

NOVARTIS AG  
Form 6-K  
June 30, 2005

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# SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

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## 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 June 2005  
(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:

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

Yes:  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:

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## Edgar Filing: NOVARTIS AG - Form 6-K

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**INVESTOR RELATIONS RELEASE**

**FDA grants priority review for Exjade® for the treatment of chronic iron overload due to blood transfusions**

**Basel, Switzerland, June 22, 2005** Novartis announced today that its New Drug Application for Exjade® (deferasirox) has been granted priority review by the U.S. Food and Drug Administration (FDA) as a once-daily oral iron chelator for the treatment of chronic iron overload due to blood transfusions.

The FDA grants priority review to products that could potentially offer a significant improvement compared to marketed products in the treatment, diagnosis or prevention of a disease. A novel, easy to administer oral iron chelator, Exjade is taken once daily, after dispersing tablets in a glass of water or orange juice. The current standard of care in iron chelation, deferoxamine is effective, but typically requires subcutaneous infusion lasting eight to twelve hours per day, for five to seven days a week for as long as the patient continues to receive blood transfusions. In many patients, the need for transfusion and chelation therapy may be life-long.

"The priority review by the FDA reflects the potential of Exjade to fulfill a significant unmet medical need for patients with chronic iron overload," said Diane Young, MD, vice president, global head, Clinical Development, Novartis Oncology. "We hope that once Exjade becomes available as a treatment option, it will not only improve the quality of life of those patients who for years have endured the discomfort of deferoxamine, but will also provide a new and acceptable treatment option for those who have been risking their lives by avoiding chelation therapy altogether because of the burdensome nature of the current standard of care."

A priority review establishes an action date no later than six months after the submission date, which for Exjade was in May 2005. At that time, Novartis also submitted registration applications for Exjade in the European Union, Switzerland and Australia. Exjade, also known as investigational agent ICL670, has also been granted priority review in Australia and fast track status in Switzerland. Further, Exjade has received Orphan Drug status in the U.S., EU and Australia.

Iron overload is a potentially life-threatening condition that results from frequent blood transfusions required to treat certain types of anemias and other disorders, including thalassemia, sickle cell disease, other rare anemias and myelodysplastic syndromes. If left undiagnosed or untreated, iron overload can lead to damage to the liver, heart and endocrine glands, and can be fatal. Transfused patients are often treated for iron overload with a type of drug therapy called iron chelation, which removes excess iron from the body.

### **Filing data**

The Exjade global clinical trials program enrolled more than 1,000 patients and is the largest ever prospectively implemented for an investigational iron chelator. The filings are based on the results of pivotal clinical trials, including a Phase III head-to-head trial vs. deferoxamine, which showed that Exjade significantly reduced liver iron concentration (LIC), an accepted indicator for body iron content, at doses of 20 and 30mg/kg/day in adult and pediatric patients receiving blood transfusions. The studies demonstrated that Exjade led to the maintenance or reduction of absolute LIC in regularly transfused patients with different underlying diseases.

The primary endpoint of the trial was the achievement of a specified reduction in LIC after one year of therapy. Those with lower initial LIC values on the deferoxamine arm were permitted to remain on their pre-study doses and were compared to patients receiving the lower doses of 5 or 10 mg/kg/day of ICL670. Therefore, many of these individuals received significantly higher doses of deferoxamine relative to ICL670. At 20 and 30 mg/kg/day ICL670 demonstrated non-inferiority when compared to deferoxamine. However, at doses of 5 and 10 mg/kg/day Exjade did not achieve non-inferiority. Thus, there is a clear dose response relationship for Exjade, demonstrating that 20 and 30 mg/kg/day are the clinically relevant doses.

In the clinical studies in both adults and children as young as two years of age, Exjade was generally well tolerated, with the most frequently reported adverse events being nausea, vomiting, diarrhea, abdominal pain, skin rash and mild stable increases in serum creatinine, usually within the normal range.

### **Additional Information**

To learn more about Exjade clinical trials, health care providers can call either 0800 328 9875 or +44 (0) 1506 814895.

The foregoing release contains forward-looking statements that can be identified by terminology such as "that represent," "potential," "becomes available," "if approved," "would be," "will improve," or similar expressions, or by express or implied discussions regarding potential additional marketing approvals or future sales of Exjade. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results with Exjade to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Exjade will receive any additional marketing approvals in any other countries, or that it will reach any particular sales levels. In particular, management's expectations regarding commercialization of Exjade could be affected by, among other things, additional analysis of Exjade 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.

For prescribing information on deferoxamine please contact your local Novartis affiliate.

**About Novartis**

Novartis AG (NYSE: NVS) is a world leader in pharmaceuticals and consumer health. In 2004, the Group's businesses achieved sales of USD 28.2 billion and pro forma net income of USD 5.6 billion. The Group invested approximately USD 4.2 billion in R&D. Headquartered in Basel, Switzerland, Novartis Group companies employ about 81,400 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**

**FTY720, a novel once-daily oral medication, shows promising results in treatment of multiple sclerosis**

*Over two million people worldwide are estimated to suffer from multiple sclerosis, which is the leading cause of neurological disability in young adults* Multiple Sclerosis International Federation  
([http://www.msif.org/en/ms\\_the\\_disease/quick\\_facts.html](http://www.msif.org/en/ms_the_disease/quick_facts.html))

*Currently approved therapies have only limited clinical effect and require frequent injections*

**Basel, Switzerland, June 21, 2005** Phase II data presented today at the 15th European Neurological Society (ENS) meeting in Vienna showed that FTY720, a novel oral medication for the treatment of multiple sclerosis (MS), reduced the rate of clinical relapses by more than 50% and inflammatory disease activity as measured by magnetic resonance imaging (MRI) by up to 80% over six months compared to placebo.

Benefits of FTY720 therapy were seen as soon as after two months of treatment and continued to increase over the six month treatment period compared to placebo. Over 90% of patients completed the study.

"FTY720 has shown a significant and consistent effect on both clinical relapses and MRI measures in just six months. With its novel mode of action and the added benefit of an oral formulation taken once daily, further clinical development of FTY720 might have a major impact on the way we treat MS in the future. We hope that the magnitude of benefits shown in phase II will be confirmed in the larger scale phase III study program," said Professor Ludwig Kappos, MD, Department of Neurology, University Hospital, Basel, Switzerland.

Based on the positive Phase II study results, Novartis is currently discussing with regulatory authorities the FTY720 Phase III program which is expected to be launched in the fourth quarter of 2005 involving centers in North America and Europe.

MS is the most common chronic, disabling disease of the central nervous system affecting young people in the prime of their lives. It is the leading cause of neurological disability in young adults.<sup>1</sup> Currently marketed MS therapies have only limited clinical effect with an average reduction in relapse rates of about 30% based on two year studies.

Furthermore, they require frequent injections ranging from daily to weekly. Patient surveys show that second to limited efficacy one of the main obstacles to initiating and maintaining MS therapy long-term are the patient's fear of needles, the inconvenience of injecting and side effects associated with current therapies, such as flu-like symptoms and injection site reactions. Primary market research TNS healthcare 8/04, NOP World Health Report on MS 11/04.

The six-month results are from a large double-blind, placebo-controlled, Phase II study conducted at 32 centers in 11 countries (Europe and Canada) in 281 patients with relapsing MS, the most common form of the disease. The study evaluated the effect of FTY720 on disease activity as measured by MRI and clinical relapses as well as its tolerability and safety over a treatment period of six months. Study participants were randomized in equal numbers to receive either FTY720 1.25 mg, FTY720 5 mg, or placebo.

**FTY720 phase II study results** FTY720 in relapsing MS: Results of a double blind placebo controlled trial with a novel oral immunomodulator. Clinical Abstract of data presented at the 15th European Neurological Society meeting, Vienna, June 18-22, 2005.

Relapse rates were reduced by 55% in the FTY720 1.25mg group ( $p=0.009$ ) and 53% in the FTY720 5mg group ( $p=0.014$ ) compared to placebo. Time to first confirmed relapse was significantly prolonged in both FTY720 groups ( $p=0.007$  in FTY720 1.25 mg,  $p=0.012$  in FTY720 5 mg) and 86% of patients in both FTY720 treatment groups remained relapse-free over six months compared to 70% of patients on placebo ( $p=0.007$  in FTY720 1.25 mg,  $p=0.008$  in FTY720 5 mg).

Inflammatory disease activity as measured by the total number of gadolinium (Gd) enhancing T1 MRI lesions was reduced by up to 80% ( $p<0.001$  in FTY720 1.25 mg,  $p<0.006$  in FTY720 5 mg) over six months of treatment. Furthermore, new disease activity as measured by new T2 MRI lesions was reduced by more than two thirds in both FTY720 doses ( $p<0.001$ ) compared to placebo.

Effects on relapses and MRI were seen as soon as after two months of treatment and continued to increase over the six month treatment period compared to placebo. "These consistent effects on MRI and clinical outcomes with both treatment doses are very encouraging as this short-term study was primarily powered to detect effects on MRI lesions but not on clinical outcomes," concluded Professor Kappos.

FTY720 appeared to be generally well tolerated with 92% of patients completing the six-month treatment period and 98% of those patients volunteered to continue in the ongoing extension phase. Most frequently reported adverse events were related to non-serious infections (such as colds), gastrointestinal disorders (such as diarrhea and nausea), nervous system disorders (such as headaches) and respiratory disorders (such as short breath and cough). The overall incidence of adverse events was higher in the FTY720 5 mg group compared to the FTY720 1.25 mg and placebo groups.

#### **FTY720 Phase III MS study program**

These findings need to be confirmed in larger scale clinical studies of longer duration. As FTY720 is also being developed for use in renal transplantation, the US Food and Drug Administration (FDA) has asked Novartis to conduct an overall safety analysis of FTY720's transplantation safety database. As a result, the Phase III program in MS is expected to be launched in the fourth quarter of 2005 involving centers in North America and Europe.

"Novartis has been a leader in neuroscience for more than 50 years. FTY720 is important because it affirms our commitment to provide people with MS, their families and treating physicians with a long-awaited significant improvement in MS therapy," said Jörg Reinhardt, Global Head of Development.

#### **About FTY720**

FTY720 is a once-daily oral medication with a novel mode of action offering the potential of an innovative approach to MS treatment. It is the first sphingosine-1-phosphate (S1P) receptor modulator.

FTY720 differs from currently approved treatments because it is the only medication that binds the receptors of S1P, present on the surface of lymphocytes, which are a subpopulation of white blood cells. In MS, lymphocytes circulating in the central nervous system (e.g. the brain and spinal cord) attack the myelin sheath that surrounds and protects nerve fibers (axons) which are responsible for transmitting nerve signals to other parts of the body.

As a consequence of receptor binding, the lymphocytes can no longer respond to the molecule that signals them to circulate to sites of inflammation in the body and they stay in the lymph nodes. However, the lymphocytes remain functional and may still be activated within the lymph nodes as part of the immune response.

FTY720 has been developed by Novartis Pharma and licensed from Mitsubishi Pharma Corporation.

### **About Multiple Sclerosis**

Over two million people worldwide are estimated to suffer from multiple sclerosis, which is the leading cause of neurological disability in young adults.<sup>1</sup> MS is the most common inflammatory and neurodegenerative disorder of the central nervous system, including the brain, spinal cord and optic nerves. Multiple Sclerosis International Federation ([http://www.msif.org/en/ms\\_the\\_disease/index.html](http://www.msif.org/en/ms_the_disease/index.html)) It is usually diagnosed between age 20 and 40 and is twice as common in women as men.<sup>1</sup> A patient can go for months, years or even decades without a relapse. Multiple Sclerosis International Federation ([http://www.msif.org/en/ms\\_the\\_disease/types\\_of\\_ms.html](http://www.msif.org/en/ms_the_disease/types_of_ms.html)) However about 50% of sufferers need a cane for walking up to 100 meters after 15 years. Weinshenker BG. Natural history of multiple sclerosis. Ann Neurol 1994, 36: S6-S11.

MS typically presents in relapsing forms. The relapsing-remitting (RRMS) course is the most common form of the disease. Patients suffer acute self-limiting attacks (relapses) of neurological dysfunction followed by complete or incomplete remission in function. Over time, transmission of electrical nerve impulses is disrupted, nerve cells are destroyed, and patients experience symptoms ranging from fatigue, tingling, numbness and blurred vision to poor muscle control with partial or complete paralysis, speech or mental impairment.

About 50% of patients advance to the secondary progressive (SPMS) course within 10 years.<sup>6</sup> MS has a significant impact on the patient's social activities, employment and overall quality of life.



This release contains certain forward-looking statements relating to Novartis' business, which can be identified by the use of forward-looking terminology such as "long-awaited breakthrough," "the first of several new and exciting," "innovative approach," or similar expressions, or regarding potential future revenue from FTY720. Such forward-looking statements reflect the current views of Novartis regarding future events, and involve known and unknown risks, uncertainties and other factors that may cause actual results with FTY720 to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that FTY720 will be approved for any additional indications or labeling in any market. Nor can there be any guarantee of potential future sales of FTY720. Neither can there be any guarantee regarding the long-term impact of a patient's use of FTY720. In particular, management's expectations regarding commercialization of FTY720 could be affected by, among other things, unexpected clinical trial results; unexpected regulatory actions or delays or government regulation generally; Novartis' ability to obtain or maintain patent or other proprietary intellectual property protection; competition in general; government, industry and general public pricing pressures, and other risks and factors referred to in Novartis' current Form 20-F on file with the US Securities and Exchange Commission. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those anticipated, believed, estimated or expected. Novartis 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 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.

Novartis AG (NYSE: NVS) is a world leader in pharmaceuticals and consumer health. In 2004, Novartis' businesses achieved sales of USD 28.2 billion and a net income of USD 5.8 billion. Novartis invested approximately USD 4.2 billion in R&D. Headquartered in Basel, Switzerland, the Novartis group of companies employ about 81,400 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 extends tender offer for Eon Labs, Inc. through July 1, 2005**

**Basel, June 21, 2005** Novartis announced today that Zodnas Acquisition Corp., an indirect wholly owned subsidiary of Novartis, is extending its cash tender offer to acquire all outstanding public shares of Eon Labs, Inc. (NASDAQ: ELAB) from the prior expiration date of 12:00 midnight New York City time on June 20, 2005 to 5:30 pm New York City time on July 1, 2005.

Accordingly, the tender offer and withdrawal rights will expire at 5:30 pm New York City time on July 1, 2005. However, if shares are not accepted for payment by July 21, 2005, Eon shareholders will be able to withdraw their tendered shares at any time after July 21, 2005 and before their shares are accepted for payment.

Based on a preliminary count by the depositary for the offer, there were tendered and not withdrawn 22,152,720 shares of Eon Labs common stock as of 12:00 midnight on June 20, 2005 and an additional 2,297,759 shares are guaranteed to be delivered within the next three days.

The completion of the tender offer and the purchase by Novartis of the 67.7 percent stake in Eon Labs from Santo Holding (Deutschland) GmbH, Eon's majority shareholder, are subject to the receipt of U.S. regulatory approval. Novartis will purchase Santo's shares immediately following completion of the tender offer.

A hearing on plaintiff's motion for a preliminary injunction in In re Eon Labs, Inc. Shareholders Litigation is currently scheduled for July 8, 2005 in the Delaware Chancery Court in the U.S. Novartis does not currently expect to receive regulatory approval prior to the court's hearing. However, Novartis, Eon and Santo have agreed that Novartis will not complete the tender offer or the purchase of Santo's shares while the motion for preliminary injunction is pending.

This document contains "forward-looking statements" within the meaning of the US Private Securities Litigation Reform Act. Forward-looking statements are statements that are not historical facts and are generally identified by the words "expects", "anticipates", "believes", "intends", "estimates", "will", or similar expressions, or by express or implied discussions regarding strategies, plans and expectations (including synergies). These statements include, but are not limited to, financial projections and estimates and their underlying assumptions, statements regarding the benefits of the business transactions described herein, including future financial and operating results. Such statements reflect the current plans, expectations, objectives, intentions or views of management with respect to future events, are based on the current beliefs and expectations of management and are subject to significant risks, uncertainties and assumptions. Management's expectations could be affected by, among other things, competition in general, the general economic environment and other risks such as, but not limited to, those referred to in Novartis AG's 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 differ materially from those set forth or implied by the forward-looking statements.

The following factors, among others, could cause actual results to differ materially from those set forth in the forward-looking statements: the ability to obtain governmental approvals for the transaction on the proposed terms and schedule; the risk that the businesses will not be integrated successfully; the risk that the cost savings and any other synergies from the transaction may not be fully realized or may take longer to realize than expected; disruption from the transaction making it more difficult to maintain relationships with customers, employees or suppliers; social and political conditions such as war, political unrest and terrorism or natural disasters; and general economic conditions and normal business uncertainty and competition and its effect on pricing, spending, third-party relationships and revenues. These forward-looking statements speak only as of the date of this press release and no undertaking has been made to update or revise them if there are changes in expectations or if any events, conditions or circumstances on which any such forward looking statement is based. Forward-looking statements made in connection with a tender offer are not subject to the "safe harbor" provided for in the Private Securities Litigation Reform Act of 1995.

**Securityholders of Eon are urged to read the tender offer statement, LETTER OF TRANSMITTAL AND OTHER MATERIALS relating to the tender offer, as THEY contain important information, including the various terms of, and conditions to, the tender offer. Securityholders can obtain a copy of the tender offer statement, LETTER OF TRANSMITTAL AND OTHER RELATED MATERIALS FREE OF CHARGE at the SEC's internet site (<http://www.sec.gov>) or from the information agent for the tender offer, Georgeson Shareholder Communications Inc., by calling (877) 278-4774 (call toll-free). We urge EON securityholders to carefully read those materials prior to making any decisions with respect to the tender offer.**

#### About Novartis

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Further information is available at [www.novartis.com](http://www.novartis.com).

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 know-how make Sandoz a renowned partner in pharmaceuticals, biogenerics and industrial products. Sandoz employs approximately 13,000 people in over 110 countries and reported sales of USD 3.0 billion in 2004.

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**MEDIA RELEASE COMMUNIQUE AUX MEDIAS MEDIENMITTEILUNG**

**New data reinforce powerful blood pressure-lowering efficacy with Diovan®/Co-Diovan® based regimens**

*New evidence of cardiovascular and metabolic benefits further underscores strength of Diovan in high-risk hypertension patients*

**Milan, Italy, June 20, 2005** People with moderate to severe hypertension treated with a combination of Diovan® (valsartan) and the diuretic hydrochlorothiazide (HCTZ) benefited from superior blood pressure reductions over those treated with amlodipine, according to the VAST study presented at the 15th European Meeting on Hypertension.

In addition, further data presented at the meeting underscored the benefits of powerful blood pressure lowering and potential protective metabolic and cardiovascular effects with Diovan-based treatment regimens, both as monotherapy and in combination with the diuretic HCTZ.

Diovan, the No. 1 angiotensin II-receptor blocker (ARB) worldwide, is also available in a once-daily fixed-dose combination with HCTZ as Co-Diovan® (valsartan and HCTZ), a potent agent for the treatment of hypertension.

According to the VAST study, patients with moderate to severe hypertension treated with a combination of Diovan and HCTZ (160/25) benefited from superior blood pressure reductions over those treated with amlodipine 10mg.

"We already know that valsartan provides effective blood pressure-lowering and heart-saving benefits to people who have had a heart attack or have heart failure. Now these new data add to our understanding of valsartan's efficacy in people with even earlier forms of heart disease," said Luis Ruilope, MD, Hospital 12 de Octubre of Madrid, Spain, the primary investigator of VAST and an investigator for VALUE. "Large-scale trials have repeatedly shown that most high-risk patients with hypertension require aggressive treatment, either with a powerful monotherapy or more often with an effective fixed-dose combination, to reach healthy blood pressure goals."

The results of VAST and the new analyses of VALUE follow the mandate from experts and guidelines which emphasize the critical need for more aggressive initial management of hypertension. Although cardiovascular disease (CVD) can be treated or prevented, according to the World Health Organization (WHO), across the globe around 17 million people die of CVD-related events each year, for which hypertension is a major contributing factor. Also, alarmingly, of those patients with hypertension who are treated, nearly 7 out of 10 do not achieve the goal of 140/90 mmHg as recommended by treatment guidelines. Patients with moderate to severe hypertension (160/100 mmHg), such as those in VAST, are at four times greater risk for cardiovascular events than those with optimal blood pressure (<120/80 mmHg). In a sub-study of VAST, a significantly greater proportion of patients treated with Diovan plus HCTZ 160/25 mg reached their blood pressure goal ( $\leq$ 130/80 mmHg, measured by ambulatory monitoring) versus amlodipine 10mg (60.8% Diovan + HCTZ 160/25 mg vs. 48.4% Diovan + HCTZ 160/12.5 mg vs. 50.9% amlodipine 10mg;  $p < 0.05$  for Diovan + HCTZ 160/25 mg vs. amlodipine 10mg). Ruilope L et al. 24-Hour Ambulatory Blood-Pressure Effects of Valsartan + Hydrochlorothiazide Combinations Compared with Amlodipine in Hypertensive Patients at Increased Cardiovascular Risk. *Blood Pressure Monitoring* 2005 10:85-91.

"As demonstrated by one of the largest clinical trials programs in its class, Diovan provides a unique range of benefits to patients with cardiovascular disease," said Joerg Reinhardt, Head of Development, Novartis Pharma AG. "We have shown benefit over amlodipine, both as an effective monotherapy, where we have shown benefit in both heart failure and new onset diabetes, and in combination with a diuretic. The overall program has shown Diovan to effectively help patients get to goal and maintain a healthy blood pressure while providing additional longer-term cardioprotective benefits."

#### **More on VAST Presented at European Meeting on Hypertension**

VAST (Valsartan/HCTZ versus Amlodipine in Stage II hypertensive patients with additional risk factors) was a multicenter, multinational, randomized, double-blind, active-controlled, parallel group, 24-week study designed to evaluate the efficacy of Diovan + HCTZ 160/12.5 mg, Diovan + HCTZ 160/25 mg and amlodipine 10 mg on systolic blood pressure in a broad population of 1,088 patients with moderate to severe high blood pressure and additional cardiovascular risk factors. Mean systolic blood pressure at baseline was 167 mmHg, 166 mmHg, 166 mmHg for Diovan + HCTZ 160/12.5 mg, Diovan + HCTZ 160/25 mg and amlodipine, respectively. The mean diastolic blood pressure at baseline was 94 mmHg, 93 mmHg and 94 mmHg respectively.

Diovan + HCTZ 160/25 mg demonstrated superior efficacy in reducing systolic blood pressure vs. amlodipine 10mg ( $p < 0.05$ ). Mean changes in blood pressure were: -29.7  $\pm$  0.7 mmHg, 27.1  $\pm$  0.7 mmHg and 27.6  $\pm$  0.7 mmHg for the Diovan + HCTZ 160/25 mg, Diovan + HCTZ 160/12.5 mg and amlodipine groups, respectively. The difference in diastolic blood pressure between the groups was not statistically significant. Both Diovan + HCTZ 160/25 mg and 160/12.5 mg compared with amlodipine 10mg had a significantly lower rate of treatment-related adverse events (15.4% and 13.9% respectively vs. 42.7%;  $p < 0.05$ ).<sup>1</sup>

#### **More on VALUE Presented at European Meeting on Hypertension**

The new analyses of VALUE (Valsartan Antihypertensive Long-Term Use Evaluation) trial presented documented that Diovan-based antihypertensive regimens provide patients with important cardiovascular and metabolically protective effects.

One of these analyses suggested that patients taking Diovan experienced similar blood pressure reductions with significantly fewer heart failure events compared to patients taking amlodipine monotherapy ( $p = 0.045$ ). There were no differences in effects on stroke, MI or the primary endpoint of cardiac morbidity and mortality observed between the two treatment regimens in this analysis.<sup>2</sup>

The second analysis from the VALUE trial suggested that the Diovan-based regimen was associated with a significant 23% reduction in the development of type II diabetes in high-risk patients compared with the amlodipine-based regimen. This finding was more significant in those patients at highest risk for developing diabetes.<sup>3</sup>

### **About Diovan**

Novartis remains on the forefront of cardiovascular medicine, through development of innovative products like Diovan, one of the most prescribed antihypertensives in the world today. Novartis recently announced the successful completion of the EU Mutual Recognition Procedure (MRP) in 14 countries for Diovan for the treatment of heart attack survivors and the completion of a type II variation application for the treatment of people with heart failure.

Diovan is available as a powerful first-line treatment for high blood pressure in more than 90 countries and is the only agent in its class with the indication for the treatment of heart failure in patients who also take usual therapy including diuretics, digitalis and either beta blockers or ACE inhibitors, but not both and in people at risk of a recurrent heart attack or other serious outcomes such as cardiovascular mortality, hospitalization for heart failure, resuscitated cardiac arrest or stroke. For heart failure, more than 60 countries have granted this approval and for post-heart attack more than 50. Additional marketing authorization applications are pending both for the treatment of post-heart attack and heart failure.

Novartis is committed to improving research, especially in cardiovascular and metabolism care. The Diovan clinical trial program represents one part of this commitment, involving more than 50,000 patients across the cardiovascular continuum. Recently completed Diovan megatrials include VALUE in hypertension patients at high-risk for cardiovascular complications, VALIANT in post-heart attack patients and Val-HeFT in heart failure patients. Ongoing studies include NAVIGATOR, the largest outcomes trial ever conducted on the delay or prevention of cardiovascular events and type II diabetes in patients with impaired glucose tolerance.

The foregoing release contains forward-looking statements that can be identified by terminology such as "potential," "are pending" or similar expressions, or by express or implied discussions regarding potential new indications or labeling and marketing approvals for Diovan or Co-Diovan or regarding potential future sales of Diovan or Co-Diovan. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results with Diovan or Co-Diovan to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Diovan or Co-Diovan will be approved for any additional indications or labeling in any other market. Nor can there be any guarantee regarding potential future sales of Diovan or Co-Diovan. In particular, management's expectations regarding commercialization of Diovan or Co-Diovan could be affected by, among other things, additional analysis of Diovan or Co-Diovan 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; industry, government, and general public pricing pressures; and other risks and factors referred to in the Company's current Form 20-F on file with the US Securities and Exchange Commission. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those anticipated, believed, estimated or expected. Novartis 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 2004, the Group's businesses achieved sales of USD 28.2 billion and pro forma net income of USD 5.6 billion. The Group invested approximately USD 4.2 billion in R&D. Headquartered in Basel, Switzerland, Novartis Group companies employ about 81,400 people and operate in over 140 countries around the world. For further information please consult <http://www.novartis.com>.

### **References:**

Ruilope L, et al. Fixed-Dose Valsartan + Hydrochlorothiazide Combination Therapy Compared With Amlodipine Monotherapy In Hypertensive Patients With Additional Cardiovascular Risk Factors: The VAST Study. *Clinical Therapeutics* 2005 27:578-88. In addition, two new analyses of the VALUE trial demonstrated that Diovan may reduce the development of heart failure Julius S et al. VALUE Study: Outcomes In 7080 Patients Treated With Monotherapy. Presented June 19 at ESH 2005. and the onset of type II diabetes Kjeldsen SE, et al. Effects of Valsartan Preventing the Development of Type 2 Diabetes in High Risk Hypertensive Patients: Analysis from the VALUE Trial. Presented June 18 at ESH 2005. in high-risk patients with hypertension when compared with amlodipine. These findings follow recent marketing authorizations throughout Europe for the use of Diovan as a potentially lifesaving treatment for people who have had a recent heart attack and to treat people with existing heart failure.

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**INVESTOR RELATIONS RELEASE**

**Novartis receives EU marketing authorization for Diovan to treat people with heart failure**

*Leading antihypertensive is the only agent of its kind indicated to treat both heart attack survivors and people with heart failure*

*Diovan provides a new treatment option for more than 4.5 million Europeans with heart failure*

**Basel, June 13, 2005** Novartis announced today that it has successfully completed an EU type 2 variation procedure in 14 countries for Diovan® (valsartan) for the treatment of people with heart failure. Diovan, a powerful antihypertensive agent, is now indicated as a potentially life-saving therapy for people with symptomatic heart failure when an ACE inhibitor can not be used, or as add-on therapy to ACE inhibitors when beta blockers can not be used. Diovan provides a new treatment option for the more than 4.5 million people with heart failure in the countries that are covered by this variation procedure. (Based on US prevalence and incidence rates applied to EU population figures.).

This approval comes shortly after Novartis successfully completed an EU Mutual Recognition Procedure (MRP) for Diovan to treat heart attack survivors, making it the only agent in its class (angiotensin receptor blocker or ARB) indicated to treat hypertension, heart attack survivors and people with heart failure.

"Having an agent with a broad range of indications is particularly useful for clinicians because in the 'real world' many causes of cardiovascular disease overlap and one illness predisposes a person for another. Using a lesser number of drugs in patients like this is a good thing for both clinician and patient alike." said Professor Tognoni, key investigator from Val-HeFT.

Heart failure occurs when the heart, after becoming damaged by a heart attack, high blood pressure or other conditions, loses its ability to pump enough blood through the body. Nearly eight million people suffer from heart failure and 600,000 new cases are reported every year in the EU.1

"Physicians clearly need new treatments for heart failure, since almost two out of five (Komajda M, Lapuerta P, Hermans N, et al. Adherence to guidelines is a predictor of outcome in chronic heart failure: the MAHLER survey. *Eur Heart J* 2005.) European heart failure patients are currently not receiving optimal therapy," said Joerg Reinhardt, Head of Development, Novartis Pharma AG. "Diovan has demonstrated its versatility across a spectrum of cardiovascular conditions: high blood pressure, the aftermath of a recent heart attack and now heart failure. We remain committed to developing the full potential of this agent to help us bring the best treatment to people who need cardiovascular care."

The new heart failure indication is based on data from Val-HeFT (Valsartan Heart Failure Trial). This trial demonstrated that Diovan reduced combined mortality and morbidity by 13.2% in heart failure patients also taking standard therapy, including a striking 33% reduction in mortality in heart failure patients not taking ACE inhibitors.



Heart failure develops slowly, often over years, as the heart gradually loses its pumping ability and works less efficiently, eventually leading to death. Heart failure is a debilitating condition that affects a patient's quality of life and life expectancy. While patients can make changes to their diet and physical activity, they will nevertheless require sustained drug treatment to improve the symptoms and outcomes associated with this condition.

#### **New EU approval based on landmark Val-HeFT trial**

With this authorization, Diovan will shortly be indicated in the following countries: Austria, Belgium, Denmark, Finland, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, The Netherlands, Portugal, Spain, and Sweden. Upon granting of national marketing authorizations by these EU countries, Diovan will be approved in nearly 80 countries to treat people with heart failure. It was the first drug in its class indicated to treat heart failure, based on the positive findings of Val-HeFT. Val-HeFT examined 5,010 patients in 302 centers in 16 countries and compared the effects of Diovan vs. placebo in heart failure patients who also took usual treatments individually prescribed by their doctors, including ACE inhibitors, beta blockers, diuretics, or digitalis. It showed that Diovan significantly reduced combined heart failure mortality and morbidity by 13.2% and reduced hospitalization for heart failure by 27.5% versus placebo in patients also taking their individually prescribed heart failure drugs. In patients who were not prescribed ACE inhibitors, Diovan reduced mortality by 33% and mortality/morbidity by 44%.

Other findings from Val-HeFT showed that Diovan improves the signs and symptoms of heart failure, ejection fraction (a measure of the severity of the disease), NYHA functional class (a measure of disease progression) and positively affects several prognostic markers for poor outcomes, including brain natriuretic peptide (BNP), norepinephrine (NE) (Anand I et al. Changes in Brain Natriuretic Peptide and Norepinephrine Over Time are Related to Subsequent Mortality and Morbidity in Heart Failure: Results from Val-HeFT. Abstract presented at AHA 2002.), and aldosterone. (Latini R. Valsartan produces a sustained decrease in plasma aldosterone independent of age, gender or race: Results from Val-HeFT. Abstract presented at ACC 2003.) A sub-study also demonstrated that atrial fibrillation occurrence further worsens the prognosis in patients with HF. Adding Diovan to prescribed therapy (93% ACE inhibitors, 35% beta blockers) significantly reduced the incidence of atrial fibrillation by nearly 35% (Maggioni AP et al. Valsartan reduces the incidence of atrial fibrillation in the patients with heart failure in Val-HeFT. Abstract presented at AHA 2003.).

In addition, Diovan was also the first agent in its class to be approved for heart attack survivors based on the VALIANT (VALsartan In Acute myocardial iNfarcTion) trial, one of the largest long-term studies ever conducted in people who have survived a heart attack. VALIANT demonstrated that Diovan improved survival and reduced cardiovascular events in high risk patients following a heart attack. Diovan is the only cardiovascular agent ever demonstrated by a head-to-head trial to have matched the proven benefits of an ACE inhibitor in these patients.

#### **About Diovan**

The most prescribed ARB globally and one of the fastest-growing high blood pressure drugs on the market today, Diovan is available as a powerful first-line treatment for high blood pressure in more than 90 countries and in more than 65 for the treatment of heart failure in patients who also take usual therapy including diuretics, digitalis and either beta blockers or ACE inhibitors, but not both. In the US and Switzerland, among other countries, Diovan is indicated for the treatment of heart failure in patients who cannot tolerate ACE inhibitors. Diovan is also indicated in more than 50 countries to treat patients who have survived a heart attack.

This new indication for Diovan is for the treatment of people with symptomatic heart failure when ACE inhibitors can not be used, or as add-on therapy to ACE inhibitors when beta blockers can not be used.

Novartis is focused on improving the care of patients with high blood pressure and heart disease through world-class research. The Diovan clinical trial program, one of the largest in the world, represents an impressive research commitment across the cardiovascular continuum, involving approximately 50,000 patients. In addition to Val-HeFT and VALIANT, recently completed Diovan trials include VALUE in high blood pressure patients at risk for cardiovascular complications. Ongoing studies include the NAVIGATOR trial, the largest outcomes trial ever conducted on the prevention of cardiovascular disease and type 2 diabetes in patients with impaired glucose tolerance.

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**INVESTOR RELATIONS RELEASE**

**Novartis announces completion of Hexal AG acquisition, integrates company with Sandoz**

**Basel, June 7, 2005** Novartis announced today the completion of its acquisition of the generic pharmaceutical company Hexal AG in Germany on June 6. The acquisition was approved by the European Commission in late May.

Hexal is being integrated into the Sandoz division of Novartis as part of previously announced strategic acquisitions to create the world leader in the generic drug industry.

Following the transactions, which also include the acquisition of Eon Labs, Inc. (NASDAQ: ELABS), Sandoz will have a competitive and broad product portfolio with a strong presence in key markets, offering a portfolio of more than 600 active ingredients in more than 5,000 dosage forms. The combined company will employ more than 20,000 people, and its global headquarters will be located in Holzkirchen, Germany.

Novartis is in the process of seeking US regulatory approval to acquire Eon Labs following a request for additional information from the US Federal Trade Commission. The tender process to acquire the publicly held shares of Eon Labs began on May 23. The tender offer, set at USD 31.00 per share, is scheduled to expire on June 20, 2005, and is subject to completion of the regulatory process and the contemporaneous purchase of a 67.7 percent stake in Eon Labs from its control shareholder.

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 know-how make Sandoz a renowned partner in pharmaceuticals, biogenetics and industrial products. Sandoz employs approximately 13,000 people in over 110 countries and reported sales of USD 3.0 billion in 2004.

This document contains "forward-looking statements" within the meaning of the US Private Securities Litigation Reform Act. Forward-looking statements are statements that are not historical facts and are generally identified by the words "expects", "anticipates", "believes", "intends", "estimates", "will", or similar expressions, or by express or implied discussions regarding strategies, plans and expectations (including synergies). These statements include, but are not limited to, financial projections and estimates and their underlying assumptions, statements regarding the benefits of the business transactions described herein, including future financial and operating results. Such statements reflect the current plans, expectations, objectives, intentions or views of management with respect to future events, are based on the current beliefs and expectations of management and are subject to significant risks, uncertainties and assumptions. Management's expectations could be affected by, among other things, competition in general, the general economic environment and other risks such as, but not limited to, those referred to in Novartis AG's 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 differ materially from those set forth or implied by the forward-looking statements.

The following factors, among others, could cause actual results to differ materially from those set forth in the forward-looking statements: the ability to obtain governmental approvals for the transaction on the proposed terms and schedule; the risk that the businesses will not be integrated successfully; the risk that the cost savings and any other synergies from the transaction may not be fully realized or may take longer to realize than expected; disruption from the transaction making it more difficult to maintain relationships with customers, employees or suppliers; social and political conditions such as war, political unrest and terrorism or natural disasters; and general economic conditions and normal business uncertainty and competition and its effect on pricing, spending, third-party relationships and revenues. These forward-looking statements speak only as of the date of this press release and no undertaking has been made to update or revise them if there are changes in expectations or if any events, conditions or circumstances on which any such forward looking statement is based. Forward-looking statements made in connection with a tender offer are not subject to the "safe harbor" provided for in the Private Securities Litigation Reform Act of 1995.

**Securityholders of Eon are urged to read the tender offer statement LETTER OF TRANSMITTAL AND OTHER MATERIALS relating to the tender offer, as THEY contain important information, including the various terms of, and conditions to, the tender offer.. Securityholders can obtain a copy of the tender offer statement. LETTER OF TRANSMITTAL AND OTHER RELATED MATERIALS FREE OF CHARGE at the SEC's internet site (<http://www.sec.gov>) or from the information agent for the tender offer, Georgeson Shareholder Communications Inc., by calling (877) 278-4774 (call toll-free). We urge EON securityholders to carefully read those materials prior to making any decisions with respect to the tender offer.**

#### About Novartis

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**MEDIA RELEASE COMMUNIQUE AUX MEDIAS MEDIENMITTEILUNG**

**Novartis partners with East African Botanicals to expand cultivation and extraction of natural ingredient used in anti-malarial Coartem®**

*Contracts to purchase extracted artemisinin stimulate cultivation of more than 1,000 hectares of Artemisia annua in Kenya, Tanzania and Uganda*

*East African Botanicals scale-up efforts boosted by financial and technical support from Novartis*

*Local economies benefit from job creation in agricultural and manufacturing sectors*

**Basel, June 6, 2005** As the leading global supplier of artemisinin-based combination therapies (ACTs) to treat multi drug-resistant forms of malaria, Novartis has established a close partnership with Kenya-based East African Botanicals (EAB) to significantly increase agricultural cultivation of *Artemisia annua* and extraction of artemisinin. Artemisinin is used to produce artemether, one of two active ingredients in Coartem® (artemether-lumefantrine), a highly effective anti-malarial that Novartis provides on a not-for-profit basis to the public sector in malaria-endemic developing countries.

Based on orders from Novartis for artemisinin plus financial and technical support, EAB is expanding the cultivation of *Artemisia annua* to more than 1,000 hectares in Kenya, Tanzania and Uganda. Combined with the areas already under cultivation, mostly in China, this new planting will bring agricultural production to a level of approximately 10,000 hectares. This is sufficient to allow Novartis to increase its production significantly in 2005 and 2006 exceeding 100 million treatments by year end 2006, while also helping to improve local economies in Asia and Africa.

"Novartis has proven to be our most important partner as we move to large-scale production of artemisinin in East Africa," said Patrick Henfrey, Chief Executive Officer of Advanced Bio Extracts (ABE). The main operating entities of ABE are African Artemisia (AA) operating in Tanzania, East African Botanicals Kenya and East African Botanicals Uganda. "By placing firm orders for extracted artemisinin, providing financial support for infrastructure improvements, and delivering technical support and know-how, Novartis has made a major contribution to creating a sustainable market for this key natural ingredient."

Prior to 2005, *Artemisia annua* was mainly sourced from remote mountain regions in China, where the plant grows wild. Due to recent dramatic increases in demand for ACTs, however, new sources utilizing commercial agricultural production both in Asia and Africa are necessary to create a sustainable supply chain for Novartis and other ACT producers.

Future demand for ACTs in general is anticipated to rise to several hundred million treatments over the next few years. In order to produce these quantities, immense volumes of raw material extracted from *Artemisia annua* are required. To spread the risk of climatic factors that might impact the harvest of *Artemisia annua*, it is important to diversify the geographic areas under cultivation. In addition, expanding cultivation and extraction capacity in Africa makes sense given the fact that most patients affected by malaria live on the African continent.

"Our goal is to help EAB quickly and significantly increase its production capacity and create a stable market for artemisinin," said Silvio Gabriel, Executive Vice President, Malaria Initiatives, Novartis AG. "This will allow us to meet our own production goals for Coartem and bring this life-saving medicine to millions more patients suffering from malaria."

East African Botanicals plans to extract artemisinin from *Artemisia annua* in its Kenyan facility beginning in the fourth quarter of 2005.

The partnership between Novartis and East African Botanicals is also having a positive impact in Kenya, Tanzania and Uganda. Novartis financing has enabled EAB to offer firm purchasing agreements to numerous farmers, including many on small lots. The financial support also helps EAB with the construction of an extraction-and-purification facility in Athi River, Kenya; the purchase and expansion of an extraction factory in Uganda; and the acquisition of building materials from local manufacturers. Overall, these activities will create hundreds of jobs, improving the local economy and upgrading safety standards.

With the support provided to East African Botanicals, Novartis is building on its partnership model with strategic suppliers. Since 1994, Novartis has been working intensively with Chinese suppliers of artemether and lumefantrine used in the manufacture of Coartem. That collaboration continues today with a focus on technology transfer to China, helping local drug substance manufacturers upgrade their facilities to international GMP standards and providing quality assurance support as they expand manufacturing capacity to meet surging demand for ACTs.

Novartis said its Chinese partners remain central to the supply of Coartem. The Chinese researched and discovered the medicinal value of artemisinin and Chinese scientists played a pivotal role in the research and development of artemether, a derivative of artemisinin, used to manufacture Coartem. Finally, Chinese scientists from the Institute of Microbiology and Epidemiology of the Academy of Military Medical Sciences contributed to research leading to the combination of artemether and lumefantrine, which has become the world's leading ACT to combat multi drug-resistant malaria.

#### **About Coartem**

Coartem is a highly effective and well tolerated anti-malarial that achieves cure rates of up to 95%, even in areas of multi-drug resistance. It is indicated for the treatment of falciparum malaria, the most dangerous form of malaria. Coartem is the only pre-qualified, fixed-dose ACT combining artemether and lumefantrine. This fixed-dose combination is of great benefit to patients as it facilitates treatment compliance and supports optimal clinical effectiveness.

Coartem was co-developed by Novartis in collaboration with Chinese partners who also continue to supply the active ingredients artemether and lumefantrine. The final Coartem tablets are produced by Novartis in China. Coartem is currently registered in 77 countries worldwide and more than seven million patients have benefited from this innovative treatment since its first registration in October 1998. Coartem has been extensively studied in multi-center clinical trials involving more than 3,000 patients.

This release contains certain forward-looking statements that can be identified by the use of forward-looking terminology, such as "continues", "will bring", "to increase production significantly in 2005 and 2006", "has made a major contribution to creating a sustainable market", "is anticipated", "our goal is", "will allow", "plans to", "will create", or similar expressions, or by express or implied discussions regarding Novartis' ability to meet its projected production goals of Coartem. 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 Coartem to be materially different from any future results, performance, or achievements expressed or implied by such statements. There can be no guarantee that Novartis will be able to achieve any particular level of Coartem production in the future. Any such results can be affected by, among other things, the ability to obtain the necessary raw materials, uncertainties relating to regulatory actions or government regulation generally, as well as factors discussed in the Company's Form 20-F filed with the US Securities and Exchange Commission. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those described herein as anticipated, believed, estimated or expected. 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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Novartis was recently honored with the 2005 Excellence in Corporate Philanthropy Award from the Committee to Encourage Corporate Philanthropy. In 2004, over 4.25 million patients around the world benefited from Novartis programs valued at USD 570 million. These initiatives range from drug donation and research programs to combat neglected diseases like malaria, tuberculosis and leprosy in developing nations to patient assistance programs that help cancer patients receive the most innovative and effective treatments available.

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*East African Botanicals scale-up efforts boosted by financial and technical support from Novartis*

*Local economies benefit from job creation in agricultural and manufacturing sectors*

**Basel, June 6, 2005** As the leading global supplier of artemisinin-based combination therapies (ACTs) to treat multi drug-resistant forms of malaria, Novartis has established a close partnership with Kenya-based East African Botanicals (EAB) to significantly increase agricultural cultivation of *Artemisia annua* and extraction of artemisinin. Artemisinin is used to produce artemether, one of two active ingredients in Coartem® (artemether-lumefantrine), a highly effective anti-malarial that Novartis provides on a not-for-profit basis to the public sector in malaria-endemic developing countries.

Based on orders from Novartis for artemisinin plus financial and technical support, EAB is expanding the cultivation of *Artemisia annua* to more than 1,000 hectares in Kenya, Tanzania and Uganda. Combined with the areas already under cultivation, mostly in China, this new planting will bring agricultural production to a level of approximately 10,000 hectares. This is sufficient to allow Novartis to increase its production significantly in 2005 and 2006 exceeding 100 million treatments by year end 2006, while also helping to improve local economies in Asia and Africa.

"Novartis has proven to be our most important partner as we move to large-scale production of artemisinin in East Africa," said Patrick Henfrey, Chief Executive Officer of Advanced Bio Extracts (ABE). The main operating entities of ABE are African Artemisia (AA) operating in Tanzania, East African Botanicals Kenya and East African Botanicals Uganda. "By placing firm orders for extracted artemisinin, providing financial support for infrastructure improvements, and delivering technical support and know-how, Novartis has made a major contribution to creating a sustainable market for this key natural ingredient."

Prior to 2005, *Artemisia annua* was mainly sourced from remote mountain regions in China, where the plant grows wild. Due to recent dramatic increases in demand for ACTs, however, new sources utilizing commercial agricultural production both in Asia and Africa are necessary to create a sustainable supply chain for Novartis and other ACT producers.

Future demand for ACTs in general is anticipated to rise to several hundred million treatments over the next few years. In order to produce these quantities, immense volumes of raw material extracted from *Artemisia annua* are required. To spread the risk of climatic factors that might impact the harvest of *Artemisia annua*, it is important to diversify the geographic areas under cultivation. In addition, expanding cultivation and extraction capacity in Africa makes sense given the fact that most patients affected by malaria live on the African continent.



"Our goal is to help EAB quickly and significantly increase its production capacity and create a stable market for artemisinin," said Silvio Gabriel, Executive Vice President, Malaria Initiatives, Novartis AG. "This will allow us to meet our own production goals for Coartem and bring this life-saving medicine to millions more patients suffering from malaria."

East African Botanicals plans to extract artemisinin from *Artemisia annua* in its Kenyan facility beginning in the fourth quarter of 2005.

The partnership between Novartis and East African Botanicals is also having a positive impact in Kenya, Tanzania and Uganda. Novartis financing has enabled EAB to offer firm purchasing agreements to numerous farmers, including many on small lots. The financial support also helps EAB with the construction of an extraction-and-purification facility in Athi River, Kenya; the purchase and expansion of an extraction factory in Uganda; and the acquisition of building materials from local manufacturers. Overall, these activities will create hundreds of jobs, improving the local economy and upgrading safety standards.

With the support provided to East African Botanicals, Novartis is building on its partnership model with strategic suppliers. Since 1994, Novartis has been working intensively with Chinese suppliers of artemether and lumefantrine used in the manufacture of Coartem. That collaboration continues today with a focus on technology transfer to China, helping local drug substance manufacturers upgrade their facilities to international GMP standards and providing quality assurance support as they expand manufacturing capacity to meet surging demand for ACTs.

Novartis said its Chinese partners remain central to the supply of Coartem. The Chinese researched and discovered the medicinal value of artemisinin and Chinese scientists played a pivotal role in the research and development of artemether, a derivative of artemisinin, used to manufacture Coartem. Finally, Chinese scientists from the Institute of Microbiology and Epidemiology of the Academy of Military Medical Sciences contributed to research leading to the combination of artemether and lumefantrine, which has become the world's leading ACT to combat multi drug-resistant malaria.

#### **About Coartem**

Coartem is a highly effective and well tolerated anti-malarial that achieves cure rates of up to 95%, even in areas of multi-drug resistance. It is indicated for the treatment of falciparum malaria, the most dangerous form of malaria. Coartem is the only pre-qualified, fixed-dose ACT combining artemether and lumefantrine. This fixed-dose combination is of great benefit to patients as it facilitates treatment compliance and supports optimal clinical effectiveness.

Coartem was co-developed by Novartis in collaboration with Chinese partners who also continue to supply the active ingredients artemether and lumefantrine. The final Coartem tablets are produced by Novartis in China. Coartem is currently registered in 77 countries worldwide and more than seven million patients have benefited from this innovative treatment since its first registration in October 1998. Coartem has been extensively studied in multi-center clinical trials involving more than 3,000 patients.

This release contains certain forward-looking statements that can be identified by the use of forward-looking terminology, such as "continues" "will bring", "to increase production significantly in 2005 and 2006", "has made a major contribution to creating a sustainable market", "is anticipated", "our goal is", "will allow", "plans to", "will create", or similar expressions, or by express or implied discussions regarding Novartis' ability to meet its projected production goals of Coartem. 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 Coartem to be materially different from any future results, performance, or achievements expressed or implied by such statements. There can be no guarantee that Novartis will be able to achieve any particular level of Coartem production in the future. Any such results can be affected by, among other things, the ability to obtain the necessary raw materials, uncertainties relating to regulatory actions or government regulation generally, as well as factors discussed in the Company's Form 20-F filed with the US Securities and Exchange Commission. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those described herein as anticipated, believed, estimated or expected. 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 2004, the Group's businesses achieved sales of USD 28.2 billion and pro forma net income of USD 5.6 billion. The Group invested approximately USD 4.2 billion in R&D. Headquartered in Basel, Switzerland, Novartis Group companies employ about 81,400 people and operate in over 140 countries around the world.

Novartis was recently honored with the 2005 Excellence in Corporate Philanthropy Award from the Committee to Encourage Corporate Philanthropy. In 2004, over 4.25 million patients around the world benefited from Novartis programs valued at USD 570 million. These initiatives range from drug donation and research programs to combat neglected diseases like malaria, tuberculosis and leprosy in developing nations to patient assistance programs that help cancer patients receive the most innovative and effective treatments available. For further information please consult <http://www.novartis.com>.

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## INVESTOR RELATIONS RELEASE

### Novartis licenses rights to develop and commercialize new hepatitis treatment

*Agreement complements Novartis hepatitis pipeline with new class of treatments*

**Basel, June 2, 2005** Novartis announced today that it has signed an exclusive global license agreement with Anadys Pharmaceuticals for ANA975 for the treatment of chronic hepatitis C virus (HCV).

Under the terms of the agreement, Novartis obtains the rights to develop, manufacture and commercialize ANA975 for HCV as well as to develop ANA975 in additional infectious disease indications, including hepatitis B virus infection (HBV). ANA975, an oral prodrug of Anadys' small molecule compound isatoribine, belongs to a new class of drugs being developed to regulate innate immunity by interacting with Toll-Like Receptor 7 (TLR7). ANA975 is currently in Phase I development for the treatment of HCV. Anadys successfully completed several proof of concept studies with isatoribine in patients with HCV.

HCV and HBV are progressive liver diseases that chronically affect approximately 170 million and 350 million people respectively, worldwide. Chronic infections with hepatitis C and B viruses can eventually lead to cirrhosis, liver failure and hepatocellular carcinoma (liver cancer). Currently available treatments are often associated with limited efficacy, poor tolerability and/or resistance concerns.

"With this agreement, we are adding complementary compounds to the direct antivirals already in our hepatitis pipeline," said Thomas Ebeling, Chief Executive Officer of Novartis Pharma AG. "As the most advanced oral immunomodulator in development for hepatitis, ANA975 represents a potentially important advance in bringing more effective, tolerable therapy to hepatitis patients worldwide."

Novartis further obtained an exclusive option to license additional TLR7-based therapeutics developed by Anadys for HCV and HBV. Additionally, Novartis has the option to in-license Anady's rights to ANA380, a nucleotide analog in Phase II development for treating chronic HBV.

Novartis, in collaboration with Idenix, is already developing two complementary drug candidates for the treatment of chronic HBV, LDT600 (telbivudine) and LDC300 (valtorcitabine). Novartis has an exclusive option to license and collaborate with Idenix in the development and commercialization of other drug candidates in their portfolio, including direct antiviral hepatitis C compound NM283 (valopicitabine).

### About Hepatitis

Each year three to four million people worldwide become newly infected with HCV. The current standard of care in HCV is combination therapy of subcutaneous interferon, an immunomodulator, and ribavirin, an antiviral. This combination therapy is often associated with high incidence of side effects and has limited efficacy in the most prevalent, genotype-1, of HCV genotypes.

Despite immunization programs for hepatitis B, 5% of the world's population is chronically infected with HBV. Currently available therapies for chronic HBV include antivirals and subcutaneous interferon. More than one million individuals die worldwide from HBV-related chronic liver disease each year, demonstrating the urgent need for new treatment options.

The foregoing press release contains forward-looking statements that can be identified by the use of forward-looking terminology such as "pipeline", "potentially", or similar expressions, or by express or implied discussions regarding the potential development, regulatory approvals and commercialization of ANA975, ANA380, LDT600, LDC300 and NM283. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that any of these products will be approved for sale in any market, or that any of them will achieve any particular level of sales. Any such commercialization can be affected by, among other things, uncertainties relating to product development and clinical trials, including unexpected clinical trial results; unexpected 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 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.

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For further information please consult <http://www.novartis.com>.

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**SIGNATURES**

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

**Novartis AG**

Date: June 30, 2005

By:           /s/ MALCOLM B. CHEETHAM          

Name: Malcolm B. Cheetham  
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