-care Plus, an enhanced one-bottle lens-care disinfection system. The company also received US marketing clearance for *Focus DAILIES Progressives*, the world's first daily disposable multi-focal lens for presbyopic correction.

Operating income

Operating income dipped CHF 19 million (USD 11 million) to CHF 87 million (USD 48 million), owing to exceptional factors associated with the acquisition of Wesley Jessen (CHF 31 million; USD 17 million). Investments in Marketing & Distribution grew slower than sales, while Research & Development increased slightly to 5.5% of sales. General & Administration costs increased at a higher rate than sales, owing to expenses related to the integration of Wesley Jessen. As a result, the operating margin dropped 7.3 percentage points to 9.9%. Excluding these exceptional costs CIBA Vision achieved an operating income of CHF 118 million (USD 66 million) and an operating margin of 13.4%.

Animal Health

Sales

Sales were down 2% in local currencies. Shortfalls in the US, due to the economic slow-down and competitive pressures in the flea treatment segment, and set-backs in the UK, due to the devastating effect of foot-and-mouth disease, were largely offset by the performance in Latin America and Asia. Significant sales growth was achieved by *Tiamulin* (respiratory and gastroenteric diseases in pigs) and by the recently acquired vaccine businesses. *Fortekor*, the heart failure product for dogs, also grew strongly, boosted by the additional indication of renal insufficiency in cats.

Operating income

In spite of the drop in sales, operating income was maintained at CHF 66 million (USD 37 million). The operating margin rose from 12.8% to 13.5% as productivity improved and exceptional costs associated with the Agribusiness spin-off last year did not recur. As a result, General & Administration costs improved, whilst major investments in Marketing & Distribution were associated with a doubling of the sales force in the US. Research & Development investments were also stepped-up by CHF 7 million (USD 4 million) to CHF 45 million (USD 25 million) (9% of sales) as new projects, in particular in the vaccine business, were initiated.

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 "expects", "estimates", "promising", "will", "anticipates" or similar expressions, or by discussions of strategy, plans or intentions. Such statements include descriptions of new products expected to be introduced or have been introduced by the Group and anticipated customer demand for such products. Such statements reflect the current views of the Group with respect to future events and are subject to certain risks, uncertainties and assumptions. Many factors could cause the actual results, performance or achievements of the Group to be materially different from any future results, performances or achievements that may be expressed or implied by such forward-looking statements. Some of these are uncertainties relating to clinical trials and product development, unexpected regulatory delays or government regulation generally, and obtaining and protecting intellectual property, as well as factors discussed in the Group'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.

Novartis (NYSE: NVS) is a world leader in healthcare with core businesses in pharmaceuticals, consumer health, generics, eye-care, and animal health. In 2000, the Group's ongoing businesses achieved sales of CHF 29.1 billion (USD 17.2 billion) and a net income of CHF 6.5 billion (USD 3.9 billion). The Group invested approximately CHF 4.0 billion (USD 2.4 billion) in R&D. Headquartered in Basel, Switzerland, Novartis employs about 70,000 people and operates in over 140 countries around the world. For further information please consult <http://www.novartis.com>

For details of the first-half performance and financials please consult Novartis' half-year report 2001, which is available via the internet at:

http://www.novartis.com/downloads/corporate_publications/halfyear01_e.pdf or, on request from Novartis International AG, Novartis Communication, 4002 Basel, Switzerland.

Sales from continuing activities by sector

	First half 2001		First half 2000	Change		
	USD m	CHF m	CHF m	in CHF m	in CHF %	in local currencies %
Pharmaceuticals	5,383	9,689	8,669 ¹	1,020	12	13
Generics	623	1,121	1,012 ¹	109	11	12
Consumer Health	1,824	3,283	3,157 ¹	126	4	4
CIBA Vision	489	881	618 ¹	263	43	45
Animal Health	272	490	514	-24	-5	-2
Total	8,591	15,464	13,970	1,494	11	12

Operating income from continuing activities by sector

	First half 2001			First half 2000		Change	
	USD m	CHF m	% of sales	CHF m	% of sales	in CHF m	in %
Pharmaceuticals	1,497	2,695	27.8	2,551 ¹	29.4	144	6
Generics	78	141	12.6	215 ¹	21.2	-74	-34
Consumer Health	214	385	11.7	385 ¹	12.2	0	0
CIBA Vision	48 ²	87 ²	9.9	106 ¹	17.2	-19	-18
Animal Health	37	66	13.5	66	12.8	0	0
Corporate and other expenses	59	106		-57		163	
Total	1,933	3,480	22.5	3,266	23.4	214	7

¹ Restated to reflect the transfer, as of 1 January 2001, of the Ophthalmics business from CIBA Vision to Pharmaceuticals and the switch of certain products between sectors

² Excluding exceptionals associated with the Wesley Jessen acquisition (CHF 31 million), operating income would have been CHF 118 million, reflecting an increase of 11% in Swiss francs and an operating margin of 13.4%.

Consolidated income statement for continuing activities

	First half 2001		First half 2000	Change in	
	USD m	CHF m	CHF m	CHF m	%
Total sales	8,591	15,464	13,970	1,494	11
Cost of goods sold	2,113	3,804	3,454	350	10
Gross profit	6,478	11,660	10,516	1,144	11
Marketing & Distribution	3,034	5,462	4,539	923	20
Research & Development	1,117	2,010	1,870	140	7
General & Administration	393	708	841	-133	-16
Operating income	1,934	3,480	3,266	214	7
Income from associated companies	43	77	24	53	221
Financial income, net	529	952	926	26	3
Income before taxes and minority interests	2,506	4,509	4,216	293	7
Taxes	427	768	806	-38	-5
Minority interests	7	12	14	-2	-14
Net income	2,072	3,729	3,396	333	10

All USD figures are convenience translations of CHF into USD at a rate of 1.80. These translations should not be construed as representations that the Swiss franc amounts actually represent such US dollar amounts as could be converted into US dollars at the rate indicated or at any other rate

Top 20 pharmaceutical products

	US First half 2001		% Change in local currencies	RoW First half 2001		% Change in local currencies	Total First half 2001		% Change in local currencies	
	USD m	CHF m		USD m	CHF m		USD m	CHF m		
<i>Sandimmun/Neoral</i>	143	257	-25	372	670	1	515	927	-10	-8
<i>Diovan/Co-Diovan</i>	212	382	40	236	424	66	448	806	52	53
<i>Cibacen/Lotensin</i>	323	582	27	61	110	-6	384	692	23	20
<i>of which Lotrel</i>	192	346	47	0	0	0	192	346	51	47
<i>Aredia</i>	240	432	28	131	236	27	371	668	28	28
<i>Lamisil</i>	180	324	19	167	300	17	347	624	17	18
<i>Voltaren</i>	6	10	-74	297	535	-5	303	545	-14	-10
<i>Sandostatin(group)</i>	94	170	47	131	236	21	225	406	29	31
<i>Miacalcic</i>	138	249	13	76	136	12	214	385	14	12
<i>Lescol</i>	82	148	-6	109	196	6	191	344	-1	1
<i>Tegretol</i>	66	118	-2	117	210	-3	183	328	-4	-2
<i>Leponex/Clozaril</i>	64	115	-24	84	151	4	148	266	-11	-10
<i>Estraderm (group)</i>	53	96	4	74	134	-8	127	230	-4	-3
<i>Exelon</i>	69	125	311	53	95	95	122	220	175	174
<i>Foradil</i>	3	6	-	107	193	20	110	199	21	24
<i>Famvir (group)</i>	76	136	-	29	53	-	105	189	-	-
<i>Visudyne</i>	64	115	241	35	63	278	99	178	259	254
<i>Nitroderm TTS</i>	0	0	-	91	163	-2	91	163	-9	-4
<i>Zaditen</i>	0	0	0	83	150	-6	83	150	-13	-6
<i>Parlodel</i>	18	32	93	43	78	-12	61	110	-2	3
<i>Desferal</i>	19	35	28	38	68	25	57	103	25	26
<i>Top ten total</i>	1,484	2,672	14	1,697	3,053	10	3,181	5,725	11	12
<i>Top twenty total</i>	1,850	3,332	24	2,334	4,201	12	4,184	7,533	15	17
<i>Rest of portfolio</i>	354	635	10	845	1,521	1	1,199	2,156	1	3
Total	2,204	3,967	21	3,179	5,722	9	5,383	9,689	12	13

All USD figures are convenience translations of CHF into USD at a rate of 1.80. These translations should not be construed as representations that the Swiss franc amounts actually represent such US dollar amounts as could be converted into US dollars at the rate indicated or at any other rate.

PRE -ANNOUNCEMENT - ANNONCE PRÉALABLE - VORANKÜNDIGUNG

Basel, 14.8.2001

To the Editors

Please note that we will publish our 2001 **first-half results** on **Thursday 16 August 2001** at approximately 7.30 a.m. (Swiss time) through the usual channels.

To account for the Agribusiness spin-off, the transfer of the Ophthalmics business from CIBA Vision to Pharmaceuticals and the switch of certain products between sectors, the first-half 2000 income statement has been restated. To assist you in your preparation we are attaching the restated figures.

*

Hinweis an die Redaktionen

Wir bitten Sie um Kenntnisnahme, daß wir unsere **Halbjahresergebnisse 2001** auf dem üblichen Weg am **Donnerstag, 16. August 2001**, um ca. 7.30 Uhr (Schweizer Zeit) publizieren werden.

Um die Ausgliederung von Agribusiness, den Transfer des Augenheilmittelgeschäfts von CIBA Vision zum Sektor Pharma sowie weitere Produktübertragungen zwischen den Sektoren wiederzugeben, wurde die Erfolgsrechnung des ersten Halbjahres 2000 angepasst. In der Anlage finden Sie die angepassten Zahlen.

*

A l'attention de la rédaction

Par la présente, nous vous informons que le chiffre **d'affaires du Groupe Novartis pour le premier semestre 2001** sera publié par la voie habituelle le **jeudi 16 août 2001** (suisse) environ.

Les comptes de résultat du premier semestre 2000 ont été retraités pour que soit tenu compte de la scission d'Agribusiness, du transfert des activités ophtalmiques de CIBA Vision vers le secteur Pharma et du passage de certains produits d'un secteur à l'autre. Vous trouverez, ci-joint, les données retraitées afin que la comparaison soit plus aisée.

*

In CHF millions

	1st Half 2000 Reported	Restated
<u>Sales</u>	18,961	13,970
Cost of goods sold	5,566	3,454
<u>Gross profit</u>	13,395	10,516
Marketing & distribution	5,407	4,539
Research & development	2,259	1,870
General & administration	1,245	841
<u>Operating income</u>	4,484	3,266
Income from assoc. companies	31	24
Financial income, net	851	926
<u>Income before taxes and minority interests</u>	5,366	4,216
Taxes	1,156	806
Minority interests	24	14
<u>Net income</u>	4,186	3,396

Sector Sales in CHF millions

	1st Half 2000 Reported	Restated
Pharmaceuticals	8,477	8,669
Generics	994	1,012
Consumer Health	3,102	3,157
CIBA Vision	883	618
Animal Health	514	514
Total ongoing sales	13,970	13,970

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MEDIA RELEASE - COMMUNIQUE AUX MEDIAS - MEDIENMITTEILUNG**Leukemia drug Glivec® may help improve therapy in advanced CML based on research insights**

Basel, 3 August, 2001 – Research published by UCLA scientists in the 3 August, 2001 issue of *Science* gives important insights into the potential biological mechanism behind the already known phenomenon of reappearance of leukemic cells despite continued therapy with Glivec® (imatinib)¹. This research was previously reported in the 22 June, 2001 on-line version of *Science*, and is based on biochemical and molecular analyses of existing clinical information from eleven patients in the advanced stage (blast crisis phase) of chronic myeloid leukemia (CML). These patients initially had responded to the drug and then relapsed. The clinical response and relapse rates of patients participating in trials of Glivec have been presented and discussed at previous medical meetings and published in the *New England Journal of Medicine*. Relapse can occur in any stage of the disease; however it is much more likely in the most advanced phases. The pronounced activity of Glivec at these advanced stages is unusual given that other therapies are not effective. These findings are in contrast to those observed when patients are treated in the early stage of the disease (chronic phase); relapse rates reported to date have been very low with 98% of chronic phase CML patients alive after one year of Glivec therapy.

In the research published in *Science*, two biological reasons for the relapse in advanced stages were demonstrated: the first was a mutation of the Bcr-Abl gene, resulting in the production of a protein that Glivec could no longer inhibit. The second was that many additional copies of the gene appeared, again preventing the drug from exerting its effect on leukemic cells.

“The research published in *Science* helps clarify a potential biological basis for the reappearance of leukemic cells in patients with advanced stage CML,” said David Parkinson, Vice President, Global Oncology Clinical Research at Novartis Oncology. “This understanding will help us take steps to possibly increase the effectiveness of Glivec in advanced stages of disease.”

Glivec has been approved in several countries, including the US and Switzerland, for the treatment of patients with chronic myeloid leukemia in blast crisis, accelerated phase, or in chronic phase after failure of interferon-alpha therapy. The effectiveness of Glivec is based on overall hematologic and cytogenetic response rates together with a favorable safety profile. Results are not yet available from controlled trials demonstrating the effects of Glivec on survival.

Maturing clinical data demonstrate response rate increases with extended time of treatment in all disease phases

The application for marketing authorization was based on data from more than 1,000 patients participating in a global clinical trials program. The effectiveness of Glivec is based on overall hematologic and cytogenetic response rates. An updated analysis of the phase II clinical data that served as the basis for registration of Glivec in patients with chronic myeloid leukemia (CML) in blast crisis, accelerated phase, or in chronic phase after failure of interferon-alpha therapy, confirm and

¹ In the US: Gleevec™ (imatinib mesylate); outside the US: Glivec (imatinib)

extend the original observations in all three phases of the disease. These include a reduction or return to normal in hematologic blood counts, and a reduction or disappearance in the number of Philadelphia chromosomes in the bone marrow.

In chronic phase CML, patients previously failing interferon-alpha therapy, the updated data confirm near complete, durable hematologic responses in greater than 90% of patients, with more than half of the patients achieving a complete or near complete disappearance of the Philadelphia chromosome in the bone marrow. Patients in the accelerated phase of the disease have continued high levels of hematologic responses, with good cytogenetic response rates for this population of patients. Blast crisis patients continue to demonstrate rapid hematologic blood count responses which are sustained in nearly a third of the responding patients. This confirms the activity of Glivec in this stage of the disease and forms the basis for use of Glivec in combination with other chemotherapeutic agents in patients with blast crisis.

CML is a hematologic stem cell disorder caused by an acquired or induced abnormality in the DNA of the stem cells in bone marrow. This results in a gene that produces an abnormal protein. The protein disrupts the bone marrow's normally well-controlled production of white blood cells and results in a massive increase in the concentration of white blood cells in the blood. CML progresses through three phases – chronic, accelerated and blast crisis. After about five years of the chronic, or most common phase, the disease develops eventually into the advanced stages – accelerated then end-stage or "blast crisis"—which usually results in the death of patients in two to six months.

Contraindications and adverse events

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 1% of patients in chronic phase, 2% in accelerated phase and 5% in blast crisis. Glivec is contraindicated in patients with known hypersensitivity. Women of childbearing potential should be advised to avoid becoming pregnant. If Glivec is used during pregnancy or if the patient becomes pregnant while taking Glivec, the patient should be apprised of the potential hazard to the fetus. The most common side effects included nausea, fluid retention, muscle cramps, diarrhea, vomiting, hemorrhage, musculoskeletal pain, skin rash, headache, fatigue, arthralgia, dyspepsia and dyspnea, as well as neutropenia and thrombocytopenia. There are no long-term safety data on Glivec treatment.

New clinical trials underway

In conjunction with clinical investigators, Novartis has planned or is initiating additional trials evaluating Glivec in combination with other drugs and in increased doses for patients in advanced phases of CML, Glivec in combination with bone marrow transplant, and Glivec in other leukemias and solid tumors.

Solid tumor program

Unlike in CML where one defect (Bcr-Abl) has been identified as responsible for cancer cell growth in chronic phase, in solid tumors there are usually multiple defects, and Glivec is expected to be used in combination with other anti-cancer agents. As Glivec inhibits select proteins, Glivec is unlikely to work effectively as a single agent. However, the results from these first single agent trials will provide crucial data to help design combination trials in the most promising areas. In one kind of solid tumor – gastrointestinal stromal tumors (GIST) – Glivec has had some preliminary promising results as a single agent. These tumors are unusual in that nearly all of them appear to be driven by the activity of a single protein (C-Kit or CD 117). The preliminary data evaluating Glivec in the treatment of GIST were presented at the plenary session of the May 2001 meeting of the American Society of Clinical Oncology (ASCO) meeting and Novartis is preparing to file registration dossiers for this indication globally by end of year.

The foregoing release contains forward-looking statements that can be identified by terminology such as "may help improve," "planned," "initiating," and "continued increases," 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 FDA's further requirements is not guaranteed and management's expectations regarding commercialization of Glivec could be affected by, among other things, additional analysis of data; new data; unexpected clinical trial results; unexpected regulatory actions or delays or government regulation generally; the company's ability to obtain or maintain patent or other proprietary intellectual property protection; competition in general; and other risks and factors referred to in the Company's current Form 20-F on file with the Securities and Exchange Commission of the United States. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those anticipated, believed, estimated or expected.

About Novartis

Novartis (NYSE: NVS) is a world leader in healthcare with core businesses in pharmaceuticals, consumer health, generics, eye-care, and animal health. In 2000, the Group's ongoing businesses achieved sales of CHF 29.1 billion (USD 17.2 billion) and a net income of CHF 6.5 billion (USD 3.9 billion). The Group invested approximately CHF 4.0 billion (USD 2.4 billion) in R&D. Headquartered in Basel, Switzerland, Novartis employs about 69,000 people and operates in over 140 countries around the world. For further information please consult <http://www.novartis.com>.

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Novartis agreement with Compugen to speed completion of Novartis human protein database

Agreement will accelerate identification of new drug targets

Basel, Switzerland and Tel Aviv, Israel, 2 August 2001 – Novartis AG and Compugen Ltd. today announced a joint agreement for Novartis to utilize Compugen's technology services to accelerate identification of drug targets based on the analysis of fundamental protein data.

“At a time when biotechs and pharmas are adapting to leverage the therapeutic potential of the human genome, Novartis aims to set the standard for how the pharmaceutical industry can swiftly translate the promise of this new science into meaningful therapies,” said Paul Herrling, Ph.D., Head of Global Research for Novartis Pharma AG. “Through such efforts as this agreement with Compugen, Novartis aims rapidly to identify and develop innovative rational therapies that will offer significant benefits to more patients.”

Under the agreement, Novartis will use Compugen's LEADS computational biology platform to create a complete database that will detail gene expression at the minuscule level of RNA - the chemical that transmits the code for DNA. This expansive database of transcriptomes will represent the thousands of genes known from the public domain, as well as those identified within Novartis and its global network of industry and academic collaborators.

In addition, Compugen will provide Novartis with a proprietary “DNA chip design” that will represent Novartis' transcriptome database. Novartis researchers will then use the gene chips produced from this design to detect rapidly which of the thousands of genes are expressed in various diseases. Then, Novartis will work to identify new drug therapies that address these specific targets.

Mor Amitai, Ph.D., President and Chief Executive Officer, Compugen Ltd. commented, “We are very pleased that after a thorough evaluation, Novartis has determined that Compugen's technology is the best suited to analyze the vast amount of data represented in its proprietary sequence databases and in the public domain. Compugen will analyze both EST and genomic databases to create for Novartis a reliable representation of transcriptomes of various organisms.”

Using its proprietary LEADS computational biology platform, Compugen has identified thousands of novel genes and alternatively spliced variants believed to be unique. In addition, Compugen's chip design system incorporates new knowledge of gene expression and a semi-automatic design process to improve the accuracy of DNA chips.

Herrling said that in order to harness external innovation, Novartis now channels 27% of its research budget into external collaborations. In the increasingly important domain of functional genomics, Novartis has forged a number of strategic partnerships, complementing its own in-house expertise.

This press release contains "forward-looking statements" which include words such as "accelerate identification", "aims", "translate", "will", "to create a complete database", or similar expressions or discussions of strategy, plans or intentions. These forward-looking statements are subject to risks and uncertainties that may cause the actual results, performance or achievements of the companies to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. Some of these risks are: changes in relationships with collaborators; the impact of competitive products and technological changes; risks relating to the development of new products; the ability to implement technological improvements; the ability of the companies to obtain and retain customers. Some of those factors are discussed in the Novartis Group's Form 20-F filed with the Securities and Exchange Commission and/or under the heading "Risk Factors" in Compugen's Registration Statement on Form F-1 filed with the Securities and Exchange Commission.

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About Compugen

Compugen (NASDAQ: CGEN) develops and markets platforms, tools and products that accelerate post-genomic research, the advanced study of proteins and protein pathways and drug target discovery. Products and services commercialized to date include: LEADS, Gencarta™, DNA Chip design, Z3, LabOnWeb.com and Bioccelerators. Compugen's in-house molecular biology laboratories provide validation of its methodologies and also conduct original genomic and proteomic research. For additional information, please visit Compugen's Corporate Web Site at www.cgen.com and the Company's Internet research engine for molecular biologists, www.LabOnWeb.com.

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MEDIA RELEASE • COMMUNIQUE AUX MEDIAS • MEDIENMITTEILUNG**Novartis files application with EMEA for Zometa® in cancer-related bone complications*****Filing data from largest trials ever in these indications***

Basel, 2 August 2001 – Novartis announced today that it has submitted a marketing authorisation application for Zometa® (zoledronic acid) to the European Agency for the Evaluation of Medicinal Products (EMA) for the treatment of bone metastases associated with a broad range of tumour types. These include prostate, breast and lung cancer, and multiple myeloma. Bone metastases, or the spread of cancerous cells from the original tumour to the bone, can lead to complications often called skeletal related events (SREs) [e.g., fractures, compression of the spine, severe bone pain and hypercalcaemia]. Zometa is the most potent bisphosphonate available on the market.

To date, Novartis has received marketing clearances for Zometa in the treatment of tumour-induced hypercalcaemia (TIH), also known as hypercalcaemia of malignancy (HCM) in the EU, and more than 30 other countries, including Switzerland, Brazil, Canada and Australia. HCM is the most common life-threatening metabolic complication of cancer.

Upon approval of Zometa in HCM by the US Food and Drug Administration, for which the application is pending, Novartis will file a supplemental application in the US for the treatment of bone metastases.

The filing is based on data from more than 3,000 patients, who were enrolled in the largest set of clinical trials ever conducted to evaluate the efficacy and tolerability of bisphosphonates in the treatment of bone metastases. The trials evaluated 4 mg of Zometa given in 15-minute infusions every three or four weeks. In prostate cancer, Zometa demonstrated statistically significant efficacy compared to placebo in the treatment of bone metastases, and significantly delayed the onset of the first skeletal related event (SRE). In lung cancer, Zometa had a significantly positive impact on median time to the first SRE when compared to placebo. These studies mark the first time any bisphosphonate has demonstrated efficacy in treating these conditions in prostate and lung cancer in well-controlled clinical trials. In breast cancer and multiple myeloma, Zometa was as effective and well tolerated as pamidronate disodium (Aredia®) – the current standard of treatment – with the added convenience of a 15 minute infusion time versus the two to four hours for pamidronate disodium.

“Bone complications can be extremely debilitating to cancer patients, and seriously impact their day to day activities. Zometa offers these patients a highly effective treatment with a convenient 15 minute infusion time,” said David Epstein, President, Novartis Oncology. “Novartis is pleased to bring forward another drug that will help make a marked difference in the lives of cancer patients and their families.”

Bone Complications of Metastatic Cancer

Bone metastases/lesions are common complications in prostate, breast and lung cancer, and multiple myeloma, and can have severe clinical consequences.

Current therapeutic options for complications of bone metastases include: chemotherapy, hormonal therapy, radiotherapy, analgesics for pain management, and surgery. Pamidronate disodium (Aredia) is approved for use in breast cancer and multiple myeloma; however, it is not approved for use in bone metastases associated with prostate and lung cancer.

Contraindications and adverse events

Zometa is contraindicated in patients with clinically significant hypersensitivity to zoledronic acid, other bisphosphonates or any of the excipients in the formulation of Zometa. It should not be used during pregnancy or breast-feeding unless the benefits to the mother outweigh the risks to the fetus. Bisphosphonates, including Zometa, have been associated with reports of renal function changes. Therefore, as with pamidronate disodium 90 mg, standard hypercalcaemia-related metabolic parameters and clinical parameters of renal function should be carefully monitored after initiating Zometa therapy.

The most commonly reported adverse reactions to Zometa are similar to those reported for other bisphosphonates like pamidronate disodium 90 mg, and can be expected to occur in approximately one-third of patients either for Zometa or for pamidronate disodium 90 mg. Intravenous administration has been most commonly associated with a flu-like syndrome, including bone pain, fever, fatigue and nausea. Hypocalcaemia, hypophosphatemia, local reactions at the infusion sites, rare cases of rash and conjunctivitis have also been reported following treatment with Zometa. Occasionally anorexia was reported. Overall, Zometa has an acceptable safety profile similar to other bisphosphonates.

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 “significant,” “first time,” “will file,” “application,” and “demonstrated” or similar expressions, or by discussions of strategy, plans or intentions. Such statements include descriptions of Zometa, a new product expected to be introduced by the Company and anticipated customer demand for such products. Such statements reflect the current views of the Company with respect to future events and are subject to certain risks, uncertainties and assumptions. Many factors could cause the actual results, performance or achievements of the Company to be materially different from any future results, performances or achievements that may be expressed or implied by such forward-looking statements. Some of these are uncertainties relating to unexpected regulatory delays, 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 materialise, or should underlying assumptions prove incorrect, actual results may vary materially from those described herein as anticipated, believed, estimated or expected.

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MEDIA RELEASE • COMMUNIQUE AUX MEDIAS • MEDIENMITTEILUNG**Novartis files Estradot[®], smallest hormone replacement patch, in the European Union**

Basel, 2 August 2001 – Novartis Pharma AG announced today that it has applied for marketing authorisation for Estradot[®] (transdermal 17-beta estradiol) in the European Union under the Mutual Recognition Procedure, which would give the drug marketing authorisation in all European Union Member States. Estradot was recently approved in the Netherlands (which will act as the Reference Member State) for the treatment of menopausal symptoms and the prevention of post menopausal osteoporosis.

Estradot offers a convenient, comfortable and cosmetically attractive means of administering hormone replacement therapy. An advance over previous technology, Estradot provides improved adhesion, reduced skin irritation and is almost invisible on the skin.

“Estradot further consolidates our strong global portfolio in Women’s Health product Thomas Ebeling, CEO, Novartis Pharma. “Given its success in the US we have high aspirations for Estradot in Europe, where hormone replacement patches are extremely popular.”

Developed and manufactured by Noven, Estradot is licensed by Novartis in all countries outside the US and Japan. In the US Novartis and Noven market the product as Vivelle-Dot[™] through their jointly-owned Women’s Health company, Vivelle Ventures LLC (also known as Novogyne Pharmaceuticals).

Robert C. Strauss, Noven’s President, CEO and Chairman, added, “We are pleased that Novartis continues to advance the European approval process for Estradot, which underscores Novartis’ continuing commitment to our advanced transdermal products and technologies.”

About Hormone Replacement Therapy

Novartis pioneered transdermal hormone replacement therapy in the 1980s, meeting the needs of peri- and post-menopausal women requiring relief from menopausal symptoms and protection against osteoporosis. Menopausal symptoms include hot flushes and night sweats, disturbed sleep, memory loss, and skin atrophy, as well as the potential long-term consequence of osteoporosis. It is estimated that by 2005, 36% of women will be aged over 50 and have a potential need for alleviation of distressing menopausal symptoms that compromise their quality of life.

The forgoing press release contains forward-looking statements which can be identified by terminology such as “applied”, “would”, “aspirations”, “estimated” 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. The successful commercialisation of Estradot 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, competition in general as well as factors discussed in the Form 20-F filed by Novartis AG, and the Form 10-K and Form 10-Qs filed by Noven, with the Securities and Exchange Commission.

About Novartis

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About Noven

Noven Pharmaceuticals, Inc. (Nasdaq: NOVN), headquartered in Miami, Florida, is a leader in the development of transdermal and transmucosal drug delivery technologies and products. Noven's existing products include advanced estrogen transdermal delivery systems (including Vivelle[®] and Vivelle-Dot[™], licensed to Novogyne, and Estradot[™], licensed to Novartis) and combination estrogen/progestin transdermal delivery systems (including CombiPatch[™], licensed to Novogyne, and Estalis[®], licensed to Novartis). With a range of additional products in development, including once-daily MethyPatch[®] for Attention Deficit Hyperactivity Disorder, Noven is committed to becoming the world's premier developer, manufacturer and marketer of transdermal and transmucosal drug delivery systems.

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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: August 21, 2001

By: /s/ Raymund Breu

Name: Raymund Breu

Title: Chief Financial Officer