

# SHEARMAN & STERLING

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November 7, 2001

## VIA EDGAR

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 October 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, Louis Lehot 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)  
Louis Lehot (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 October 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' irritable bowel syndrome (IBS) treatment Zelmac® approved in Switzerland (30 October 2001)
2. Novartis' R&D day spotlights pipeline and commercial assets to drive sustained growth (30 October 2001)
3. European marketing authorisation application submitted for Myfortic™ – an enteric-coated adjunctive immunosuppressant in transplantation (26 October 2001)
4. Study results suggest Dexmethylphenidate HCL is an effective treatment for ADHD (26 October 2001)

5. Novartis receives FDA approvable letter for Diovan® (valsartan) for the treatment of heart failure in patients not on an ACE inhibitor (25 October 2001)
6. Novartis: R&D Day 2001 (25 October 2001)
7. New data further underlines the safety and efficacy of Zelmac® (tegaserod) in treating multiple symptoms of Irritable Bowel Syndrome (IBS) (24 October 2001)
8. Atopic triad increasingly affects children (23 October 2001)
9. FDA grants priority review for Zometa® in the treatment of a serious cancer complication (23 October 2001)
10. Novartis and Cytos sign research and license option agreements to develop a new class of therapies for chronic diseases (23 October 2001)
11. New data on Novartis drug Zometa® for treatment of breast cancer and multiple myeloma-related bone complications published in major medical journal (22 October 2001)
12. Novartis submits supplemental NDA with US FDA for Glivec® for treatment of certain GI tumors (19 October 2001)
13. Visudyne™ therapy reimbursement in US expanded to include patients with occult form of wet age-related macular degeneration (19 October 2001)
14. Laboratory results confirm Novartis employee did not contact anthrax (17 October 2001)
15. Novartis says it will not increase prices of reimbursable medicines in Switzerland for the next two years (17 October 2001)
16. Suspicious letter received at Novartis (17 October 2001)
17. FDA Advisory Committee issues split decision on recommendation to approve Diovan® (valsartan) for heart failure indication (12 October 2001)
18. FDA approves Focus® Night & Day™ contact lenses in the US for extended wear for up to thirty nights of continuous wear (12 October 2001)
19. New non-steroid cream Elidel® offers relief to babies suffering from eczema (12 October 2001)
20. Novartis: Invitation to the R&D Day 2001 (11 October 2001)
21. New data shows underdiagnosis of Irritable Bowel Syndrome (IBS) burdens patients and healthcare systems worldwide (10 October 2001)
22. Pre-Announcement: 2001 nine-month and third-quarter sales (5 October 2001)
23. Invitation for Telephone Conference (5 October 2001)



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- Investor Relations Release -

## Novartis' irritable bowel syndrome (IBS) treatment Zelmac® approved in Switzerland

Basel, Switzerland, 30 October 2001 - Novartis announced today that the Swiss Health Authority, the Intercantonal Office for the Control of Medicines (IKS), has granted marketing approval for Zelmac® (tegaserod). Zelmac is the first medication clinically proven to provide a symptomatic treatment for women with abdominal pain and constipation associated with irritable bowel syndrome (IBS). Zelmac will be available in Switzerland within the next few days.

A number of other countries follow the approval of the IKS including several Asia Pacific and Latin American countries, where the drug will soon be launched. Zelmac was recently launched in the Czech Republic, Mexico, Venezuela and Columbia and has gained approvals elsewhere. Novartis is working with the USA Food and Drug Administration (FDA), the European Agency for the Evaluation of Medicinal Products (EMEA) and other regulatory authorities in order to help bring the benefits of this important new therapy to patients in need.

“The approval of Zelmac in Switzerland is a crucial step in our ongoing efforts to launch Zelmac globally. As we continue to negotiate with other regulatory bodies, we will leverage this approval as evidence of the safety and efficacy of Zelmac for IBS patients.” said Thomas Ebeling, CEO, Novartis Pharma AG.

Until now, there was no single effective therapy available in Switzerland to treat multiple symptoms of IBS, a chronic, life-altering disorder that can have a significant impact on daily functioning and overall well-being.

In clinical trials involving more than 4,500 patients, two-thirds of patients treated with Zelmac experienced overall symptom relief, including improvements in abdominal pain/discomfort, bloating and constipation<sup>1</sup>. The majority had relief within one week.<sup>2</sup> The drug was well tolerated with an adverse event profile similar to that of placebo, with the exception of headache and diarrhea, which in most cases was mild and transient.<sup>3,4</sup> Discontinuations based on adverse events were 6.4 % for the Zelmac treated group compared with 4.6 % for the placebo group in the final trial.<sup>1</sup>

The foregoing press release contains certain forward-looking statements related to the business of Novartis, which can be identified by the use of forward-looking terminology such as “to relieve”, “will soon be”, “is working”, “help bring the benefits”, “ongoing”, “continue” 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. Management's expectation regarding the commercial potential of tegaserod in any market could be affected by, amongst other things, uncertainties relating to product development, regulatory actions or delays or government regulation generally, the ability to obtain or maintain patent or other proprietary intellectual property protection and competition in general, as well as factors discussed in the Company's Form 20F filed with the Securities and Exchange Commission. Should one or more of these risks or uncertainties materialise, or should underlying assumptions prove incorrect, actual results may vary materially from those described herein as anticipated, believed, estimated or expected.

Novartis AG (NYSE: NVS) is a world leader in healthcare with core businesses in pharmaceuticals, consumer health, generics, eye-care, and animal health. In 2000, the Novartis Group's ongoing businesses achieved collective 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. Novartis AG is headquartered in Basel, Switzerland. Novartis Group companies employ about 70 000 people and operate in over 140 countries around the world. For further information please consult <http://www.novartis.com>

**References:**Mueller-Lissner S, et al. Tegaserod, a 5-HT<sub>4</sub> partial agonist, relieves symptoms in irritable bowel syndrome patients with abdominal pain, bloating and constipation. *Aliment Pharmacol Ther* 2001;16:1655–66.

2. Integrated summary of efficacy. January 2000. Novartis, data on file.
3. Lefkowitz M, et al. Tegaserod provides relief of symptoms in female patients with irritable bowel syndrome (IBS) suffering from abdominal pain and discomfort, bloating and constipation. (Abstr). *Gastroenterology* 2001;120:A104.
4. Integrated summary of safety. December 2000. Novartis data on file.



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- Investor Relations Release -

## Novartis' R&D day spotlights pipeline and commercial assets to drive sustained growth

- *R&D and commercial portfolio focused on eight attractive markets in Primary Care, Transplantation, Oncology, and Ophthalmics*
- *Broad innovative platform of 69 projects in clinical development*
- *Strong launch pipeline for 2002-4*

Basel / New York, 30 October 2001 – Novartis is to unveil further details of its continuing growth strategy with a review of its Pharmaceutical Research and Development portfolio for representatives of the investor and financial communities and the media in New York today. The event and press briefing will be webcast starting at 1.30 p.m. CET (7.30 a.m., New York time) (<http://www.novartis.com>).

The solid double-digit increase in Pharmaceutical sales in the first nine months of this year was driven by strong performances in the cardiovascular and oncology businesses and in the key US market. With 15 approvals and 11 submissions in the US, EU and Japan, successfully launched new products like *Gleevec/Glivec* and *Zometa*, and a substantial launch pipeline for 2002-2004, Novartis has a solid platform for sustained growth.

The pipeline has been augmented with a number of new projects, several of which have been licensed in, replacing six projects that have now been launched and seven that Novartis is no longer pursuing. With a total of 69 pipeline projects the company plans a substantial number of launches or roll-outs by the end of 2005.

Daniel Vasella, Chairman and CEO, pointed out that: “Our strategy of concentrating on healthcare with the core business of Pharmaceuticals has delivered concrete results. The dynamic performance in Pharmaceuticals has been driven by the competitive growth of our priority products and the expansion of the key US market. We will consistently pursue our growth strategy by investing further in our pipeline and commercial assets.”

## Highlights of top projects in attractive areas

### Primary Care

#### Cardiovascular

All product names in italics are registered trademarks of Novartis AG

***Diovan***: Novartis' strategy to exploit the full potential of its blockbuster antihypertensive is expressed in the mega-trial program to further support existing and new indications. The program includes some 43 000 patients and five major trials investigating areas of high medical need: long-term use (VALUE), heart failure (Val-HeFT), acute myocardial infarction (VALIANT), blood pressure control in diabetes (ABCD2V), and impaired glucose tolerance outcomes (NAVIGATOR).

In addition, new formulations to increase treatment flexibility include a 320-mg dose and new *Co-Diovan* ranges.

On the basis of the ValHeft study, *Diovan* has been filed for the indication of heart failure in major markets and recently received an approvable letter from the FDA for use in patients not on ACE inhibitors. US approval is contingent upon further analysis of existing data or possibly the provision of additional data.

**SPP100**: Novartis holds a call-back option for this renin inhibitor, which was outlicensed to Speedel, a company that was supported by the Novartis Venture Fund. Currently in Phase II, SPP100 could show potential for treating several conditions in cardiovascular disease. With Phase III due to start towards the end of 2002, initial filings in hypertension and renal protection are anticipated for 2004 and 2005 respectively.

#### Diabetes

**LAF237**, a dipeptidyl-peptidase IV (DPP IV) inhibitor, represents a new generation of oral treatments for diabetes. In studies conducted to date, DPP IV inhibitors have shown a promising effect on fasting glucose and HBA<sub>1C</sub>, in addition to lowering prandial glucose. LAF237 is in Phase II and further studies will clarify the potential protective effect on pancreatic beta-cells, which deteriorate in diabetes.

#### Schizophrenia

**Iloperidone**, currently in Phase III of clinical development, is poised to enter a market where current therapies are associated with significant side effects that often lead to medication switches. Data so far suggest a favorable adverse event profile during long-term treatment. Additional studies are being initiated to strengthen the product's competitive profile and to satisfy a regulatory requirement for two positive pivotal studies. Initial filings are planned for 2003. A depot formulation for improved compliance and convenience is also in development.

#### Osteoporosis

**Zometa**, in addition to its use in oncology, is about to enter Phase III of development for Paget's disease and osteoporosis, where it has shown an increase in bone mineral density over one year after a single injection.

## Transplantation

Two new transplant drugs are slated for launch by 2003, *Myfortic* and *Certican*.

*Myfortic* could potentially be a therapeutic improvement over the pro-drug mycophenolate mofetil because it appears to offer faster and more sustained active drug exposure to a greater number of patients. It has just been filed in Europe and submission for approval in the US is anticipated early in 2002.

*Certican* has recently delivered positive results in heart transplant trials. These are to be added to kidney transplant data as a combined application for approval expected to be filed in the second half of 2002.

**FTY720**, a novel concept in selective immunosuppression, is being evaluated for prevention of acute rejection and graft loss in kidney transplant patients. The drug has been shown to protect the transplant against T-cells without changing the host's ability to respond to antigens. Currently in Phase II, FTY720 has shown very low acute rejection rates.

## Pain relief / inflammation

**COX189** is a new anti-inflammatory and pain-relief drug in Phase III of an extensive clinical development program. Trials have investigated its potential benefits in osteo- and rheumatoid arthritis and pain. Initial data suggesting potential safety benefits, such as a low incidence of gastrointestinal and cardiovascular side effects, are to be further investigated in a large clinical trial program involving more than 18 000 patients anticipated to begin in December. Initial filing is planned for the end of 2002.

## Dementia

*Exelon*: New trials are underway to evaluate *Exelon* in vascular dementia (VantagE) and in dementia in Parkinson's Disease. In addition, *Exelon* is being compared in a head-to-head trial (Exceed) against donepezil.

## Oncology

Pilot studies are underway to explore the potential efficacy of *Gleevec/Glivec* beyond chronic myeloid leukemia and gastrointestinal stromal tumors (GISTs), both in mono- and combination therapy. In the different tumor types being investigated, the biological relevance of the target is key. Results in small-cell lung cancer, prostate cancer, and glioma are expected in 2002.

**PTK787**, an angiogenesis inhibitor, blocks blood vessels that supply tumors. The compound is a co-development, co-marketing project with Schering AG. With Phase II in progress, the drug is expected to become available around 2005. PTK787 could be the first oral drug of its kind to reach the market.

**EPO906** exerts its anti-tumor activity by inhibiting microtubule depolymerization in cancer cells. Early results in several solid tumors have been promising and, with Phase II trials underway, the compound is estimated to become available around 2005.

## Discovery in the post genomic era

The mapping of the human genome has vastly increased the number of potential targets for drug interaction from 500 to more than 10 000. Novartis has reorganized its research efforts to further enhance productivity and increase the flow of new compounds entering development; in 2000, the number of new substances funneled into development was 20% greater than the median of the top ten pharmaceutical companies.

Advances in genomics may also provide an opportunity to segment patient populations more carefully, leading to preventative medicines and associated prolonged treatment timeframes. On the other hand, a single target can also act across a variety of diseases and new technologies could help recognize common pathways between different illnesses.

In the context of these changes, the discovery process has moved from being a sequential to a parallel one. Key activities have become 'industrialized', enhancing both speed and efficiency. At the same time, a multiparallel approach has allowed target validation at every stage.

Novartis is establishing new units, including the Drug Discovery Centre, focused on specific gene and protein families and searching for 'drugable' targets that provide the potential for therapeutic intervention. The integration of the Novartis Functional Genomics and Disease network is intended to lead to more causal preventative, safer therapies and new kinds of treatments based on common biological mechanisms that cause diverse disease symptoms.

## Licensing agreement update

Novartis has decided not to execute its option for collaboration with Novo Nordisk on their insulin sensitizer NN622. Worldwide exclusive rights to develop and commercialize another insulin sensitizer, DRF4158, were obtained in May from Dr. Reddy's Laboratories Ltd.

Novartis Ophthalmics has expanded its alliance with QLT Inc. to co-develop photodynamic therapy with verteporfin (*Visudyne*) in the treatment of skin cancer and other dermatological conditions. The Phase III program is expected to begin in early 2002.

European rights to pitavastatin, currently in clinical Phase II development for the regulation of dyslipidemia, were acquired in April. New results of trials conducted by Sankyo have indicated muscle side-effects at very high doses, prompting the initiation of additional dose-finding studies.

## Regulatory update

Novartis reported a number of achievements in this area including the reduction of the average development time from 12 years in 1995-7 to the current eight and a half years. Despite an increasingly conservative regulatory climate, Novartis has achieved eight approvals in the US since January 2000 (*Trileptal*, *Visudyne*, *Exelon*, *Rescula*, *Starlix*, *Foradil*, *Glivec/Gleevec* and *Zometa*).

***Zelmac/Zelnorm***: Following the FDA's non-approvable decision for *Zelmac/Zelnorm*, a new treatment for irritable bowel syndrome, Novartis appealed the FDA decision and has submitted an expert assessment produced by three separate working parties of 22 independent experts, who addressed the drug's safety and efficacy in Phase III studies. The numerical imbalance in cholecystectomies between the *Zelmac/Zelnorm* and placebo groups was no longer present in their re-analysis and there was no evidence to link the drug with an increased risk of cholecystectomy. Discussions with the FDA are ongoing.

With regard to the regulatory status in the EU, scientific advice is expected from the EMEA by mid-November and new clinical trials are to be started in early 2002. The Swiss regulatory authorities have just given marketing approval for *Zelmac*. More than 70 other countries usually follow this approval. *Zelmac* has met with a high level of satisfaction in its first market Mexico, where more than 80% of patients surveyed were satisfied or extremely satisfied. An advanced development program is planned for exploring the efficacy in new indications, including chronic constipation, functional dyspepsia and gastro-esophageal reflux disease.

***Xolair***: Discussions are also being held with the FDA regarding the resubmission of *Xolair*, a novel treatment in development for asthma and allergic, either at the end of 2002 or in 2003 depending on the FDA's request for new data. In Europe, next steps include a focus on treating 'at-risk patients' with the initiation of studies in this population. New trials are to be started by early 2002. *Xolair* is a monoclonal antibody to IgE in development by Novartis Pharma AG, Genentech Inc and Tanox Inc.

***Elidel***, the novel non-steroidal treatment for atopic dermatitis (eczema), is undergoing regulatory review. Studies have reported safe and effective long-term control and, importantly, prevention of flares. These and other distinct advantages over conventional treatments should position *Elidel* favorably in a market with major unmet needs (42 million patients). Initial launch is expected by mid 2002. Further projects include ointment and oral formulations of *Elidel*.

***Zometa*** has been filed in the US and EU for bone-related cancer complications across a broad range of tumor types.

***Gleevec/Glivec*** received a positive opinion from the Committee for Proprietary Medicinal Products in Europe for chronic myeloid leukaemia. Approvals both in the EU and Japan are anticipated this quarter, which would make this one of the first drugs to gain registration in all three major markets in the same year. A supplementary new drug application has been filed in the US for the treatment of patients with unresectable (inoperable) and/or metastatic malignant GISTs.

## Planned Launches 2001 – 2005

2001	2002	2003	2004	2005	
Starlix®	Elidel™	COX189A	Zelmac®/Zelnorm™ IBS	LAF237A	ICL670A
Zometa®	Glivec®/Gleevec™ CML Japan	Certican®	OctreoTher™	PKC412A	SPP100 <sup>1</sup>
Glivec®/Gleevec™	Glivec®/Gleevec™ GIST	myfortic™	Iloperidone	EPO906A	PTK787A
Foradil® US	Diovan® CHF	Apligraf® EU Wound healing	Xolair®	PKI166A	Foradil® HFA Aerosol
Femara® first-line	Zometa® Bone met. treat.	Visudyne™ Japan	Zelmac®/Zelnorm™ Funct. dyspepsia	Sandostatin® LAR® Diab. retinopathy	Femara® adj.
Foradil® COPD	Lamisil® Syst. myc.	Foradil® MDDPI	Zelmac®/Zelnorm™ Chr. constipation	Exelon® TDS Alzheimer's	Iloperidone depot
Estalis® Osteoporosis	Ritalin® LA ADHD	Lamisil® Tinea capitis	Elidel™ ointment	Diovan® VALUE/VALIANT	Starlix®/ Metformin
	Lotrel® 10/20 mg Hypertension	Lotrel® 10/40 mg Hypertension		Trileptal® NP Neuropathic pain	Elidel™ oral
	Co-Diovan® High dose				
			NME rollout		
			NME		
			LCM		

1 / R&D Day / 10.2001 / DV

<sup>1</sup> Out-licensed to Speedel, call back option for Novartis

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### Major new pipeline projects

#### Cardiovascular, metabolism, endocrine

LAG078	dyslipidemia
NKS104	dyslipidemia
Starlix	combination with metformin, and 'Navigator' trial
Lotrel	10–40 mg, and 10–20 mg

#### Arthritis/bone

AAE581	osteoporosis
Miacalcic	oral formulation
Zoledronic acid	rheumatoid arthritis

#### Nervous system

TKA731	chronic pain
SRA997	cognitive disorders
Exelon	vascular dementia and Parkinson's dementia

#### Oncology

LAQ824	cancer
Zometa	bone metastasis prevention
RAD001	cancer

## **Ophthalmics**

PKC412

diabetic macular edema

*Visudyne*

minimal classic AMD, occult AMD, and AMD in Japan

This press 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 “intended”, “contingent”, “potential”, “promising”, “indicate”, “poised”, “is/are expected to”, “will”, “planned”, “should”, “shown”, “could be”, or “anticipated” or similar expressions, or by discussions of strategy, plans or intentions. Such statements include descriptions of the Company’s investment in research and development programs and anticipated expenditures in connection therewith, descriptions of new products expected to be introduced by the Company and anticipated customer demand for such products and products in the Company’s existing portfolio. 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. These factors can be found in the Company’s Form 20F filed with the Securities and Exchange Commission and include, among other things, unexpected regulatory delays, uncertainties relating to clinical trials and product development, the introduction of competing products, increased government pricing pressures, and the Company’s ability to obtain or maintain patent and other proprietary intellectual property protection. 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 AG (NYSE: NVS) is a world leader in healthcare with core businesses in pharmaceuticals, consumer health, generics, eye-care, and animal health. In 2000, the Novartis Group’s ongoing businesses achieved collective 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. Novartis AG is headquartered in Basel, Switzerland. Novartis Group companies employ about 70 000 people and operate in over 140 countries around the world. For further information please consult <http://www.novartis.com>

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### **VIRTUAL PRESS BRIEFING: 30 October 2001, 07.30 EST (13.30 CET)**

Short highlight presentations will be given for journalists via the internet at <http://www.novartis.com> or by direct telephone call in:

Europe/RoW: +41 91 610 41 35

US: (412) 380 74 00

At the end of the presentations there will be a short Q&A session.

Presentation slides can be downloaded in advance from the virtual press kit on the media pages at <http://www.novartis.com>

Further information from the Novartis Corporate Press Office: +41 61 324 22 00

## **European marketing authorisation application submitted for Myfortic™ – an enteric-coated adjunctive immunosuppressant in transplantation**

Basel, 26 October 2001 – Novartis Pharma AG yesterday submitted a marketing authorisation application in Europe for registration of Myfortic™ – the enteric-coated formulation of mycophenolate acid – through the mutual recognition procedure (MRP). The application seeks an indication for Myfortic for the prevention of acute rejection in renal transplant patients in combination with Neoral® (cyclosporin microemulsion) and corticosteroids.

The data package submitted includes results from a total of 11 clinical trials involving 877 renal transplant patients receiving Neoral-based immunosuppressive therapy.

Tony Rosenberg, Global Head of the Transplantation Business Unit at Novartis Pharma AG commented: “Balancing the effectiveness of immunosuppression with patients’ safety to optimise transplantation outcomes is our key goal. In this regard Myfortic is an important new development, allowing more patients to benefit from the full potency of mycophenolate with excellent tolerability. Myfortic will further strengthen the already impressive transplantation portfolio of Novartis, the foundation of which is of course Neoral, in addition to giving customers a new and effective choice for adjunctive immunosuppression.”

Myfortic is an antimetabolite designed as a chronic adjunctive immunosuppressive treatment for renal transplant patients. The enteric coating of Myfortic allows direct delivery and absorption of mycophenolate in the small intestine but not in the stomach. A well-controlled clinical trial has shown that significantly more patients on Myfortic reached therapeutic mycophenolate exposure above 30 mg·h/l\* compared to the existing formulation of mycophenolate, both in the early phase after transplantation and at six months.<sup>2</sup>

This pharmacokinetic benefit was achieved with no compromise on patient safety compared to existing mycophenolate therapy, suggesting that enteric-coated Myfortic has the potential to offer improved gastro-intestinal tolerability relative to drug exposure.

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\* Patients below an exposure of 30 mg·h/l are at increased risk for acute rejection episodes<sup>1</sup>

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# # #

**References**

1. Shaw L. *et al.* (2001): Current Issues in Therapeutic Drug Monitoring of Mycophenolic Acid: Report of a Roundtable Discussion; *Therapeutic Drug Monitoring* **23**: 305-315
2. Schmouder R *et al.* Presented at the ‘2001 A Transplant Odyssey: The Future Is Here’ Transplantation Congress; Aug 20-23, 2001: Istanbul, Turkey. Abstract #1210

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**STUDY RESULTS SUGGEST DEXMETHYLPHENIDATE HCL IS AN EFFECTIVE TREATMENT FOR ADHD**

*Dexmethylphenidate HCl is currently under review with the U.S. Food and Drug Administration*

East Hanover, NJ, October 26, 2001 – New data presented today at the 48th Annual Meeting of the American Academy of Child and Adolescent Psychiatry (AACAP) suggest that dexmethylphenidate HCl is effective in the management of the symptoms of Attention Deficit Hyperactivity Disorder (ADHD) at half the dose of Ritalin (d,l methylphenidate HCl). Dexmethylphenidate HCl contains only the predominantly active isomer. Results from a double-blind, randomized, placebo-controlled study found that dexmethylphenidate HCl was effective in reducing ADHD symptoms in home and school settings. Keith Conners, Ph.D., Professor of Medical Psychology, Duke University Medical Center and lead author of the study presented the findings from this pivotal trial.

“Findings from this study support previous research suggesting that the d isomer of Ritalin, which contains both the d and l isomers of methylphenidate, is primarily responsible for its clinical effect,” said Dr. Conners. “The results presented today signify that dexmethylphenidate HCl, which contains only the active d isomer, is a safe and effective treatment for ADHD at half the dose of Ritalin.”

One hundred and thirty-two ADHD patients aged 6-17 were randomized to receive dexmethylphenidate HCl, d,l methylphenidate HCl or placebo. Efficacy was evaluated using the SNAP-ADHD rating scale (Swanson, Nolan, and Pelham rating scale), a standard behavioral assessment tool used in clinical trials. In this analysis, the primary outcome was measured by the change from baseline in teacher SNAP-ADHD scale scores at the conclusion of the 4-week study compared to placebo.

Findings of this pivotal trial suggest that dexamethylphenidate HCl is significantly more effective than placebo in lowering scores on the teacher SNAP-ADHD and the parent SNAP-ADHD, signifying an improvement in the clinical status of children with ADHD. Results further suggest that dexamethylphenidate HCl treats ADHD symptoms with efficacy and safety similar to Ritalin at half the dose.

The study also demonstrated that dexamethylphenidate HCl was safe and well tolerated. There were no serious adverse events reported during the trial, and the adverse events associated with dexamethylphenidate HCl were consistent with the known effects Ritalin and other methylphenidate agents.

Novartis licensed the worldwide (excluding Canada) marketing rights to dexamethylphenidate HCl from Celgene Corporation (Nasdaq: CELG) of Warren, New Jersey. Celgene submitted a new drug application (NDA) for dexamethylphenidate HCl to the U.S. Food and Drug Administration (FDA) in October 2000 and recently received an approvable letter from the FDA. Upon approval, dexamethylphenidate HCl will join the Novartis ADHD product portfolio, which includes Ritalin and Ritalin SR (methylphenidate HCl sustained-release tablets). Novartis also has an NDA pending with the FDA for Ritalin LA (methylphenidate HCl extended-release capsules), designed to be a once-daily formulation of Ritalin. Ritalin LA will be manufactured for Novartis Pharmaceuticals Corporation by Elan Corporation, plc. (NYSE: ELN) using SODAS<sup>®</sup> technology\*, a proprietary drug delivery technology of Elan Corporation, plc. This formulation of Ritalin was developed by Elan Pharmaceutical Technologies, the drug delivery division of Elan Corporation, plc., and was licensed to Novartis. Celgene Corporation also holds a patent on the polymer used in the manufacturing of Ritalin LA.

ADHD is a neurobiologic disorder that interferes with an individual's ability to regulate activity level and behavior and sustain focus on tasks in developmentally appropriate ways. Scientific research indicates that ADHD may be related to disturbances in certain neurotransmitters in the brain. ADHD is the most common childhood psychiatric disorder. It has been well studied for more than 40 years and is supported by a substantial body of scientific evidence.

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

\*SODAS<sup>®</sup> is a registered trademark of Elan Corporation, plc.

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The foregoing press release contains forward-looking statements that can be identified by forward-looking terminology such as "will", "may be", "potential", "suggest", "signify", "is designed to", or similar expressions. Such forward looking statements involve known and unknown risks, uncertainties and other factors that may cause the actual results to be materially different from any

future results, performance, or achievements expressed or implied by such statements. In particular, management's expectation regarding the commercialization of dexmethylphenidate could be affected by amongst other things, regulatory actions or delays or government regulation generally, the ability to obtain or maintain patent or other proprietary intellectual property protection and competition in general, as well as factors discussed in the Company's Form 20F filed with the Securities and Exchange Commission. Should one or more of these risks or uncertainties materialise, or should underlying assumptions prove incorrect, actual results may vary materially from those described herein anticipated, believed, estimated or expected.

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- Investor Relations Release -

## **Novartis receives FDA approvable letter for Diovan® (valsartan) for the treatment of heart failure in patients not on an ACE inhibitor**

East Hanover, New Jersey / Basel, Switzerland, 25 October 2001 – Novartis announced today that it has received an “approvable” letter from the US Food and Drug Administration (FDA) for Diovan® (valsartan) for the treatment of heart failure in patients not on an ACE inhibitor. Final approval is contingent on further analysis of existing data or possibly the submission of additional data.

Diovan, a highly selective angiotensin II receptor blocker (ARB) marketed by Novartis, is already approved for first-line treatment of hypertension in more than 80 countries, including the US, and is one of the fastest-growing branded prescription antihypertensives. An estimated three million patients worldwide take Diovan for high blood pressure.

“We are pleased with FDA’s assessment of Diovan in the treatment of heart failure and we will meet with the Agency to discuss further data requirements in order to achieve final approval as soon as possible,” said Thomas Ebeling, Chief Executive Officer, Novartis Pharma AG.

The filing was based on the Valsartan Heart Failure Trial (Val-HeFT), the largest study ever conducted in heart failure. “Val-HeFT was unprecedented because it evaluated the effects of Diovan in patients who were already receiving existing heart failure therapy,” said Professor Jay Cohn, Lead Investigator of Val-HeFT, Cardiovascular Division, University of Minnesota Medical School. “The robustness of the data and the consistency of its findings across primary and secondary endpoints support an important clinical role for Diovan in this devastating disease.”

Val-HeFT demonstrated that Diovan vs. placebo leads to significant reductions in morbidity and hospitalizations for heart failure in patients who already take therapy prescribed by their physicians. The rate of all-cause mortality was similarly low in the two groups. The most commonly reported adverse events included dizziness and hypotension.

Heart failure, or progressive weakening of the heart muscle, is the fastest-growing cardiovascular disease in the world and has reached epidemic proportions in industrialized nations. Twenty million people worldwide have heart failure and the condition is the most common reason why patients aged 65 or older are hospitalized.

An “approvable” letter is a significant step in the FDA drug approval process. However, FDA “approval” is required in order to market a product for a new indication. If approved, Diovan will be the only ARB indicated in the US for treatment of heart failure. Diovan is also undergoing

review for heart failure in several international markets, including Germany, the UK, France and Switzerland.

Diovan is supported by one of the world's largest clinical trial programs with an ARB. Besides Val-HeFT, other trials examining the effect of Diovan beyond its existing indication for hypertension include VALUE (high-risk patients with hypertension), VALIANT (post-myocardial infarction patients), and NAVIGATOR (patients with impaired glucose tolerance at high risk for cardiovascular events). Diovan is also the primary agent in a clinical trial involving adult type-2 diabetes patients with either normal or high blood pressure (ABCD-2V).

All ARBs carry a warning that the drugs should not be used in pregnant women due to the risk of injury and even death to the fetus. For full US prescribing information, visit the Novartis website at <http://www.pharma.us.novartis.com/what/pi.html#cardio> and select Diovan.

This release contains certain "forward-looking statements", relating to the business of Novartis, which can be identified by the use of forward-looking terminology such as "will meet to discuss further requirements", "support an important clinical role", "approvable", "if approved" or similar expressions. Such forward looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results to be materially different from any future results, performance or achievements expressed or implied by such statements. There are no guarantees that the aforementioned approvable letter will result in increased sales of Diovan. Any such commercialization can be affected by, amongst other things, uncertainties relating to product development, regulatory actions or delays or government regulation generally, the ability to obtain or maintain patent or other proprietary intellectual property protection and competition in general, as well as factors discussed in the Company's Form 20F filed with the Securities and Exchange Commission. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those described herein as anticipated, believed, estimated or expected.

Located in East Hanover, New Jersey, Novartis Pharmaceuticals Corporation is an affiliate of the Novartis Group. Novartis AG (NYSE: NVS) is a world leader in healthcare with core businesses in pharmaceuticals, consumer health, generics, eye-care, and animal health. In 2000, the Novartis Group's ongoing businesses achieved collective 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. Novartis AG is headquartered in Basel, Switzerland. Novartis Group companies employ about 70,000 people and operate in over 140 countries around the world. For further information please consult <http://www.novartis.com>

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- Novartis: R&D Day 2001 -

**Reminder: The Novartis Pharmaceutical Research & Development Day for investors and analysts takes place on**

**Tuesday, October 30, 2001**

Location:	The Waldorf Astoria Starlight Roof 301 Park Avenue New York 10022	
Time:	Registration and coffee starts 8:30AM Presentations to start 9:00AM	
Webcast:	Follow on the web through: <a href="http://www.novartis.com">www.novartis.com</a> For your convenience a link is already available, on <a href="http://www.novartis.com/investors/index.shtml">http://www.novartis.com/investors/index.shtml</a> for tests.	
The conference can also be followed through a Audio dial in option.		
<b>Dial in numbers:</b>	<b>+41 91 610 41 11 or "Free Phone" +800 2467 8700 (Europe and ROW)</b> <b>+ 1 800 860 2442 USA</b>	

**Playback**

Date:	Tuesday, October 30, 2001
Time:	4:00 pm for 48 hrs
Phone numbers:	+ 41 91 610 2500 Europe and ROW + 1 877 344 7529 USA
<b>Code:</b>	<b>181</b>

Investors will be able to view the presentation live on the Internet on October 30, 2001.

The presentations will be available on the Internet 30 minutes prior the start of the R&D Day presentation.

**Attachments:**

1. If you wish to attend please find attached a **reply form** that should be e-mailed or faxed back to: [raquel.rodriguez@group.novartis.com](mailto:raquel.rodriguez@group.novartis.com) no later than October 26, 2001.
2. Program

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- Reply Form -

- I will attend the New York Presentation
- I will follow the presentations on the Internet

Name \_\_\_\_\_

Company \_\_\_\_\_

Phone \_\_\_\_\_

Fax \_\_\_\_\_

E-mail \_\_\_\_\_

**If you have not already replied, please e-mail or fax this form to  
Novartis Investor Relations  
no later than October 26, 2001.**

e-mail: [raquel.rodriguez@group.novartis.com](mailto:raquel.rodriguez@group.novartis.com)  
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If you have any questions or need any additional information please contact:

Raquel Rodriguez  
Novartis International AG  
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Phone: +41 61 324 79 44

\* \* \*

## **Agenda to the R&D Day**

Arrival and Registration and Coffe	08:30 am – 09:00 am
<b>Part I</b>	
<b>Introduction, Pharma performance, US business update, Oncology business update</b>	09:00 am
D. Vasella	
T. Ebeling	
P. Costa	
D. Epstein	
<b>Coffee Break</b>	10:10 am
<b>Part II</b>	
<b>Development update</b>	10:30 am
J. Reinhardt	
J. Shannon	
D. Parkinson	
<b>Q&amp;A with panel</b>	11:40 am
<b>Small Break</b>	12:00 pm
<b>Part III</b>	
<b>Novartis Research, Concluding Remarks</b>	12:20 pm
P. Herrling	
D. Vasella	
<b>Q&amp;A with panel</b>	12:55 pm
<b>Buffet lunch</b>	01:15 pm
<b>Booths with medical and marketing specialists</b>	01:15 pm – 03:30 pm
<b>Break-out session Oncology</b>	02:00 pm
<b>Break-out session Cardiovascular</b>	02:40 pm



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MEDIA RELEASE · COMMUNIQUE AUX MEDIAS · MEDIENMITTEILUNG

## **New data further underlines the safety and efficacy of Zelmac® (tegaserod) in treating multiple symptoms of Irritable Bowel Syndrome (IBS)**

Basel, Switzerland 24 October, 2001 – Zelmac® (tegaserod) offers rapid and sustained relief from the symptoms of abdominal pain/discomfort, bloating and constipation in patients with irritable bowel syndrome (IBS), according to a study published this month in *Alimentary Pharmacology & Therapeutics*.<sup>1</sup>

“These very encouraging findings support what other studies have demonstrated—that Zelmac provides patients with continued, sustained relief of the multiple symptoms of IBS,” said Stefan Muller-Lissner, M.D., lead study author and Head, Department of Internal Medicine at the Park-Klinik Weissensee, Berlin. “The onset of relief was seen within one week and was sustained over a 12-week period.”

The multinational, double-blind, placebo-controlled study was designed to evaluate the efficacy and safety of Zelmac in patients with IBS. In the study, 881 IBS patients were randomly assigned to receive Zelmac or placebo for 12 weeks. Those treated with Zelmac at 12 mg daily experienced significantly greater relief of their overall IBS symptoms than those on placebo (46.3% with Zelmac vs 34.5% with placebo) as measured by the Subject’s Global Assessment (SGA) of Relief, which evaluates overall well-being, abdominal pain and discomfort, and altered bowel habit.<sup>1</sup>

The effect on abdominal pain and discomfort (29.9% with Zelmac vs 22.6% with placebo) was sustained throughout the three-month treatment phase. Patients taking Zelmac also had a reduction of the number of days with significant abdominal bloating compared to patients taking placebo (-11.3% with Zelmac vs. +2.1% with placebo.)<sup>1</sup> Adverse events were similar in all groups. Transient diarrhoea was the only adverse event that appears to have increased in frequency with Zelmac treatment<sup>1</sup>.

Zelmac is approved for the treatment of abdominal pain and discomfort, bloating, and altered bowel function in IBS patients whose main symptoms are pain/discomfort and constipation in the Czech Republic, Mexico, Venezuela, Columbia and Tanzania. The Swiss Health Authority, Intercantonal Office for the Control of Medicines (IKS), is currently reviewing Zelmac for marketing approval. Novartis remains committed to working with the U.S. Food and Drug Administration (FDA), the European Agency for the Evaluation of Medicinal Products (EMEA) and other regulatory authorities to help bring the benefits of this new therapy to patients in need.

IBS is one of the most common gastrointestinal disorders<sup>2</sup> and can have a significant impact on quality of life, with profound social and economic consequences<sup>3-5</sup>.

The foregoing press release contains certain forward-looking statements related to the business of Novartis, which can be identified by the use of forward-looking terminology such as “very encouraging”, “continued, sustained relief”, “can have”, “is expected”, “remains committed” 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. Management's expectation regarding the commercial potential of tegaserod in any market could be affected by, among other things, uncertainties relating to product development, regulatory actions or delays or government regulation generally, the ability to obtain or maintain patent or other proprietary intellectual property protection and competition in general, as well as factors discussed in the Company's Form 20F filed with the Securities and Exchange Commission. Should one or more of these risks or uncertainties 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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#### References:

- 1 Muller-Lissner SA, Fumagalli I, Bardhan KD, Pace F, Pecher E, Nault B, Ruegg P. Tegaserod, a 5-HT<sub>4</sub> receptor partial agonist, relieves symptoms in irritable bowel syndrome patients with abdominal pain, bloating and constipation. *Alimentary Pharmacology & Therapeutics* 2001; 15: 1655-66.
- 2 Thompson WG, Longstreth GF, Drossman DA, Heaton KW, EJ Irvine, Muller-Lissner SA. Functional bowel disorders and functional abdominal pain. *Gut* 1999; 45 (Suppl II): II43-II47).
- 3 Hahn BA, Yan S, Strassels S. Impact of irritable bowel syndrome on quality of life and resource use in the US and the UK. *Digestion* 1999; 60: 77-81.
- 4 Whitehead WE, Burnett CK, Cook EW, Taub E. Impact of irritable bowel syndrome on quality of life. *Dig Dis Sci* 1996; 41: 2248-53.
- 5 Camilleri M, Williams DE. Economic burden of irritable bowel syndrome: proposed strategies to control expenditures. *Pharmacoeconomics* 2000; 17: 331-8.



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MEDIA RELEASE · COMMUNIQUE AUX MEDIAS · MEDIENMITTEILUNG

## Atopic triad increasingly affects children

*Understanding of triad may allow for better treatment options*

San Francisco, CA, 23 October 2001 – Atopic individuals have a genetic tendency to have hypersensitive reactions to allergens. This hypersensitivity usually manifests in the form of allergic rhinitis, asthma, and/or atopic dermatitis, although the exact reason why one condition develops over another is unknown. Studies have shown not only a significant association between these diseases, also known as the atopy triad, but also an increase in prevalence, particularly in children. Physicians met to discuss the connection between these diseases at a symposium held yesterday at the American Academy of Pediatrics (AAP) National Convention in San Francisco. In addition, data was presented on potential and new treatment advancements that may help children suffering from atopic dermatitis and asthma.

"Many patients who have one condition within the triad often suffer from one or both of the others," said Dr. William Berger, Clinical Professor, Department of Pediatrics, Division of Allergy and Immunology at the University of California-Irvine, and one of the presenters at the symposium. "While more research is needed to better understand the nature and reasons behind this triad of conditions, we are working to apply what is known to significantly improve patients' treatment options and therefore their overall quality of life." Studies show that asthma and/or allergic rhinitis develop in 35 percent to 50 percent of atopic dermatitis patients, and about 60 percent of those patients have a family history of one or more atopic diseases. Patients who suffer from one or more of the triad conditions may also experience a significantly reduced quality of life. In fact, many of the children with atopic dermatitis and/or asthma experience disrupted sleep due to wheezing (as a result of asthma) or itching (as a result of atopic dermatitis). Children with these conditions also report feelings of isolation, and low self-esteem. While the atopy triad is a complex set of conditions that are not yet fully understood, the good news for patients, particularly children, is that research continues to provide new information and advances in treatment options.

### **Atopic Dermatitis**

Perhaps the most under-recognized triad condition is atopic dermatitis, commonly known as eczema. Affecting up to 65 percent of sufferers within the first year of life and 90 percent of sufferers before the age of five, atopic dermatitis is a highly prevalent condition in pediatric patients.

There are limited treatment options for children with atopic dermatitis. However, new data presented at the AAP symposium showed pimecrolimus (ASM 981) cream 1%, a steroid-free treatment in development for atopic dermatitis, to be safe and effective in the short-term treatment

and long-term management of the disease. The new long-term data were from a 6-month analysis of a 12-month long-term study to assess the efficacy and safety of pimecrolimus in 251 infants (3-23 months of age) with atopic dermatitis. The multi-center, parallel group, double-blind, controlled, study compared a long-term pimecrolimus-treatment regimen with a current conventional therapy regimen of emollients for dry skin and topical corticosteroids for flares. In both treatment groups, emollients were allowed for dry skin. The patients' parents applied either pimecrolimus or vehicle at the earliest signs or symptoms of the disease. Topical corticosteroids of mid-potency were used by both treatment groups to treat flares not controlled by either study medication.

Results showed that more than twice as many infants in the pimecrolimus-treatment group (70%) as compared to the conventional therapy group, made it through the entire six months without a single flare. But half as many pimecrolimus-treated patients (16% vs. 35%) dropped from the study. These relationships held true no matter the severity of the patient's eczema. The study also demonstrated pimecrolimus to have a steroid-sparing effect. Patients in the pimecrolimus group required treatment with corticosteroids less often and for a shorter duration than those patients in the conventional therapy group. The mean number of days of corticosteroid use in the conventional therapy group was approximately double that observed in the pimecrolimus group. Additional safety analysis showed no significant difference in the incidence of adverse events between the two treatment groups. In particular, there was no difference between skin infections, either bacterial or viral. Six-month and 12-month data from another study of the same design involving older children and adolescents were also presented and showed consistent results to that from the infant long-term study.

"Pimecrolimus is clinically proven to reduce flares, as well as the need for corticosteroids, in both infants and children suffering from atopic dermatitis," said John Y.M. Koo, MD, Vice Chairman and Associate Clinical Professor of Dermatology at the University of California-San Francisco. "When available, pimecrolimus will be a welcomed advance in the treatment of pediatric atopic dermatitis." Dr. Koo was also a presenter at the symposium.

Pimecrolimus is being studied and developed by Novartis Pharmaceuticals Corporation specifically for the treatment of inflammatory skin disorders. It is currently under review by the Food and Drug Administration (FDA) as a potential, steroid-free therapy for the treatment of atopic dermatitis.

### **Asthma**

In addition to atopic dermatitis, physicians at the AAP symposium also focused on asthma and treatment options available for the nearly five million children who suffer from this chronic disease. The most common chronic childhood illness, asthma is an inflammatory disorder of the airways with symptoms including difficulty breathing, wheezing, coughing, shortness of breath and chest tightness. More than 30 percent of children with asthma visit hospital emergency rooms each year to treat and control their symptoms.

As with other chronic conditions, the goal for treatment of asthma is the successful long-term management of the disease. FORADIL<sup>®</sup> AEROLIZER<sup>™</sup> (formoterol fumarate inhalation powder) offers the unique benefit of acting within five minutes and lasting for up to 12 hours. In a 12-month study of 518 children with asthma, ages 5-years-old to 12-years-old, those treated with FORADIL AEROLIZER demonstrated a significant improvement in lung-function. In addition, the study showed a reduced need for rescue medications. FORADIL AEROLIZER is administered twice daily via a dry powder inhaler called the Aerolizer<sup>™</sup> inhaler, which unlike traditional metered-dose inhalers provides patients with the reassurance that they are in control of their

dosing. Adverse reactions with FORADIL AEROLIZER were similar in nature to those experienced with other asthma drugs and include increased heart rate, nervousness, tremor, muscle cramps, nausea, and sleeplessness. FORADIL AEROLIZER 12mcg should not be used more than twice a day or used to relieve sudden symptoms – they should be treated with rescue medication like albuterol. FORADIL AEROLIZER should be used with caution in patients with heart problems. FORADIL AEROLIZER is not a substitute for inhaled or oral corticosteroids.

This release contains certain “forward-looking statements”, relating to the Company’s business, which can be identified by the use of forward-looking terminology such as “may,” “potential,” “possibility,” “when approved,” “will,” or similar expressions, or by discussions of strategy, plans or intentions. Such statements include descriptions of the potential benefit of pimecrolimus (ASM 981) as evidenced by initial clinical trial results. Those statements reflect the current views of the Company with respect to future events and are subject to certain risks, uncertainties and assumptions. Many factors could cause the actual results, performance or achievements of the Company to be materially different from any future results, performances or achievements that may be expressed or implied by such forward-looking statements. There are no guarantees that the aforementioned clinical trials will result in the commercialization of pimecrolimus (ASM 981) in any market. Any such commercialization can be affected by, among 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 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.

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- Investor Relations Release -

## **FDA grants priority review for Zometa® in the treatment of a serious cancer complication**

Basel, 23 October 2001 – Novartis announced today that Zometa® (zoledronic acid) has been designated a priority review by the US Food and Drug Administration (FDA) in the treatment of bone complications (metastases) associated with a broad range of tumor types. These included patients with prostate cancer, lung cancer, and other tumor types for which no intravenous bisphosphonate therapy is currently approved for treatment, as well as patients with breast cancer and multiple myeloma. The FDA grants priority review for therapies that may offer a significant improvement over available treatments.

Novartis submitted the new drug application (NDA) for the use of Zometa to the US FDA on 22 August 2001. Submission to the EMEA in the European Union was made on 30 July 2001.

“Novartis is pleased that the FDA acknowledges the potential benefit Zometa has in treating bone metastases associated with a broad range of cancers,” said David Epstein, President, Novartis Oncology. “Novartis continues to work with the FDA to ensure Zometa is thoroughly evaluated in the most timely manner possible.”

This application is based on data from three large international clinical trials evaluating more than 3,000 patients with myeloma, breast cancer, prostate cancer, lung cancer and other solid tumors. This is the largest set of clinical trials ever conducted to evaluate the efficacy and tolerability of a bisphosphonate in treating cancerous bone lesions.

Bone metastases/lesions are common complications in prostate, breast and lung cancer, and multiple myeloma patients, often with severe debilitating consequences.

Novartis has previously received marketing clearance for Zometa in the treatment of tumor-induced hypercalcaemia (TIH), also known as hypercalcaemia of malignancy (HCM), in more than 40 countries, including the European Union (EU), United States, Switzerland, Brazil, Canada and Australia.

### **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 “may offer,” “significant,” “improvement,” “potential benefit,” and “evaluated,” 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 efficacy or safety of Zometa, 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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MEDIA RELEASE · COMMUNIQUE AUX MEDIAS · MEDIENMITTEILUNG

## **Novartis and Cytos sign research and license option agreements to develop a new class of therapies for chronic diseases**

*Novartis explores potential of Cytos' novel approach to therapeutic vaccines in allergy, rheumatoid arthritis, and chronic nervous system disorders*

Basel and Zurich, Switzerland, 23 October 2001 – Novartis Pharma AG and Cytos Biotechnology AG announced today that they have entered into three separate research and commercial license option agreements to develop therapeutic vaccines for the treatment of allergy, rheumatoid arthritis, and chronic nervous system disorders. After completion of initial research programs with Cytos, and following exercise of its options, Novartis will acquire exclusive worldwide development, manufacturing and marketing rights to the drug candidates that it accepts from Cytos. Under the terms of the agreements, Cytos will receive research funding and pre-commercialization milestone and license payments of up to CHF 70 million, and royalties on sales of the products resulting from the collaboration.

Recent advances in genomics and biology have led to a better understanding of the molecular mechanisms of disease processes. This in turn is driving a shift towards causal and disease-modifying therapies, rather than those treating only the symptoms of disease. The application of Cytos' technology to disease-related proteins permits the development of a new class of therapeutic vaccines, named Immunodrugs™, with the potential to cure or delay progression of major chronic diseases. This is achieved by presentation of the selected disease-related protein to the patient's immune system in a highly repetitive array known to efficiently trigger an immune response. The resulting therapeutic vaccine instructs the immune system to produce specific antibodies that block or activate the disease-associated antigen with the goal of prevention, long-lasting stabilization or reversion of the disease process. Cytos' novel approach to immunotherapy may thus represent a transition from passive immunization with monoclonal antibodies to the active engagement of the patient's immune system in the treatment process.

Paul Herrling, Head of Global Research for Novartis Pharma, said, "We find highly attractive the potential represented in Cytos' novel therapeutics for the treatment of chronic diseases. The Cytos approach holds the promise of complementing and extending our own competitive in-house programs. We look forward to a successful collaboration that could contribute a new class of therapeutic entities to our development pipeline within the next couple of years."

Wolfgang Renner, CEO of Cytos, commented: "The agreements launch important programs for Cytos and demonstrate the Novartis commitment to our therapeutic vaccines platform; a technology with very broad applications in many diseases. The collaborations enable us to explore

these drugs with one of the world's leading pharmaceutical companies. We are very excited about this outstanding opportunity and look forward to a productive collaboration.”

This foregoing press release may contain forward-looking statements that include words or phrases such as, “will”, “aim at”, “could”, “may” or other similar expressions. These forward-looking statements are subject to a variety of significant uncertainties, including scientific, business, economic and financial factors, and therefore actual results may differ significantly from those presented. Cytos is not under any obligation to update such statements. There can be no assurance that the therapeutic vaccines developed by Cytos will enter clinical trials, that clinical trial results will be predictive for future results, that the drug candidates will be the subject of filings for regulatory approval, that any drug candidates will receive marketing approval from the U.S. Food and Drug Administration or equivalent regulatory authorities, or that vaccines which result from this collaboration will be marketed successfully. This document does not constitute an offer or invitation to subscribe or purchase any securities.

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**Cytos Biotechnology AG** is a privately held Swiss company that is engaged in the discovery, development and commercialization of a new class of biopharmaceutical products, the Immunodrugs™, that serve to prevent or cure chronic diseases affecting millions of people worldwide. Cytos' Immunodrugs™ aim at instructing the patient's immune system to produce specific antibodies that fight disease processes. Founded in 1995 as a spin-off from the Swiss Federal Institute of Technology (ETH), Cytos has its headquarters in Zurich, Switzerland, with a subsidiary in Konstanz, Germany. To date, Cytos has raised CHF 61 million (USD 36 million) from leading international venture capital institutions. It currently employs around 100 people in Zurich and Konstanz, 45 of whom hold a PhD.

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MEDIA RELEASE · COMMUNIQUE AUX MEDIAS · MEDIENMITTEILUNG

## **New data on Novartis drug Zometa<sup>®</sup> for treatment of breast cancer and multiple myeloma-related bone complications published in major medical journal**

*Breast cancer data presented at European Cancer Conference; therapy infused in fraction of time of previous generation therapies*

Basel, 22 October 2001 – Clinical data published in the September 2001 issue of *The Cancer Journal* demonstrate that the Novartis drug Zometa<sup>®</sup> (zoledronic acid) reduces the incidence of cancer-related bone complications called skeletal related events (SREs) in patients with multiple myeloma or advanced breast cancer. The data also show that treatment with Zometa delays the time to onset of the first SRE. Additionally, the authors conclude that the fast and convenient 15-minute infusion time of Zometa offers benefit to physicians and patients. The breast cancer data from this study is being presented at the European Cancer Conference in Lisbon, Portugal on 21 October.

Skeletal related events are a serious, painful and sometimes life-threatening complication of bone metastases. They were defined in the study as pathologic fractures, spinal cord compression, surgery to bone, radiation therapy to bone and hypercalcaemia of malignancy. Current therapeutic options for complications of bone metastases include: chemotherapy, hormonal therapy, radiotherapy, analgesics for pain management, surgery and the use of intravenous bisphosphonates.

“The shorter infusion time of Zometa offers patients the important benefit of greater convenience than previous generation therapies,” said Lee Rosen, MD, Assistant Professor in the Department of Medicine, Hematology and Oncology at UCLA Medical Center, a primary investigator and study author. “The data, combined with the convenient infusion time suggest Zometa should be the new standard of treatment for bone complications of breast cancer and multiple myeloma.”

### **Study Details**

This international Phase III, randomized, double-blind, double-dummy trial was designed to compare the efficacy of the 15-minute infusion of Zometa (4 or 8/4 mg) to that of Aredia<sup>®</sup> (pamidronate disodium, 90 mg) infused over two hours. The study included 1,648 patients with either stage III multiple myeloma (a cancer of the plasma cells), or advanced breast cancer. The final efficacy analyses focused on comparisons of 4 mg Zometa versus pamidronate, as the higher Zometa dose did not provide added efficacy, but was associated with reduced tolerability. The primary efficacy endpoint was the proportion of patients experiencing at least one SRE by the 13<sup>th</sup> month.

The proportion of study participants who had experienced at least one SRE at month 13 was approximately 44% in the Zometa 4 mg group and 46% in the pamidronate disodium group. In addition, the median time to first SRE, a secondary endpoint, was approximately one year in both treatment groups. The multiple myeloma portion of the data was presented earlier this month in an abstract at the Recent Advances in The Management of Multiple Myeloma meeting, at the German Cancer Research Centre, in Heidelberg, Germany.

### **About Zometa**

To date, Novartis has received marketing clearances for Zometa in the treatment of tumor-induced hypercalcaemia (TIH), also known as hypercalcaemia of malignancy (HCM), in more than 40 countries, including the EU, United States, Switzerland, Brazil, Canada and Australia. HCM is the most common life-threatening metabolic complication of cancer. Novartis has recently filed in the EU and the US for the treatment of bone metastases associated with a broad range of tumor types. These include prostate, breast and lung cancer, and multiple myeloma.

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- Investor Relations Release -

## Novartis submits supplemental NDA with US FDA for Glivec® for treatment of certain GI tumors

*Approval would represent first new treatment option beyond surgery for gastrointestinal stromal tumors; represents first filing of a signal transduction inhibitor in a solid tumor*

Basel, 19 October 2001 – Novartis announced today that it has submitted a supplementary New Drug Application (sNDA) to the US Food and Drug Administration (FDA), seeking marketing authorisation for its novel drug Glivec® (imatinib)<sup>1</sup> for the treatment of patients with unresectable (inoperable) and/or metastatic malignant gastrointestinal stromal tumours (GISTs).

GISTs are the most common malignant form of sarcoma arising in the gastrointestinal tract. Historically, GISTs have been very difficult to treat due to their high levels of resistance to treatment with traditional chemotherapy and radiation therapy. For patients with metastatic or unresectable disease, GISTs represent an incurable malignancy with a median survival of approximately ten to twelve months. Until now, surgery has been the only treatment option, resulting in essentially palliation of this disease. There are approximately 12,000 new cases each year of malignant GIST worldwide.

“GISTs are very difficult to treat and there are very few options beyond surgery for these patients,” said David Parkinson, MD, vice president, clinical research, Novartis Oncology. “Glivec is extremely active against the molecular abnormality that helps trigger GISTs, and Novartis believes it represents a significant advance in overall treatment of the disease.”

### Glivec Background

After a priority review, the U.S. FDA approved Glivec on 10 May 2001 for the treatment of patients with chronic myeloid leukemia (CML) in the blast crisis, accelerated phase or in chronic phase after failure of interferon-alpha therapy. The effectiveness of Glivec in CML is based on overall hematologic and cytogenetic response rates. There are no controlled trials demonstrating a clinical benefit such as improvement in disease-related symptoms or increased survival. This represented the fastest approval of any cancer drug. Glivec is currently approved for marketing in more than 30 countries, including the United States, Switzerland and Australia. Glivec received a positive recommendation by the European Union’s Committee for Proprietary Medicinal Products (CPMP) in July 2001, and an approval by the European Commission is anticipated shortly.

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

### **About Glivec and GISTs**

The submission for US FDA approval is supported by data from a Phase II, open-label, multinational study conducted in 147 patients with unresectable or metastatic malignant GIST. Patients were randomized to receive either 400 mg or 600 mg of Glivec daily for up to 24 months. The overall response rate is 40% based on confirmed partial responses at the time of the data cut-off for the submission. An additional 32% of patients in this study achieved a clinically significant reduction in tumor size. Only 12% of patients progressed in the study.

### **Contraindications and Adverse Events**

Glivec has been well tolerated in patients with GIST. Although almost all patients had adverse events reported at least once during the trial, only a very small percentage had these recorded as either grade 3 or 4 in severity. Five patients (3.4%) withdrew from the study due to adverse events. In this clinical trial, the most common adverse events were nausea; diarrhea; periorbital edema; fatigue; muscle cramps; abdominal pain; dermatitis; vomiting; flatulence; lower limb edema; nasopharyngitis; insomnia; back pain; and pyrexia. The adverse events in patients with GIST are similar to those in patients with CML, and the majority of CML patients treated with Glivec also experienced adverse events at some time. Most events were of mild to moderate grade, but drug was discontinued for adverse events 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. Serious and severe side effects, such as hepatotoxicity (1.1% to 3.5%), fluid retention syndrome (2% to 10%), neutropenia (8% to 46%) and thrombocytopenia (less than 1% to 31%) have also been reported in some patients. There are no long-term safety data on Glivec treatment.

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

The foregoing release contains forward-looking statements that can be identified by terminology such as “would represent,” “anticipated,” “seeking market authorization,” “is supported by” and “believed to target,” 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.

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MEDIA RELEASE · COMMUNIQUE AUX MEDIAS · MEDIENMITTEILUNG

## Visudyne™ therapy reimbursement in US expanded to include patients with occult form of wet age-related macular degeneration

*Importance of Visudyne therapy confirmed for additional patient population*

Basel, 19 October 2001 — Novartis Ophthalmics, the eye health unit of Novartis AG, and QLT Inc. today announced that the Centers for Medicare and Medicaid Services (CMS), formerly the Health Care Financing Administration (HCFA), has announced its intention to expand its national coverage policy for Visudyne™ (verteporfin for injection) therapy. The policy, once implemented, will include patients with occult only subfoveal choroidal neovascularization (CNV) secondary to age-related macular degeneration (AMD) — a leading cause of blindness.

The decision is the result of a formal request by the Vitreous Society as well as a series of consultations with physicians, clinical investigators and representatives from Novartis Ophthalmics and QLT. This expansion, once effective, will provide coverage for two-thirds of patients with CNV secondary to AMD.

“We are very pleased with the revised policy by CMS,” said Luzi von Bidder, head of Novartis Ophthalmics. “This decision substantially expands the number of patients who will be covered under CMS’ reimbursement guidelines and is a significant advancement for patients with the occult form of wet AMD”.

Dr. Julia Levy, president and CEO of QLT, said, “It’s very gratifying that CMS acknowledges the importance and validity of the data recently published in the American Journal of Ophthalmology showing Visudyne’s benefit in the occult form of wet AMD.”

Visudyne is commercially available in more than 50 countries for the treatment of predominantly classic subfoveal CNV caused by AMD. It is also approved in 25 countries, including the EU, US and Canada, for the treatment of subfoveal CNV due to pathologic myopia (severe near-sightedness). In the US, Visudyne has received an additional approval for CNV due to presumed ocular histoplasmosis. Approximately 90,000 to 100,000 patients have undergone Visudyne therapy worldwide.

### **About AMD**

AMD is the leading cause of blindness in people over the age of 50 and is caused by a growth of abnormal blood vessels (CNV) under the central part of the retina or macula. The vessels leak fluid and blood and can lead to the development of scar tissue that destroys the central retina, resulting in a deterioration of sight over a period ranging anywhere from two months to three years. Although the wet form (the form Visudyne is used to treat) represents an estimated 15% of

all AMD cases, it accounts for approximately 90% of the severe vision loss associated with the diseases. Worldwide, approximately 500,000 new cases of wet AMD occur each year and this estimate is expected to grow dramatically as the population ages. “Occult” and “classic” are terms used to describe the different patterns of CNV leakage as seen on fluorescein angiography.

### **About Visudyne**

Novartis Ophthalmics and QLT Inc. have developed Visudyne™ (verteporfin for injection)<sup>1</sup> therapy, the only drug therapy approved for the treatment of some forms of wet AMD. 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.

For more information, visit [www.visudyne.com](http://www.visudyne.com).

The foregoing press release contains forward-looking statements that can be identified by terminology such as “look forward,” “could significantly expand the current market,” “potential,” 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](http://www.novartisophthalmics.com) or [www.novartisophthalmics.com/us](http://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](http://www.qltinc.com).

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<sup>1</sup> Outside the US: Visudyne®; in the US: Visudyne™



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MEDIA RELEASE · COMMUNIQUE AUX MEDIAS · MEDIENMITTEILUNG

## **Laboratory results confirm Novartis employee did not contract anthrax**

*Basel City Cantonal Laboratory analysis reveals no traces of anthrax*

Basel, 17 October 2001 – Novartis is relieved to announce that the medical tests for anthrax carried out on one of its employees earlier this week have yielded negative results. The analysis was performed by the Cantonal Laboratory of the City of Basel.

On Tuesday, 9 October, a Novartis employee received a letter containing an unidentified powder, which he reported to his supervisor on Sunday, 14 October, in the light of reports in the media on cases of anthrax in the US. The company immediately launched an investigation and took the necessary measures. The employee underwent a medical examination without delay and received prophylactic treatment as a precaution.

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## **Novartis says it will not increase prices of reimbursable medicines in Switzerland for the next two years**

Basel, 17 October 2001 – Novartis today announced that it does not intend to submit any new applications for increases in the prices of its reimbursable medicines in Switzerland in 2002 and 2003. This initiative is in response to the premium increases recently announced by Swiss health insurance companies. The Federal Office for Social Security (BSV) has been notified of the company's decision.

Armin Zust, Head of Novartis Pharma Switzerland, commented: "For many families, the average rise of 10% in premiums announced by health insurers is a significant financial burden. By taking this measure, we mean to set an example and to live up to our responsibilities as a healthcare leader in Switzerland."

By voluntarily freezing the prices of its reimbursable medicines over the next two years, the company is making an effort to curb increasing healthcare costs. It is hoped that, during this period, savings can also be achieved with regard to other cost drivers that are responsible for the bulk of health insurers' expenditures.

Drugs account for only about 12% of total healthcare costs, but make up almost 20% of health insurance companies' outlays, because not all healthcare expenses are covered by the insurers. In recent years, total costs in the pharmaceuticals sector have risen annually by 7–9%, primarily because older treatments have been replaced by innovative and improved drug therapies. Although new drugs are often more expensive than older ones, they can lead to savings within the healthcare system, for example by shortening costly hospitalization periods or convalescence times. In addition, as a result of the enhanced efficacy of new drug treatments, the absolute volume of drugs prescribed has declined slightly in recent years. Finally, it should be noted that the need for medical services and treatments will grow as the population progressively ages, leading to further increases in healthcare costs.

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MEDIA RELEASE · COMMUNIQUE AUX MEDIAS · MEDIENMITTEILUNG

## Suspicious letter received at Novartis

### *Investigation of incident launched immediately*

Basel, 15 October 2001 – Last Tuesday, 9 October, a Novartis employee received a letter containing an unidentified powder, which he reported to his supervisor on Sunday, 14 October, in the light of reports in the media on cases of anthrax in the US. It was not possible, after the event, to trace the origin of the letter.

The company immediately launched an investigation and took the necessary measures. The employee underwent a medical examination without delay and received prophylactic treatment. The results of the laboratory tests are expected to be available by 19 October. Investigations are under way to establish whether any other employee could possibly have come into contact with the substance and whether any further measures need to be taken. The Basel-Stadt cantonal authorities were immediately informed of the incident. Novartis staff were also informed today.

Given the circumstances and on the basis of the findings currently available, it is unlikely that the incident is analogous to the cases reported in the US. Nevertheless, the company has felt obliged to take precautionary measures. The authorities and the public will be informed of any further details of the incident or laboratory findings as soon as they become available.

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MEDIA RELEASE · COMMUNIQUE AUX MEDIAS · MEDIENMITTEILUNG

## **FDA Advisory Committee issues split decision on recommendation to approve Diovan® (valsartan) for heart failure indication**

Basel / East Hanover, 12 October 2001 – Novartis' Pharmaceuticals affiliate in the US, Novartis Pharmaceuticals Corporation, announced yesterday that the Cardiovascular and Renal Drugs Advisory Committee to the US Food and Drug Administration (FDA) has issued a four-to-four split decision about whether to recommend approval of Diovan® (valsartan) for the treatment of heart failure. Advisory Committees to the FDA provide independent opinions and recommendations to the Agency on applications to market new drugs or approved drugs for supplemental indications. Final decisions are made by the FDA.

The supplemental new drug application (sNDA) for Diovan for heart failure was filed with the FDA on 27 April 2001, and was granted priority review status. The Diovan filing is based on the positive results of the Valsartan Heart Failure Trial (Val-HeFT), the largest trial ever conducted in heart failure involving 5010 patients in 302 centers in 16 countries. Diovan is a leading angiotensin II receptor blocker (ARB) in the treatment of high blood pressure.

“We will continue to work with the FDA regarding our filing because we believe that Diovan has shown clear benefit in heart failure,” said Paulo Costa, president and chief executive officer, Novartis Pharmaceuticals Corporation.

Val-HeFT demonstrated that Diovan leads to significant, incremental reductions in morbidity and hospitalizations for heart failure in patients who already take therapy prescribed by their physicians. Diovan has been approved for treatment of high blood pressure since 1996 and is the only ARB to demonstrate positive results in heart failure in a large-scale clinical trial.

In Val-HeFT, Diovan significantly reduced morbidity by 13.2% ( $p=0.009$ ) and hospitalizations for heart failure by 27.5% ( $p<0.001$ ) in patients who also took prescribed therapy vs. patients who took prescribed therapy with placebo, or sugar pill. Prescribed therapy could include ACE inhibitors, beta blockers, diuretics and digoxin as selected by the patients' physicians. The findings of Val-HeFT include significant improvements in ejection fraction ( $p=0.001$ ), NYHA functional class ( $p<0.001$ ), and clinical signs and symptoms of heart failure (dyspnea, fatigue, edema and rales) ( $p=0.01$ ). Val-HeFT also demonstrated that heart failure patients taking Diovan with prescribed therapy experienced a significantly better quality of life in both the physical and emotional sense ( $p=0.005$ ) vs. patients taking prescribed therapy and placebo, as measured by the Minnesota Living With Heart Failure questionnaire, a standard assessment tool. The rate of all-cause mortality was similarly low in the two groups.

Adverse events leading to withdrawal occurred in 9.9% of patients receiving Diovan and prescribed therapy vs. 7.3% of patients receiving placebo and prescribed therapy. The most

commonly reported adverse events included dizziness and hypotension. The benefits demonstrated in Val-HeFT did not appear to extend to the subgroup of patients taking Diovan in combination with both an ACE inhibitor and a beta blocker.

Heart failure, or the progressive weakening of the heart muscle, is the fastest growing cardiovascular disease in the world. Nearly five million Americans have heart failure and 1500 new cases are diagnosed every day. Heart failure is also the leading cause of hospitalization in people age 65 and over. In the US, 2600 people are hospitalized every day because of this condition – a major reason why costs for treating heart failure are expected to exceed USD 50 billion next year. High blood pressure is a common risk factor for heart failure. About 75% of heart failure patients have a prior history of hypertension.

About three million patients worldwide take Diovan for high blood pressure. Diovan is one of the fastest growing among the top 10 branded prescription antihypertensives in the US today.

Novartis is conducting one of the world's largest clinical trial programs with an ARB. Besides Val-HeFT, other trials examining the effect of Diovan beyond its existing indication for hypertension include VALUE (high-risk patients with hypertension), VALIANT (post-myocardial infarction patients), and NAVIGATOR (patients with impaired glucose tolerance at high risk for cardiovascular events). Diovan is also the primary agent in a clinical trial involving adult type-2 diabetes patients with either normal or high blood pressure (ABCD-2V).

All ARBs carry a warning that the drugs should not be used in pregnant women due to the risk of injury and even death to the fetus. For full prescribing information, visit the Novartis website at <http://www.pharma.us.novartis.com/what/pi.html#cardio> and select Diovan.

The foregoing press statement contains forward-looking statements that can be identified by terminology such as “recommendation,” “filed,” “confident” or similar expressions. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause the actual results to be materially different from any future results, performance, or achievements expressed or implied by such statements. In particular, management's expectations could be affected by, among other things, uncertainties relating to clinical trials and product development; unexpected regulatory delays, government regulation, data from further clinical studies, including, but not limited to, additional evidence concerning the efficacy of Diovan for treatment of heart failure, data concerning possible adverse effects resulting from administration of Diovan, and data derived from other studies examining the effect of Diovan for possible treatment of conditions beyond its existing indications.

Located in East Hanover, New Jersey, Novartis Pharmaceuticals Corporation (NYSE:NVS), is an affiliate of the Novartis Group, a world leader in healthcare with core businesses in pharmaceuticals, consumer health, generics, eye-care, and animal health. Headquartered in Basel, Switzerland, the Novartis Group employs about 70,000 people and operates in over 140 countries around the world.

Novartis AG (NYSE: NVS) is a world leader in healthcare with core businesses in pharmaceuticals, consumer health, generics, eye-care, and animal health. In 2000, the Novartis Group's ongoing businesses achieved collective 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. Novartis AG is headquartered in Basel, Switzerland. Novartis Group companies employ about 70 000 people and operate in over 140 countries around the world. For further information please consult <http://www.novartis.com>.

**FDA approves Focus<sup>®</sup> Night & Day<sup>™</sup> contact lenses in the US for extended wear for up to thirty nights of continuous wear**

- *First contact lens of its kind with this wearing indication in the US*
- *Revolutionary lens offers convenient, comfortable, 24-hour vision correction*

Basel / Atlanta, 12 October 2001 – Novartis' eye care unit CIBA Vision announced today that the US Food and Drug Administration (FDA) has approved Focus<sup>®</sup> Night & Day<sup>™</sup> contact lenses for extended wear for up to thirty nights of continuous wear in the US. Focus Night & Day lenses are the first high-oxygen, extended wear, soft lens with this wearing indication in the US. Focus Night & Day lenses are broadly available in Europe and elsewhere. However, these lenses have not previously been available in the US, which is the world's largest single market for soft contact lenses. US sales of disposable contact lenses totaled USD 1.2 billion last year.

“Focus Night & Day is the most significant advance in contact lenses since soft lenses were introduced more than 30 years ago,” said Stuart Heap, president of CIBA Vision's global lens business. “CIBA Vision's commitment to innovation has produced a breakthrough product that delivers what lens wearers want – convenient, continuous vision correction that easily fits with their busy and unpredictable lifestyles”.

Because they can be worn continuously for up to 30 nights and days, Focus Night & Day soft contact lenses can eliminate the daily annoyance of inserting, removing and cleaning lenses. Lenses are simply discarded after a month of providing clear and comfortable vision around the clock.

“They are also a good alternative to laser vision surgery for the millions of individuals who are not good candidates for the surgery and for those who are averse to the procedure due to its high costs, invasiveness, non-reversibility and potential complications,” Heap said.

Focus Night & Day is made from a revolutionary new silicone hydrogel material that supplies six times more oxygen to the eye (175 Dk/t) than ordinary disposable lenses. This is 40% greater than the minimum threshold (125 Dk/t) recognized by independent researchers for overnight lens wear. The unique, biocompatible properties of the lens also help minimize deposit build-up on the lens over time.

Insufficient oxygen compromises normal eye function and may cause the cornea to swell. While minimal swelling is common during sleep, even in people who do not wear contact lenses, sleeping in ordinary contact lenses substantially reduces oxygen supply to the eyes which can cause the

cornea to swell significantly and often results in very irritated eyes and uncomfortable lens wear. In research studies, users wearing Focus Night & Day lenses experienced minimal swelling similar to those wearing no lens at all and significantly less limbal redness that is typically seen with soft contact lens wear.

“Focus Night & Day lenses are the first to meet patients’ demand for the ultimate in vision correction convenience, and as an eye care practitioner, they meet my requirements for outstanding clinical performance,” said Rex Ghormley, O.D., President of Vision Care Consultants in St. Louis, Mo. and participating optometrist in the US FDA clinical trial for Focus Night & Day.

Since 1999, more than 250 000 patients in more than 40 countries have worn Focus Night & Day for up to 30 continuous nights and days. In addition, CIBA Vision has amassed more than 2 000 patient years of clinical study with Focus Night & Day, making it one of the most thoroughly researched contact lenses in history.

While virtually all people who need vision correction are candidates for Focus Night & Day, not everyone can reach the maximum wear time of 30 continuous nights. People should consult their eye care practitioner to determine if the lenses are suitable for them.

The lenses will be priced competitively with the combined cost need to wear and clean ordinary disposable contact lenses and will be offered in two base curve sizes of 8.6 mm and 8.4 mm and the power range will include +0.25D to +6.00D in 0.25D steps, -0.25D to -8.00D in 0.25D steps and -8.50D to -10.00D in 0.50D steps.

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

CIBA Vision is the eye care unit of Novartis AG (NYSE: NVS), a world leader in healthcare with core businesses in pharmaceuticals, consumer health, generics, eye-care, and animal health. In 2000, the Novartis Group's ongoing businesses achieved collective 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. Novartis AG is headquartered in Basel, Switzerland. Novartis Group companies employ about 70 000 people and operate in over 140 countries around the world. For further information please consult <http://www.novartis.com>.

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## ***New non-steroid cream Elidel® offers relief to babies suffering from eczema***

*Studies show Elidel prevents early signs and symptoms progressing to flares*

Basel, Switzerland, 12 October 2001 – The itching skin condition atopic eczema can be kept under control in 7 out of 10 babies with the new non-steroid cream Elidel®, one of the first new treatments to be developed for eczema in almost 50 years. Study results presented this week at the European Dermatology and Venereology Congress in Munich, showed that one week after starting treatment with Elidel, itching stopped or was only mild in 70% of 3- to 23-month-olds. By using the cream as soon as the first signs of eczema or itching recurred, disease flares were prevented in 70% of the babies and topical corticosteroid treatment was not required during the 6-month study. These results build on existing data already presented in patients aged 2-17.\*

“Eczema in infants has a huge impact on the entire family”, said one of the investigators taking part in the 250-patient study, Dr Mark Goodfield, Consultant Dermatologist at Leeds General Infirmary, UK. “For many patients, the itch is unbearable, the babies cannot sleep and their crying is upsetting for the whole family. When the infants are old enough to scratch themselves, they may scratch until they bleed and this, too, is particularly distressing for parents. So any relief for the baby brings relief for the whole family.”

Eczema has typically been treated with moisturisers for the dry skin stage, and intermittent use of corticosteroids to treat disease flares in which the skin becomes increasingly red, swollen, and may weep and form crusts. However, corticosteroids have to be used with caution in infants or young children, and their long-term use can cause side-effects such as skin thinning and growth retardation.

“Many parents are reluctant to use corticosteroids on children, and so there is a great need for an effective alternative,” Dr Goodfield said. “This study shows that Elidel cream has the potential to provide the sought-after alternative treatment which does not have steroid-associated side effects.”

Novartis has filed applications with the Food and Drug Administration in the US, in Canada, and with health authorities in Switzerland and Denmark (the reference member state for the European Union), for authorisation to market Elidel.

\* Data presented at the International Symposium on Atopic Dermatitis, 6-9 September 2001, Portland, Oregon, US.

Other data reported at the congress showed that:

- In this study with 250 infants, only 32% of those receiving a conventional treatment (emollients for dry skin and corticosteroids for flares) were flare-free over 6 months
- In a year-long study involving 713 patients aged 2 – 17 years, 51% of the children using Elidel at the first signs and symptoms of eczema did not have any disease flares or need topical corticosteroids. Only 28% of patients receiving the conventional treatment were flare-free over the same period.

The most common adverse event reported among the 1700 patients treated with Elidel to date is a sensation of warmth or burning where the cream is applied. This is usually mild and disappears within a few days of treatment. It occurred in 1 of 10 children aged 2 – 17 years.

Elidel (pimecrolimus, formerly known as SDZ ASM 981), which is being developed by Novartis, is the first treatment proven to affect the long-term course of atopic eczema by reducing the incidence of eczema flares and the need for topical corticosteroids. As a skin-selective inflammatory cytokine inhibitor, Elidel works by selectively targeting those cells in the skin which release the pro-inflammatory mediators in atopic eczema.

This press release contains forward looking statements which can be identified by the use of forward looking terminology such as “offers”, “can keep be kept under control”, “new”, or similar expressions. Such forward looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results to be materially different from any future results, performance or achievements expressed or implied by such statements. There are no guarantees that the aforementioned clinical trials will result in the commercialisation of Elidel in any market. Any such commercialisation 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. Any of these and other factors can cause the actual results to differ materially from the expected or predicted results.

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**- Novartis: Invitation to the R&D Day 2001 -**

**Novartis invites you to attend its Pharmaceutical Research & Development Day for investors and analysts on**

**Tuesday, October 30, 2001**

Location:	The Waldorf Astoria 301 Park Avenue-Starlight Roof New York, New York 10022
Time:	Registration starts 8:30AM Presentations to start 9:00AM; final agenda to follow soon
Webcast:	Follow on the web through: <a href="http://www.novartis.com">www.novartis.com</a>

Please Note:

Investors will be able to view the presentation live on the Internet on October 30, 2001. A test link will be sent-out in advance.

For your convenience, attached is a reply form that should be e-mailed back to: [raquel.rodriguez@group.novartis.com](mailto:raquel.rodriguez@group.novartis.com) no later than October 24, 2001.

- Reply Form -

- I will attend the New York Presentation
- I will follow the presentations on the Internet

Name \_\_\_\_\_

Company \_\_\_\_\_

Phone \_\_\_\_\_

Fax \_\_\_\_\_

E-mail \_\_\_\_\_

**If you have not already replied, please e-mail or fax this form to  
Novartis Investor Relations  
no later than October 26, 2001.**

e-mail: [raquel.rodriguez@group.novartis.com](mailto:raquel.rodriguez@group.novartis.com)  
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If you have any questions or need any additional information please contact:

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MEDIA RELEASE · COMMUNIQUE AUX MEDIAS · MEDIENMITTEILUNG

## **New data shows underdiagnosis of Irritable Bowel Syndrome (IBS) burdens patients and healthcare systems worldwide**

*Separate study presented at international medical meeting reinforces long-term safety of Novartis' Zelmac® for treatment of IBS*

Basel, Switzerland, 10 October 2001 — Novartis announced today results of an international study, "Truth In IBS", that found IBS affects up to 12% of the population, and that underdiagnosis and lack of effective treatment create a considerable burden on patients and healthcare systems. Additional data from a multicentre study reinforced that Zelmac® (tegaserod) is safe and well-tolerated in relieving the multiple symptoms of IBS (abdominal pain/discomfort, bloating, and constipation). Both studies were presented today at the 9<sup>th</sup> annual United European Gastroenterology Week (UEGW) meeting in Amsterdam.

### **"Truth In IBS" study**

To assess the global prevalence and impact of IBS, the "Truth In IBS" study was conducted in nine countries: the UK, Germany, Belgium, the Netherlands, Switzerland, Spain, Italy, France and the US. "This large, international study provides compelling new evidence that IBS is a debilitating condition for which there is no single effective treatment," said Professor Jan Tack, study author and staff member at the Department of Gastroenterology and Principal Researcher, Centre for Gastroenterological Research at the University Leuven, Belgium.

The study found that the prevalence of IBS in Europe ranges from 6% in the Netherlands to 12% in Italy, including patients who have been formally diagnosed for the condition and those who have not. Women were predominantly affected, averaging between 63% and 74% of identified IBS sufferers in the nine countries. Diagnosed and undiagnosed sufferers were all ages, with an average of 43 years. Significantly, researchers also found that more than 90% of IBS cases in Europe have not been diagnosed.<sup>1</sup>

The study was conducted in two phases, the first consisting of 5 000 screening calls in each country to identify diagnosed and undiagnosed IBS sufferers. Undiagnosed patients were identified using Manning, Rome I and Rome II diagnostic criteria captured through questionnaires concerning each patient's experience with abdominal pain, bowel function and bloating.<sup>2-4</sup> In the second phase of the study, follow-up phone interviews with identified sufferers collected further information about the impact of IBS on their lives.

Interviews determined that 89% of IBS sufferers experienced bloating, 85% constipation, and 76% abdominal pain. A majority said that IBS affected their diet (69%), concentration (60%) and physical appearance (54%), and said the symptoms have reduced their productivity at work (60%). A majority of IBS sufferers had been to healthcare professionals (90% to a primary care physician) regarding their symptoms with 17% going to a hospital at least once relating to their condition. The study also revealed IBS patients find currently available treatments to be largely ineffective against bloating (89%), constipation (85%) and abdominal pain (76%).

### **Multicentre dose-titration study**

Also at the UEGW meeting, data was presented from a long-term safety and tolerability study<sup>5</sup> which found 62% of IBS patients reported considerable relief of symptoms at 12 months when treated with Zelmec. The multicentre, dose-titration study evaluated 579 patients to reinforce past studies that established the safety of Zelmec. As in previous studies, Zelmec was found to be safe and well-tolerated with mild side effects, the most common being transient diarrhoea (10%) and headache (8%). Patients treated with Zelmec showed no haematological or biochemical abnormalities. Blood pressure and pulse rate remained normal, as did the results of urinalysis.

Previous clinical trials<sup>5-8</sup> involving more than 4 500 patients found that two thirds of patients treated with Zelmec experienced overall symptom relief, including improvements in abdominal pain/discomfort and constipation. The majority had relief within one week.<sup>4,5</sup> Zelmec has been shown to reduce abdominal pain/discomfort, bloating and constipation ( $p < 0.05$ ) in patients with IBS.<sup>7,8</sup> The drug was well-tolerated with an adverse event profile similar to that of placebo, with the exception of headache and diarrhoea, which in most cases was mild and transient.<sup>5,6</sup> Discontinuations based on adverse events were 6.8% for the Zelmec treated group compared with 4.8% for the placebo group in the final trial.<sup>8</sup>

Zelmec is approved for the treatment of abdominal pain, bloating and constipation in IBS patients in Mexico, Venezuela, Columbia and the Czech Republic. The Swiss Health Authority, Intercantonal Office for the Control of Medicines (IKS), is expected to rule on marketing approval for the treatment in the near future. Novartis remains committed to working with the US Food and Drug Administration (FDA), the European Agency for the Evaluation of Medicinal Products (EMA) and other regulatory authorities to help bring the benefits of this new therapy to patients in need.

The foregoing press release contains certain forward-looking statements related to the business of Novartis, which can be identified by the use of forward-looking terminology such as “new”, “create a considerable burden”, “well-tolerated”, “compelling new evidence”, “considerable relief”, “are expected to follow suit”, “remains committed” 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. Management's expectation regarding the commercial potential of tegaserod in any market could be affected by, among other things, uncertainties relating to product development, regulatory actions or delays or government regulation generally, the ability to obtain or maintain patent or other proprietary intellectual property protection and competition in general, as well as factors discussed in the Company's Form 20F filed with the Securities and Exchange Commission. Should one or more of these risks or uncertainties 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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## References

1. Hungin APS, et al. Prevalence and impact of Irritable Bowel Syndrome on Patients' Lives – An International Study. Presented at the 9<sup>th</sup> annual United European Gastroenterology Week (UEGW) meeting, Oct. 10<sup>th</sup>, 2001, Amsterdam, Holland.
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8. Lefkowitz M, et al. Tegaserod provides relief of symptoms in female patients with irritable bowel syndrome (IBS) suffering from abdominal pain and discomfort, bloating and constipation. (Abstr). *Gastroenterology* 2001;12:A104.



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PRE-ANNOUNCEMENT - ANNONCE PRÉALABLE - VORANKÜNDIGUNG

Basel, 5.10.2001

**To the Editors**

Please note that we will publish our **2001 nine-month and third-quarter sales** on **Thursday 11 October 2001** at approximately 7.30 a.m. (Swiss time) through the usual channels. Enhanced reporting methods have enabled us to bring the publication date **forward by seven days**.

\*

**Hinweis an die Redaktionen**

Wir bitten Sie um Kenntnisnahme, dass wir unsere **Umsatzentwicklung neun Monate und drittes Quartal 2001** auf dem üblichen Weg am **Donnerstag, 11. Oktober 2001**, um ca. 7.30 Uhr (Schweizer Zeit) publizieren werden. Dank beschleunigter Berichterstattungsmethoden konnte das Publikationsdatum um **sieben Tage vorverlegt werden**.

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**A l'attention des rédactions**

Nous aimerions vous informer que le **chiffre d'affaires du Groupe Novartis pour les neuf premiers mois ainsi que pour le troisième trimestre 2001** sera publié par la voie habituelle le **jeudi 11 octobre 2001** à environ 7h30 (heure suisse). Grâce à l'accélération de s systèmes de comptabilité la date de publication a pu être **avancée de sept jours**.

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- INVITATION FOR TELEPHONE CONFERENCE -

## Nine Months 2001 Sales

Please note that we will publish our **2001 nine-month and third-quarter sales** on **Thursday 11 October 2001** at approximately 7:30 a.m. (Swiss time) through the usual channels. Enhanced reporting methods have enabled us to bring the publication date **forward by seven days**.

Date: Thursday, October 11, 2001

Time: 5:30 p.m. Switzerland

4:30 p.m. UK

11:30 a.m. New York

Phone numbers: +41 91 610 41 11 or "Free Phone" +800 2467 8700 (Europe and ROW)

+1 800 860 2442 USA

You may access the conference call as a live audio webcast on the Internet:

<http://www.novartis.com/investors> (see Upcoming Events). This site is already available for tests and for the submission of questions in advance.

- Telephone Playback -

Date: Thursday, October 11, 2001

Time: 7:00 p.m. for 48 hrs

Phone numbers: +41 91 610 25 00 (Europe and ROW)

+1 877 344 7529

Code: 195

## 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: November 7, 2001

By: /s/ RAYMUND BREU

Name: Raymund Breu

Title: Chief Financial Officer