

NOVARTIS AG  
Form 6-K  
November 02, 2004

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## SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

### FORM 6-K

#### REPORT OF FOREIGN PRIVATE ISSUER PURSUANT TO RULE 13a-16 or 15d-16 OF THE SECURITIES EXCHANGE ACT OF 1934

Report on Form 6-K for the month of October 2004  
(Commission File No. 1-15024)

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### Novartis AG

(Name of Registrant)

Lichtstrasse 35  
4056 Basel  
Switzerland

(Address of Principal Executive Offices)

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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 if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):

Yes:  No:

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Yes:  No:

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. Femara® gains U.S. FDA approval as only post-tamoxifen treatment for early breast cancer (Basel, Switzerland, October 29, 2004)
2. Novartis Institute for Tropical Diseases and TB Alliance announce partnership to develop novel tuberculosis drugs (Singapore / New York, October 27, 2004)

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3. Novartis receives European marketing authorization for Emselex® (Basel, Switzerland, October 27, 2004)
  4. Novartis and Orion Pharma launch first Parkinson's disease study to explore potential of delaying motor complications with Stalevo® (Basel, Switzerland, October 26, 2004)
  5. Australian agency approves Omnitrope (Vienna, October 4, 2004)
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### Investor Relations Release

#### **Femara® gains U.S. FDA approval as only post-tamoxifen treatment for early breast cancer**

*New treatment option the first to help postmenopausal women with early breast cancer remain cancer-free following adjuvant tamoxifen therapy*

**Basel, Switzerland, October 29, 2004** Femara® (letrozole) is the first therapy approved by the U.S. Food and Drug Administration (FDA) for the extended adjuvant treatment of postmenopausal women with early breast cancer who have received adjuvant (post-surgery) tamoxifen therapy for five years, Novartis announced today.

"Femara truly provides hope to women who have survived early breast cancer by offering them an improved chance of remaining cancer-free," said Diane Young, M.D., vice president and global head of Clinical Development at Novartis Oncology. "This priority review approval marks the first time that nearly 100,000 women who complete tamoxifen therapy each year will have a medical option to reduce their ongoing risk of breast cancer recurrence."

The term *extended adjuvant* describes the period following adjuvant (post- surgery) treatment with tamoxifen. Even years after breast cancer diagnosis and primary treatment, the ongoing risk of breast cancer recurrence remains significant for all patients. Globally, approximately one-third of women with estrogen receptor-positive early breast cancer experience a recurrence, and over half of those recurrences occur more than five years after surgery. While tamoxifen is beneficial for five years post surgery, if used beyond that period, the risks associated with it outweigh the benefits. Extended adjuvant treatment with Femara is the first therapy to effectively reduce ongoing risk of breast cancer recurrence.

The approval for the extended adjuvant indication was based on results from the landmark, international, independent MA-17 study, which included more than 5,100 postmenopausal women and was coordinated by the National Cancer Institute of Canada Clinical Trials Group at Queens University in Kingston, Ontario, Canada, and supported by Novartis. Initial results were published in the *New England Journal of Medicine* in October 2003.

The study showed that Femara reduced the risk of cancer coming back, or disease-free survival, by 38% and significantly increased a woman's chance of staying cancer-free. This is particularly important because when breast cancer recurs, it has very often spread beyond the breast (metastatic disease), which can have serious consequences. Femara also greatly reduced the chance of breast cancer returning to another part of the body, or distant metastases, by 39%.

#### **About Femara**

Femara is a leading once-a-day oral aromatase inhibitor that is also indicated for first-line treatment of postmenopausal women with hormone receptor-positive or hormone receptor-unknown locally advanced or metastatic breast cancer and for the treatment of advanced breast cancer in postmenopausal women with disease progression following antiestrogen therapy, and as neo-adjuvant (pre-operative) therapy. Not all indications are available in every country. Novartis has filed in the European Union for the indication of extended adjuvant treatment of early breast cancer in postmenopausal women who have completed adjuvant (post-surgery) tamoxifen therapy. In addition to the U.S., this indication is now approved in the United Kingdom, Switzerland, Mexico, Korea and other countries around the world. Femara is currently available in more than 80 countries worldwide.

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### **Femara contraindications and adverse events**

The most common adverse events experienced with Femara are hot flushes, arthralgia/arthritis and myalgia. Other commonly reported adverse reactions are: nausea, fatigue, anorexia, appetite increase, peripheral oedema, headache, dizziness, vomiting, dyspepsia, constipation, diarrhea, alopecia, increased sweating, rash, myalgia, bone pain, arthritis/arthralgia, and weight increase.

Femara is contraindicated in women who are pregnant or breast-feeding as well as in women with premenopausal endocrine hormone receptor status. Femara is contraindicated in patients with known hypersensitivity to Femara or any of its excipients.

The foregoing release contains forward-looking statements that can be identified by terminology such as "provides hope," "will have," "offering ... improved chance," or similar expressions, or by express or implied discussions regarding potential future sales of Femara. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results with Femara to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Femara will reach any particular sales levels. In particular, management's expectations regarding commercialization of Femara could be affected by, among other things, additional analysis of Femara clinical data; new clinical data; unexpected clinical trial results; unexpected regulatory actions or delays or government regulation generally; the company's ability to obtain or maintain patent or other proprietary intellectual property protection; competition in general; increased government, industry, and general public pricing pressures; and other risks and factors referred to in the Company's current Form 20-F on file with the U.S. Securities and Exchange Commission. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those anticipated, believed, estimated or expected. Novartis is providing the information in this press release as of this date and does not undertake any obligation to update any forward-looking statements contained in this press release as a result of new information, future events or otherwise.

### **About Novartis**

Novartis AG (NYSE: NVS) is a world leader in pharmaceuticals and consumer health. In 2003, the Group's businesses achieved sales of USD 24.9 billion and a net income of USD 5.0 billion. The Group invested approximately USD 3.8 billion in R&D. Headquartered in Basel, Switzerland, Novartis Group companies employ about 80,000 people and operate in over 140 countries around the world. For further information please consult <http://www.novartis.com>.

Additional information regarding Femara or Novartis Oncology can be found on the websites [www.femara.com](http://www.femara.com) or [www.novartisoncology.com](http://www.novartisoncology.com). Additional media information can be found at [www.novartisoncologyvpo.com](http://www.novartisoncologyvpo.com).

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**MEDIA RELEASE    COMMUNIQUE AUX MEDIAS    MEDIENMITTEILUNG**

**Novartis Institute for Tropical Diseases and TB Alliance announce partnership to develop novel tuberculosis drugs**

**Singapore/New York, October 27, 2004** The Novartis Institute for Tropical Diseases (NITD) and the Global Alliance for TB Drug Development (TB Alliance), a public-private partnership developing affordable new TB drugs, today announced plans to pursue a joint research program into novel, promising anti-tuberculosis agents.

The research will focus on identifying more lead compounds in the nitroimidazopyran class for the treatment of tuberculosis (TB), which continues to be a major global health problem. TB now infects one-third of the world's population and causes close to nine million new cases of active TB and 2 million deaths each year.

The TB Alliance will collaborate with the NITD in Singapore to identify a next generation of nitroimidazopyran compounds related to PA-824 for further development to improve TB therapy. PA-824 is one of the lead compounds of the TB Alliance portfolio and is on track to enter Phase I trials in 2005. The successful preclinical development of PA-824 has demonstrated the potential of this class of compounds and prompted additional investigations into this family of drugs for tuberculosis.

"The partnership between Novartis and the TB Alliance opens up global, cross-disciplinary avenues to test the full potential of this exciting novel class of compounds," said Maria C. Freire, President and CEO of the TB Alliance. "It combines the know-how of the pharmaceutical industry and the agility of the TB Alliance to accelerate the development of better and affordable treatments and bring them to registration."

Since its launch in 2003, the NITD pledged to partner with the TB Alliance and committed that the Novartis Group intends to make the resulting treatments readily available to poor patients without profit in those developing countries where the disease is endemic. This commitment falls directly in line with the TB Alliance's principle of "affordability, adoption and access."

"Novartis elected to contribute discovery science to the search for new, fast-acting and affordable TB drugs. This undertaking is the tangible proof of our commitment and demonstrates the vision inherent to the NITD," said Dr. Paul Herrling, Head of Corporate Research at Novartis and Chairman of the Novartis Institute for Tropical Diseases.

The agreement between the two organizations covers research and development roles for each party. The NITD will design, synthesize and optimize a series of nitroimidazopyran analogs for TB indication, tapping its broad medicinal chemistry expertise, know-how and biological evaluation capacity. The TB Alliance will contribute chemical intermediates, scientific expertise including structure design, and support for pharmacological studies.

As evidenced by PA-824 studies, nitroimidazopyrans have attractive features as potential drugs for TB. Their new mechanism of action is critical against multi-drug-resistant TB. Both *in vitro* and *in vivo* studies demonstrated excellent biological activity of this drug class. Other preclinical studies also indicated a favorable metabolic profile allowing combination with anti-retroviral therapy in joint TB-HIV treatment.

NITD's facility in Singapore is becoming central to the search for new TB therapies. Currently with >75< [Is this number accurate?] 65 researchers, Novartis' investment in the field of tropical and

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infectious disease research is an exception in an industry that has traditionally neglected illnesses that are seen as endemic within the developing world. The program, which has already been initiated, will synthesize multiple compounds around the most promising areas for chemical modification of PA-824. Scientists at U.S. National Institutes of Allergy and Infectious Disease of the NIH in Bethesda, Maryland, will also be contributing to the project.

"Developing faster-acting TB drugs is a critical strategy in the global response to the TB epidemic. The pragmatic plan and vision of this partnership is the kind of approach necessary to reverse this devastating health threat. New therapies that reduce treatment times and combat multi-drug resistant strains of TB are indispensable in our expanding efforts," said Dr. Mario Raviglione, Director of Stop TB at the World Health Organization.

The TB Alliance is taking the lead of building the first, most comprehensive portfolio of TB drug candidates in decades, and is accelerating discovery, preclinical and clinical research of nitroimidazopyrans, quinolones, macrolides, carboxylates and other known or novel classes of antibiotics to shorten and simplify the treatment of tuberculosis. The last class of TB drugs was registered in 1970 and the lengthy treatment (6-9 months) imposed by old drugs is hindering the progress of TB control.

"After a thirty-year wait, TB patients everywhere gain new hope at each sign of affordable new drugs coming down the pipeline. We commend public-private partnerships, such as this one between Novartis and the TB Alliance, that embrace principles of affordability, access and adoption," said Winstone Zulu, a TB-HIV patient advocate from Zambia.

For more information on TB drug development, nitroimidazopyrans, PA-824 and the TB Alliance, please visit [www.tballiance.org](http://www.tballiance.org).

#### **Corporate Legal to add Forward-looking statement if needed**

This release contains certain forward-looking statements which can be identified by the use of forward-looking terminology such as "plans to pursue", "promising", "will", "is on track", "potential", "intends to", "indicated", or similar expressions, or by express or implied discussions regarding the potential development and commercialization of new products or regarding potential future sales from any such products. Such statements reflect the current views of Novartis and/or TB Alliance with respect to future events and are subject to certain risks, uncertainties and assumptions. Many factors could cause the actual results to be materially different from any future results, performances or achievements that may be expressed or implied by such forward-looking statements. There can be no guarantee that the aforementioned joint research program will lead to the development or commercialization of any new products in any market, or that any such products will reach any particular sales levels. Any such commercialization or sales can be affected by, among other things, uncertainties relating to product development and clinical trials; regulatory actions or delays or government regulation generally; the ability to obtain or maintain patent or other proprietary intellectual property protection; the ability to gain funding for clinical development; competition in general; and government, industry and general public pricing pressures; as well as factors discussed in Novartis AG's current Form 20-F on file with the Securities and Exchange Commission. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those described herein as anticipated, believed, estimated or expected. Novartis is providing this information as of this date and does not undertake any obligation to update any forward-looking statements contained in this document as a result of new information, future events or otherwise.

#### **About the Global Alliance for TB Drug Development**

The Global Alliance for TB Drug Development (TB Alliance) is a not-for-profit, public-private partnership accelerating the discovery and/or development of affordable, new anti-TB drugs that will shorten treatment, be effective against multi-drug resistant strains, and improve treatment of latent infection. In collaborations with public and private research laboratories worldwide, it is leading the development of the first, most comprehensive portfolio of TB drug candidates in three decades. It

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operates with the support of public and philanthropic funds from the Bill and Melinda Gates Foundation, the Rockefeller Foundation, the United States Agency for International Development, the Netherlands Ministry for Cooperation Development and the National Institutes of Health.

**About Novartis Novartis Institute for Tropical Diseases**

The Novartis Institute for Tropical Diseases aims to discover novel treatments and prevention methods for major tropical diseases. Initially, Dengue fever and Tuberculosis will be addressed. In those developing countries where these diseases are endemic, the Novartis Group intends to make treatments readily available and without profit to poor patients. The Institute will recruit the best scientific specialists in the world, and as a major center of excellence, will offer exceptional teaching and training opportunities for post-doctoralfellows and graduate students.

Novartis AG (NYSE: NVS) is a world leader in pharmaceuticals and consumer health. In 2003, the Group's businesses achieved sales of USD 24.9 billion and a net income of USD 5.0 billion. The Group invested approximately USD 3.8 billion in R&D. Headquartered in Basel, Switzerland, Novartis Group companies employ about 80 000 people and operate in over 140 countries around the world. For further information please consult <http://www.novartis.com>.

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### Investor Relations Release

#### Novartis receives European marketing authorization for Emselex®

*New M3 selective receptor antagonist treatment for overactive bladder*

**Basel, October 27, 2004** Novartis Pharma AG announced today that Emselex® (darifenacin hydrobromide), 7.5 mg and 15 mg, has been granted Marketing Authorization by the European Commission for the treatment of overactive bladder (OAB) in all 25 European member states as well as Norway and Iceland.

"The approval of Emselex will provide many people in Europe who experience OAB symptoms a safe and effective new treatment option," said Jörg Reinhardt, Global Head of Development, Novartis Pharma AG. "Emselex has an excellent efficacy as well as central nervous system and cardiovascular safety profile, offering physicians a new choice for treating people with overactive bladder."

Emselex is a once-daily M3 selective receptive antagonist (M3 SRA) oral treatment that works by selectively inhibiting the detrusor muscle that controls bladder contraction while sparing the M1 and M2 receptors believed to be involved in central nervous system (CNS) and cardiovascular (CV) function, respectively.<sup>(1)</sup> Emselex has been shown to reduce the number of weekly incontinence episodes by up to 77%<sup>(2)</sup> versus placebo. Additional clinical trials have shown that Emselex works without impairing cognitive function<sup>(3)</sup> and without cardiovascular safety concerns<sup>(2)</sup>.

To date, 97 clinical trials with Emselex have been carried out involving more than 10,500 subjects and patients, of whom 7,146 were treated with darifenacin. Across a range of pivotal endpoints, Emselex has been shown to significantly improve all other key symptoms of OAB, including the number of times patients had to visit the bathroom each day, bladder capacity, frequency of urgency, severity of urgency and number of incontinence episodes leading to a change in clothing or pads.<sup>(1)</sup>

#### About OAB

Symptoms of overactive bladder include urinary urgency (a sudden and compelling desire to pass urine, which is difficult to defer) with or without urge incontinence (involuntary leakage accompanied by urgency), urinary frequency (voiding the bladder too often), and nocturia (waking at night one or more times to void the bladder).

#### Disclaimer

This release contains certain forward-looking statements that can be identified by the use of forward-looking terminology, such as "will provide", or similar expressions, or by express or implied discussions regarding potential additional marketing approvals or future sales of Emselex. Such forward looking statements reflect the current views of the Company regarding future events, and involve known and unknown risks, uncertainties and other factors that may cause the actual results with Emselex to be materially different from any future results, performance, or achievements expressed or implied by such statements. There can be no guarantee that Emselex will receive any additional marketing approvals in any other countries, or that it will reach any particular sales levels. Any such results can be affected by, among other things, uncertainties relating to clinical trials, regulatory actions or delays or government regulation generally, the ability to obtain or maintain patent or other proprietary intellectual property protection, competition in general, government, industry, and general public pricing pressures, as well as factors discussed in the Company's Form 20-F filed with the

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US Securities and Exchange Commission. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those described herein as anticipated, believed, estimated or expected. Novartis is providing the information in this press release as of this date and does not undertake any obligation to update any forward-looking statements contained in this press release as a result of new information, future events or otherwise.

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#### **References**

- (1) Haab F et al. Darifenacin, an M3 Selective Receptor Antagonist, is an Effective and Well-Tolerated Once-Daily Treatment for Overactive Bladder. *European Urology*. 2004; 45: 420-429.
- (2) Chapple C. Darifenacin is effective in improving the major symptoms of overactive bladder: A pooled analysis of phase III studies. *Eur Urol Suppl* 2004;3(2):A512
- (3) Wesnes K, Lipton R, Kolodner K, Edgar C. Darifenacin, an M3 selective receptor antagonist for the treatment of overactive bladder, does not affect cognitive function in elderly volunteers. *Eur Urol Suppl* 2004;3(2):A513

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**MEDIA RELEASE COMMUNIQUE AUX MEDIAS MEDIENMITTEILUNG**

**Novartis and Orion Pharma launch first Parkinson's disease study to explore potential of delaying motor complications with Stalevo®**

*Parkinson's patients who require the start of levodopa therapy may be eligible to participate in this study*

**Basel, Switzerland, October 26, 2004** Novartis and Orion Pharma announced that they are launching STRIDE-PD (STalevoReduction In Dyskinesia Evaluation). This major study in Parkinson's disease (PD) seeks to investigate if, when used as an initial therapy, the optimized levodopa medication Stalevo (containing levodopa, carbidopa and entacapone) delays the onset of motor complications, such as dyskinesias, in comparison with the traditional formulation of levodopa/carbidopa.

STRIDE-PD will enroll approximately 740 patients at 70 centers in 14 countries: Austria, Belgium, Canada, France, Finland, Germany, Greece, Italy, Spain, Sweden, Turkey, Switzerland, the United Kingdom and the United States of America. Patient recruitment has started in September and is estimated to continue for 12 months. The first study results are expected in 2007.

Patients with PD between 30 and 70 years of age who have been diagnosed within the last five years prior to study initiation and who require the start of levodopa therapy to manage their symptoms may be eligible to participate in this two-year study.

"The importance of the STRIDE-PD study could be major. If the study shows that Stalevo is superior to traditional levodopa/carbidopa therapy in the time to onset of dyskinesias, this could change the current treatment paradigm completely," said Professor Werner Poewe, Chair of the Department of Neurology at Innsbruck University, Austria. "We would then use Stalevo from the very first day in patients needing levodopa treatment."

Levodopa is the most effective and most widely used symptomatic PD treatment and has remained the "gold standard" of care for nearly 40 years. The vast majority of people with PD eventually require levodopa treatment to control their symptoms, even if they begin their therapy with another drug. However, after several years of treatment with levodopa, patients often begin to experience motor complications, such as "wearing-off" (when the effect of one dose of medication does not last until the next scheduled dose) and dyskinesias.

Characterized by abnormal and involuntary movements, dyskinesias are a major challenge for people with PD since they can result in fragmented or jerky motions that are different from the rhythmic tremor commonly associated with PD.

"We are very excited about the launch of STRIDE-PD. Dyskinesias often become a serious problem for people with PD. Delaying the onset of these motor complications would therefore offer a real improvement in the quality of life for patients and their families," said Mary Baker, President of the European Parkinson's Disease Association (EPDA), United Kingdom.

For further information on STRIDE-PD, please also refer to [www.epda.eu.com](http://www.epda.eu.com).

**About Stalevo**

Stalevo (levodopa, carbidopa and entacapone) is a new and optimized levodopa product with a longer duration of action compared to traditional levodopa/carbidopa preparations.

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Stalevo tablets are currently indicated for certain PD patients who are experiencing "wearing-off" motor complications. In patients with "wearing-off," clinical studies have shown that the addition of entacapone to levodopa/carbidopa can significantly extend the duration of benefit of each medication dose and enhance the PD patients' ability to control body movements and perform basic functions, such as walking and dressing. Myllylä V, Haapaniemi T, Hartikainen P, Nuutinen J, Rissanen A, Kuopio A-M, Jolma T, Satomaa O, Kinnunen E, Kaakkola S. First experiences of new triple combination of levodopa/carbidopa/entacapone in the treatment of patients with Parkinson's disease (2003) *Eur J Neurol* 10:suppl1 (163(P2140))., Brooks D, Agid Y, Østergaard K, Widner H and Oertel W, on behalf of the TCINIT study group. A new triple combination tablet is easy to initiate and provides improved symptom control in patients with Parkinson's disease (2003) *Eur J Neurol* 10:Suppl1;241(P3108).

The most common side effects of Stalevo therapy are dopaminergic in nature (e.g. dyskinesia, nausea.) These side effects may be manageable with alteration in the drug dosing schedule. Other common side effects include diarrhea, hyperkinesias, urine discoloration, hypokinesia, abdominal pain, dizziness, constipation, fatigue, pain and hallucinations. For full prescribing information, visit [www.stalevo.com](http://www.stalevo.com).

Stalevo, developed by Orion Pharma, is marketed by Novartis and Orion Pharma in their respective territories. Stalevo is available in Austria, Belgium, Brazil, Denmark, Iceland, Ireland, Finland, France, Germany, Greece, Luxemburg, the Netherlands, Norway, Spain, Sweden, Switzerland, the United Kingdom and the United States.

#### **About Parkinson's disease**

PD is a chronic and progressive neurological condition that affects 6.3 million people worldwide. One percent of people over the age of 60 and two percent of people over the age of 80 suffer from this disease. *Parkinson's Disease Fact Sheet*, European Parkinson's Disease Association.

While their cause is unknown, PD symptoms are primarily the result of a degeneration of dopaminergic cells, or neurons, in the substantia nigra, a part of the brain that controls and modulates movement.

Symptoms include limbs that tremble, slowness of movement, stiffness and rigidity of limbs and gait or balance problems. As the disease progresses, these symptoms usually increase and impact a person's ability to work and function.

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**About Novartis**

Novartis has been a leader in the neuroscience area for more than 50 years, having pioneered early breakthrough treatments for Alzheimer's disease, Parkinson's disease, attention deficit/hyperactivity disorder, epilepsy, schizophrenia and migraine. Novartis continues to be active in the research and development of new compounds, is committed to addressing unmet medical needs and to supporting patients and their families affected by these disorders.

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**MEDIA RELEASE    COMMUNIQUE AUX MEDIAS    MEDIENMITTEILUNG**

**Australian agency approves Omnitrope**

**Vienna, October 4, 2004** Sandoz has received approval from the Australian Therapeutic Goods Administration (TGA) to market the recombinant DNA human growth hormone Omnitrope. The TGA has recognized the safety and efficacy of Omnitrope by approving the product.

**Company Information**

Sandoz, a Novartis company, is a world leader in generic pharmaceuticals and develops, manufactures and markets these medicines as well as pharmaceutical and biotechnological active ingredients. Decades of experience and profound know-how make Sandoz a renowned partner in its pharmaceuticals, biopharmaceuticals and industrial products franchises. Sandoz employs around 13,000 people worldwide and posted sales of USD 2.9 billion in 2003.

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**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

**Novartis AG**

Date: November 1, 2004

By:           /s/ MALCOLM B. CHEETHAM          

Name: Malcolm B. Cheetham

*Title: Head Group Financial Reporting and Accounting*

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