

NOVARTIS AG  
Form 6-K  
December 02, 2005

# 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 November 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:

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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:

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Enclosures:

1. Novartis announces the successful divestment of its Nutrition & Santé unit (Basel, November 28, 2005)
2. Tears will get you sympathy; sweat will get you change (Basel, November 25, 2005)
3. Novartis scientists honored for outstanding contributions (Basel, November 16, 2005)
4. GLOBE study finds telbivudine superior to current standard of care on antiviral measures in patients with chronic hepatitis B (Basel, November 14, 2005)
5. Novartis reaches agreement to develop and commercialize glaucoma treatment with novel mechanism of action (Basel, November 9, 2005)
6. Preliminary data from second pivotal Phase III study showed Lucentis® maintained or improved vision in 95 percent of patients with age-related macular degeneration (AMD) (Basel, November 7, 2005)
7. Novartis announces leadership of new vaccines and diagnostics business (Basel, November 3, 2005)
8. Exjade®, a breakthrough once-daily oral iron chelator, receives first approval worldwide in the US (Basel, November 3, 2005)

**Investor Relations**

**Novartis International AG**

CH-4002 Basel  
Switzerland

**Novartis Corporation**  
608 Fifth Avenue  
New York, NY 10020  
USA

**- Investor Relations Release -**

**Novartis announces the successful divestment of its Nutrition & Santé unit**

**Basel, November 28, 2005** Novartis announced today that it has signed a definitive agreement to divest its Nutrition & Santé business unit to ABN AMRO Capital France for approximately EUR 220 million (USD 260 million) on a cash and debt free basis. The transaction, which requires customary regulatory approvals, is expected to be completed in Q1 2006.

Nutrition & Santé holds the remaining dietary food assets of the former Health and Functional Food business unit, which were not sold to Associated British Foods plc in November 2002. At the time of the divestiture, Nutrition & Santé was classified as a non-core asset and has since been included within the Medical Nutrition business unit results.

Nutrition & Santé has developed a unique range of high-value dietary food products trusted by European consumers. At Novartis, we are committed to focusing on our pharmaceuticals and healthcare businesses. This transaction provides Nutrition & Santé and its employees with a new shareholder who will focus on the business and allows Novartis to realize the value of its investments into Nutrition & Santé, said Paul Choffat, Chief Executive Officer of Novartis Consumer Health.

We are enthusiastic about the acquisition of Nutrition & Santé. We are very excited to partner with the management team and we consider the company as an exceptional platform to expand in the dietary food business via organic and external growth, said Hervé Claquin, Chief Executive Officer of ABN AMRO Capital France.

Nutrition & Santé, which is headquartered in Revel, France, is a leader in the European dietary foods market through activities in functional foods (Gerblé® and Céréal®), slimming products (Gerlinéa®, Pesoforma® and Milical®), sports nutrition (Isostar®), and other nutritional specialties. Products are sold through groceries and supermarkets, pharmacies and drug stores, and specialist channels such as health-food stores and gym clubs. Nutrition & Santé reported sales of EUR 245 million and operating income of EUR 21 million for the 12 month period ended September 2005, primarily in France, Spain/Portugal, Italy and the Benelux region.

**About ABN AMRO Capital**

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ABN AMRO Capital is the global private equity business of ABN AMRO, with teams operating in seven countries worldwide including the Netherlands, UK, France, Spain, Italy, Sweden and Australia. Total funds under management (as at end June 05) by ABN AMRO Capital are EUR 2.3 billion, of which EUR 100 million of capital is provided by international investors in ABN AMRO Capital managed funds in the UK and France.

In 2005, ABN AMRO Capital led 14 buy outs for a global value of EUR 2.5 billion (EUR 578

million Equity Investment) as well as eight exits.

### **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 4.1 billion in R&D. Headquartered in Basel, Switzerland, Novartis Group companies employ about 91,700 people and operate in over 140 countries around the world.

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

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### **Novartis Global Investor Relations**

**Karen J. Huebscher, Ph.D.** +41 61 324 84 33

#### **International office**

Katharina Ambühl +41 61 324 53 16

Nafida Bendali +41 61 324 35 14

Richard Jarvis +41 61 324 43 53

Silke Zentner +41 61 324 86 12

e-mail: [investor.relations@novartis.com](mailto:investor.relations@novartis.com)

Fax: +41 61 324 84 44  
[www.novartis.com](http://www.novartis.com)

#### **North American office**

**Ronen Tamir** +1 212 830 24 33

Nina Malik +1 925 551 59 64

John Menditto +1 212 830 24 44

Jill Pozarek +1 212 830 24 45

e-mail: [investor.relations@novartis.com](mailto:investor.relations@novartis.com)

Fax: +1 212 830 24 05  
[www.novartis.com](http://www.novartis.com)

**Novartis International AG**

Novartis Communications

CH-4002 Basel

Switzerland

Tel +41 61 324 2200

Fax+ 41 61 324 3300

Internet Address:

<http://www.novartis.com>

**MEDIA RELEASE    COMMUNIQUE AUX MEDIAS    MEDIENMITTEILUNG**

**Tears will get you sympathy; sweat will get you change**

**Basel, November 25, 2005** Private initiative can change the world. That was the joint message issued by well-known speakers from a wide range of backgrounds at the international 2005 Symposium of the Novartis Foundation for Sustainable Development in Basel/ Switzerland. The large audience was given an impressive insight into charitable work in Europe, Africa, Asia, and the Caribbean, with inspirational success stories as a clear sign of people's refusal to just sit back and accept their fate.

In the private sector, entrepreneurial initiative is naturally acknowledged as the driving force behind economic success. But solidarity – not just profitability – also depends on individuals' personal commitment. Private initiative makes a difference in the humanitarian sector as well. The Symposium of the Novartis Foundation for Sustainable Development on November 25th expressed eloquently what can be achieved with commitment, know-how, and persistence. The event, which attracted a crowd of approximately 500 visitors, generated a great deal of interest.

Moving reports were provided by Karl-Heinz Böhm about the work of the *Menschen für Menschen* foundation in Ethiopia, Dietmar Schönherr about his experiences in Nicaragua, and Rupert Neudeck about how the rescue ship *Cap Anamur* is working to save boat people. These reports illustrated vividly the necessity, urgency, and scope of the work done by humanitarian aid organizations. The presentations by high-profile representatives from the south highlighted clearly that the poor also know how to help themselves. Recounting their own personal experiences, Namrata Bali (India), Esther Mujawayo (Rwanda), Ruth Montrichard (Trinidad) and the doctor Zafrullah Chowdhury (Bangladesh) provided details of successful self-help initiatives from Asia, Africa, and the Caribbean. Social commitment can also come unexpectedly from developing nations in the Southern hemisphere as demonstrated by Jenny de la Torre, a doctor from Peru who works with the homeless in Berlin/ Germany.

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Introducing the event, Alexandre F. Jetzer, Member of the Board of Directors of Novartis International, emphasized that private initiative is the driving force behind sustainable development. Initiatives that improve people's living conditions therefore deserve support. As explained by Chairman Klaus M. Leisinger, this is the core business of the Novartis Foundation for Sustainable Development. Throughout the course of the event, it was repeatedly made clear that humanitarian work was not to be viewed in isolation. As in the private sector, charitable initiatives also need a political framework that does not hinder but rather helps the work being undertaken.

The presentations from the Symposium can be found on the Website of the Novartis Foundation for Sustainable Development ([www.novartisfoundation.com](http://www.novartisfoundation.com)).



**About the Novartis Foundation for Sustainable Development**

The Novartis Foundation for Sustainable Development has been one of the leading organizations in the private sector for international development for over 25 years and is a leader in innovative, performance-related development cooperation. The activities of the Novartis Foundation are based on three cornerstones: Think-tank activities on issues of sustainable development; dialogue and networking on development policy issues as well as building alliances with various stakeholders; and practical development work in the area of access to healthcare. As a basic principle, the Novartis Foundation concentrates its financial and human resources on projects in the areas of healthcare where it can make a significant contribution. The Foundation favors pilot projects within a manageable framework where innovative solutions to health-access problems can be elaborated.

Examples of programs include: psychosocial support for AIDS orphans in Tanzania; erasing leprosy in Sri Lanka and India; improving access to effective malaria treatment in Tanzania; and enhancing financial access to basic health care in Mali through community-based health insurance. In cooperation with WHO, Novartis and the Novartis Foundation for Sustainable Development have committed to provide free leprosy treatment for all leprosy patients worldwide until the end of 2010.

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

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**Novartis International AG**

Novartis Communications

CH-4002 Basel

Switzerland

Tel +41 61 324 2200

Fax+ 41 61 324 3300

Internet Address:  
<http://www.novartis.com>

**MEDIA RELEASE    COMMUNIQUE AUX MEDIAS    MEDIENMITTEILUNG**

**Novartis scientists honored for outstanding contributions**

*Top internal scientific award for chemist involved in Diovan® discovery*

**Basel, November 16, 2005** Novartis has honored 10 scientists from the Novartis Institutes for BioMedical Research (NIBR) and Pharma Development for their exceptional contributions to the research and development of novel medicines.

At a ceremony today, nine of these scientists received the Novartis Leading Scientist Award, while the highest distinction of all – the Novartis Distinguished Scientist Award – was given to Dr. Peter Buehlmyer for his outstanding contributions to hypertension research.

Both the Leading Scientist Award and the Novartis Distinguished Scientist Award were presented in the framework of the VIVA program (Vision, Innovation, Value, Achievement), which was established in 1998. The aim of this program is to promote creativity and innovation in R&D and, in particular, to recognize outstanding scientific contributions.

Our scientists are critical to the success of Novartis and are key to maintaining our leading position in innovation. We count on their expertise and on their creativity so that we can continue to discover novel medicines for patients. said Dr. Daniel Vasella, Chairman and CEO of Novartis.

Today we are pleased to honor some of our most promising scientists, and to both thank them as well as congratulate them for their achievements. Their work will help us to uncover new research approaches, to optimize novel compounds and most importantly to ultimately introduce breakthrough medicines with new therapeutic benefits.

**Distinguished Scientist Award**

Dr. Peter Buehlmayer, Senior Research Investigator I in Global Discovery Chemistry, Autoimmunity & Transplantation, at NIBR was given the Distinguished Scientist Award. Dr. Buehlmayer's outstanding scientific contributions in the field of hypertension research were crucial in a number of projects, particularly the development of the anti-hypertension agent Diovan®, which has become the top-selling product of Novartis. The Novartis Distinguished Scientist Award, which is the highest scientific achievement award within the Group, includes a prize of CHF 40,000 as well as the right to use the title Novartis Distinguished Scientist.

### **Leading Scientist Award**

The highest scientific distinction conferred within each of the Novartis Group divisions. Pharma, Sandoz and Consumer Health is the Novartis Leading Scientist Award, which includes a prize of CHF 25,000 as well as the right to use the title Novartis Leading Scientist. The award was granted this year to the following NIBR scientists: Dr. Giorgio Caravatti, Dr. Sandra Jacob, Dr. Andreas Marzinzik, Dr. Bernhard Rohde, Dr. Juergen Wagner and Dr. Karen Wang. In Pharma Development, the award was granted to the following scientists: Dr. Alain A. Schweitzer, Dr. Abu T.M. Serajuddin and Dr. Wen-Chung Shieh.

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###

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**Novartis International AG**

Novartis Communications

CH-4002 Basel

Switzerland

Tel +41 61 324 2200

Fax+ 41 61 324 3300

Internet Address:  
<http://www.novartis.com>

**MEDIA RELEASE    COMMUNIQUE AUX MEDIAS    MEDIENMITTEILUNG**

**GLOBE study finds telbivudine superior to current standard of care on antiviral measures in patients with chronic hepatitis B**

*Achieving early, profound viral suppression associated with improved clinical outcomes*

*95% of telbivudine patients with undetectable virus at six months remain so at one year*

*Hepatitis B the second leading cause of cancer after smoking, with 1.2 million deaths annually worldwide related to hepatitis B-related chronic liver disease*

**Basel, November 14, 2005** Results from the GLOBE study, a Phase III trial in patients with chronic hepatitis B, showed that treatment of patients after one year with telbivudine (LDT600) provided superior response on all evaluated virologic markers compared to lamivudine, the current standard of care. The results were announced today at the 56th Annual Meeting of the American Association for the Study of Liver Diseases (AASLD) in San Francisco.

Patients treated with telbivudine, a specific and selective oral once-daily nucleoside, achieved a significantly greater reduction of hepatitis B virus (HBV) DNA, which resulted in more patients achieving clearance of detectable virus compared to lamivudine-treated patients. Profound reduction of virus in the blood (viral suppression) decreases the risk of disease progression and is a primary treatment goal in chronic hepatitis B.

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The GLOBE study, which compares telbivudine with lamivudine in 1,367 patients from 20 countries, is the largest study ever conducted in both HBeAg-positive and HBeAg-negative chronic hepatitis B patients. HBeAg-positive patients test positive for the hepatitis B e antigen whereas HBeAg-negative patients do not; HBeAg-negative disease generally occurs as a result of a mutation of the virus, and these patients tend to have more advanced liver damage. This study is also the first global chronic hepatitis B registration trial to include patients from China, where the disease is highly prevalent.

Despite recent advances in the treatment of chronic hepatitis B, there remains a need for new safe and effective treatment options, said Dr. Ching-Lung Lai, Professor of Medicine and Chief of the Gastroenterology and Hepatology Division at the University of Hong Kong, and lead investigator of the GLOBE study. The potent viral suppression achieved with telbivudine has the potential to reduce the serious complications associated with chronic hepatitis B and telbivudine's favorable safety and convenience profile in trials to date also make it a promising treatment option for patients, including those requiring long-term therapy.

Chronic hepatitis B is the tenth leading cause of death worldwide(1) with more than 350 million

people chronically infected (lifelong infection)(2). Additionally, chronic hepatitis B is the second leading cause of cancer after smoking, responsible for up to 80 percent of the world's primary liver cancer(3). Approximately 1.2 million individuals are estimated to die annually from hepatitis B-related chronic liver disease(4). Current unmet medical needs in chronic hepatitis B treatment include improved response rates, better long-term efficacy, reduced rates of drug resistance, improved safety and tolerability and more patient-friendly dosing regimens.

We are pleased with the positive one-year GLOBE results that we will include in key global regulatory submissions currently anticipated to be made by the end of the first quarter 2006 and look forward to obtaining the two-year data from GLOBE to evaluate the longer-term efficacy and safety of telbivudine, said Dr. James Shannon, Global Head of Development, Novartis Pharma AG.

### **Key findings from the GLOBE Study**

Results from GLOBE indicate that telbivudine produces significantly faster and more profound viral suppression compared to lamivudine after one year of treatment. Telbivudine patients achieved significantly greater HBV DNA reductions after 52 weeks in both hepatitis B e antigen (HBeAg)-positive patients (-6.5 log<sub>10</sub> vs. -5.5 log<sub>10</sub> with lamivudine; p<0.01) and HBeAg-negative patients (-5.2 log<sub>10</sub>, vs. -4.4 log<sub>10</sub> with lamivudine; p<0.01).

Similarly, after 52 weeks of treatment, significantly more patients receiving telbivudine achieved clearance of detectable HBV DNA and became PCR negative. In HBeAg-positive patients, telbivudine treatment led to loss of detectable HBV DNA in 60 percent of patients compared to 40 percent with lamivudine treatment (p<0.01). In HBeAg-negative patients, telbivudine treatment reduced HBV DNA to below detectable levels in 88 percent of patients compared to 71 percent with lamivudine treatment (p<0.01).

Analyses of the one-year GLOBE data demonstrated that, regardless of treatment, achieving profound viral suppression early in the course of therapy results in better efficacy outcomes at one year, including non-detectable virus levels (PCR negativity), liver enzyme (ALT) normalization, HBeAg seroconversion and decreased incidence of viral resistance. The majority of telbivudine-treated patients achieved PCR negativity in the first 24 weeks of treatment, and 95 percent of those patients remained PCR negative at one year.

The primary efficacy endpoint of the GLOBE study was therapeutic response, a composite endpoint coupling viral suppression (serum HBV DNA suppression below 100,000 copies/mL) with either improved liver disease markers (ALT normalization) or loss of detectable hepatitis B e-antigen (HBeAg). The study successfully reached this endpoint, which was designed to assess if telbivudine was at least as effective as lamivudine in both HBeAg-positive and HBeAg-negative patients. In HBeAg-positive patients, therapeutic response was significantly higher among patients treated with telbivudine (75 percent) compared to patients treated with lamivudine (67 percent) (p<0.05), while the response after one year was similar for HBeAg-negative patients taking either treatment (75 percent versus 77 percent, respectively).

Patients receiving telbivudine showed significantly less viral resistance and less treatment failure, compared to patients receiving lamivudine at one year. Telbivudine was associated with significantly fewer and less severe resistance-associated elevations ( flares ) of serum ALT levels, a cause of potentially fatal liver failure in chronic hepatitis B patients, compared to lamivudine. In addition, the 52-week GLOBE study results support a favorable overall safety profile for telbivudine. The diverse nature and rate of occurrence of adverse events were similar between telbivudine-treated patients and lamivudine-treated patients.

### **More about the GLOBE Study**

Histological analysis revealed that telbivudine, compared with lamivudine, provided superior improvement in liver histology after one year in HBeAg-positive patients (65 percent versus 56 percent, respectively;  $P < 0.02$ ), which indicates resolution of liver disease associated with HBV infection. In HBeAg-negative patients, histologic responses were similar for telbivudine and lamivudine (67 percent versus 66 percent, respectively). Histologic response was defined as a two-point or greater reduction in the Knodell necroinflammatory score, with no worsening in the Knodell fibrosis score.

The GLOBE trial is ongoing, with a final analysis expected to be available in late 2006 following completion of two years of treatment for all study patients.

### **About telbivudine**

Telbivudine is a specific and selective, oral, once-daily nucleoside analogue that is being developed for the treatment of chronic hepatitis B and appears to be unique in its preferential inhibition of 2nd strand HBV DNA synthesis.

### **About Hepatitis B**

Hepatitis B, a virus that affects the liver, is 50-100 times more infectious than HIV(5). HBV can cause life-long infection, cirrhosis (scarring) of the liver as well as liver cancer, liver failure and death(6). Elevated viral loads are recognized to be associated with disease progression. Therefore, a primary goal of treatment is to reduce as much as possible the quantity of virus circulating in the blood (viral suppression).

HBV is widespread in Africa and Southeast Asia, with 8-10% of the population considered to be chronically infected(7). High rates of chronic HBV infection are also found in the Amazon basin in South America as well as in the southern parts of Eastern and Central Europe(8). In these endemic areas, many people become infected when they are infants or young children. Transmission of HBV frequently occurs during the birthing process when the virus is passed on from the mother to her child(9). People who are chronically infected with HBV also can pass the virus to others through blood transfusions, sharing or reusing needles for injection or tattoos as well as through unprotected sex(10). Many chronic HBV carriers have no symptoms and feel healthy because of its silent transmission and progression,(11) making HBV a serious global public health issue.

### **Idenix/Novartis collaboration**

Idenix is developing its hepatitis B clinical product candidates, telbivudine and valtorcitabine, in collaboration with Novartis Pharma AG under a development and commercialization arrangement established in May 2003. The collaboration arrangement further provides that Novartis and Idenix will co-promote the product candidates that Novartis has licensed, including telbivudine and valtorcitabine, in the US, France, Germany, Italy, Spain and the UK. Novartis holds the exclusive license to telbivudine and valtorcitabine in the rest of the world. This collaboration also provides Novartis with an exclusive option to license and collaborate with Idenix in the development and commercialization of other product candidates in Idenix's portfolio, including valopicitabine (NM283), a direct antiviral hepatitis C product candidate.

### **About Novartis**

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Basel, Switzerland, Novartis Group companies employ about 91,700 people and operate in over 140

countries around the world. For further information please consult <http://www.novartis.com>.

The foregoing release contains certain forward-looking statements that can be identified by terminology such as "has the potential to", "promising treatment", "will include", "anticipated", "look forward to", "longer-term", "expected to", or similar expressions, or by express or implied discussions regarding potential therapeutic benefits and successful development of telbivudine and the anticipated regulatory filings required for the registration of telbivudine, or potential future revenues from telbivudine. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results with telbivudine to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that telbivudine will be approved for sale in any market or that it will reach any particular level of revenue. Management's expectations regarding telbivudine could be affected by, among other things, uncertainties relating to clinical trials; new clinical data; unexpected regulatory actions or delays or government regulation generally; the company's ability to obtain or maintain patent or other proprietary intellectual property protection; Idenix's dependence on its collaboration with Novartis Pharma AG; Idenix's ability to obtain additional funding required to conduct its research, development and commercialization activities; competition in general; government, industry and general public pricing pressures; as well as 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.

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**Investor Relations**

**Novartis International AG**  
CH-4002 Basel  
Switzerland

**Novartis Corporation**  
608 Fifth Avenue  
New York, NY 10020  
USA

**- Investor Relations Release -**

**Novartis reaches agreement to develop and commercialize glaucoma treatment with novel mechanism of action**

*In-licensing deal provides Novartis with entry into key glaucoma market*

**Basel, November 9, 2005** Novartis announced today that it has signed a global (excluding Japan) development and commercialization agreement with Senju Pharmaceutical Co., Ltd., for Y39983, a Rho Kinase inhibitor for topical treatment of glaucoma, under the sub-license rights granted by Mitsubishi Pharma Corporation to Senju.

Novartis will be responsible for developing and commercializing Y39983 in its territories. Y39983, which has entered Phase I development in Japan, is a specific and highly potent Rho Kinase inhibitor with a new mechanism of action that regulates pressure inside the eye.

This agreement will allow us to better leverage our well-established leadership and expertise in the treatment of back-of-the-eye diseases, such as wet age-related macular degeneration (AMD), to offer patients a novel treatment for glaucoma, said Nicholas Franco, President of Novartis Ophthalmics. A significant unmet medical need remains to help patients with glaucoma, and Novartis has taken the lead in the development of a next-generation treatment with Y39983. We believe this compound could become the leading treatment for patients with glaucoma.

Under terms of the agreement, Senju will receive an initial payment and additional milestone payments based on the achievement of agreed clinical, regulatory and commercialization targets, with royalties to be paid on the marketed product.

**About Glaucoma**

Glaucoma is a group of diseases of the eye that may cause vision loss and blindness due to damage to the optic nerve. Damage is caused by intraocular pressure (IOP), which is caused by a blockage in the normal outflow of aqueous humor (fluid in the eye). There are several types of glaucoma, and most varieties are chronic and require life-long control after diagnosis. Glaucoma is one of the leading causes of adult blindness, with prevalence estimates in adults 40 years and over varying from 1.3 - 4.7 percent, with significant differences in racial sub-populations.(1)

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Glaucoma, valued at USD 3.7 billion in 2005, represents the largest portion of the ophthalmics market. The glaucoma market grows at an estimated 4 percent per year and is currently dominated by Intra Ocular Pressure (IOP) lowering prostaglandin (PG) analogues.

The foregoing press release contains certain forward-looking statements that can be identified by terminology such as will be , will allow has taken the lead in the development of a next-

generation treatment, we believe could become, will receive, or similar expressions, or by express or implied discussions regarding potential development and commercialization of Y39983. Such forward-looking statements involve known and unknown risks, uncertainties or other factors that may cause the actual results to be materially different from any future results, performance, or achievements expressed or implied by such statements. There can be no guarantee that the agreement that is the subject of this release will lead to commercialization of Y39983 in any market. In particular, management's expectations relating to Y39983 could be affected by, among other things, uncertainties relating to product development and clinical trials; 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 US Securities and Exchange Commission. 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 Ophthalmics**

With worldwide headquarters in Basel, Switzerland, the Novartis Ophthalmics Business Unit is a global leader in research, development and manufacturing of leading ophthalmic pharmaceuticals that assist in the treatment of age-related macular degeneration, eye inflammation, glaucoma, ocular allergies and other diseases and disorders of the eye. Novartis Ophthalmics products are available in more than 110 different countries. Novartis Ophthalmics products are made in Switzerland, France, the United States and Canada. For more information, visit [www.novartisophthalmics.com](http://www.novartisophthalmics.com) or [www.us.novartisophthalmics.com](http://www.us.novartisophthalmics.com).

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###

**Novartis Global Investor Relations**

**Karen J. Huebscher, Ph.D.** +41 61 324 84 33

**International office**

Katharina Ambühl +41 61 324 53 16

Nafida Bendali +41 61 324 35 14

Richard Jarvis +41 61 324 43 53

Silke Zentner +41 61 324 86 12

e-mail: [investor.relations@novartis.com](mailto:investor.relations@novartis.com)

Fax: +41 61 324 84 44

[www.novartis.com](http://www.novartis.com)

**North American office**

**Ronen Tamir** +1 212 830 24 33

Nina Malik +1 925 551 59 64

John Menditto +1 212 830 24 44

Jill Pozarek +1 212 830 24 45

e-mail: [investor.relations@novartis.com](mailto:investor.relations@novartis.com)

Fax: +1 212 830 24 05

[www.novartis.com](http://www.novartis.com)

**Investor Relations**

**Novartis International AG**  
CH-4002 Basel  
Switzerland

**Novartis Corporation**  
608 Fifth Avenue  
New York, NY 10020  
USA

**- Investor Relations Release -**

**Preliminary data from second pivotal Phase III study showed Lucentis® maintained or improved vision in 95 percent of patients with age-related macular degeneration (AMD)**

*AMD is leading cause of blindness for people over age 50*

**Basel, November 7, 2005** - Novartis announced today that a second Phase III clinical study of the investigational drug Lucentis® (ranibizumab) met its one-year primary efficacy endpoint of maintaining vision in patients with wet age-related macular degeneration (AMD).

Approximately 94 percent of patients treated with 0.3 mg of Lucentis and 96 percent of those treated with 0.5 mg of Lucentis maintained vision (defined as a loss of less than 15 letters in visual acuity), or improved vision, compared to approximately 64 percent of those treated with verteporfin (Visudyne®) photodynamic therapy (PDT) ( $p < 0.0001$ ) during the first year of the two-year study.

Patients treated with Lucentis had, on average, a significant improvement in visual acuity compared to their visual acuity at study entry, an important secondary endpoint. Data from this Phase III trial along with those of MARINA will be submitted to the health authorities in 2006. One-year data from the ANCHOR study will be presented at an upcoming medical meeting.

The outstanding results of this second Phase III study demonstrate Lucentis' potential to improve vision in patients with all subtypes of wet AMD, said Nicholas Franco, President of Novartis Ophthalmics. With Lucentis, we hope to be the only pharmaceutical company to provide wet AMD patients with two effective treatments, Lucentis and Visudyne, with different and potentially complementary modes of action.

Anti-VEGF Antibody for the Treatment of Predominantly Classic CHORoidal Neovascularization in AMD (ANCHOR) is a Phase III randomized, multi-center, double-masked, active-treatment controlled study comparing two different doses of Lucentis to PDT in 423 patients with predominantly classic wet AMD. Patients were randomized 2:1 to receive intravitreal Lucentis injections (0.3 mg or 0.5 mg dose) once a month or PDT every three months for two years. Exclusion criteria included prior subfoveal laser treatment, PDT or experimental treatments for wet AMD.



Visual acuity was measured using the Early Treatment of Diabetic Retinopathy (ETDRS) chart, the standard method of quantifying visual acuity. The study is ongoing in the United States, Europe and Australia.

Preliminary safety findings were consistent with those observed in the other Phase III pivotal study

of Lucentis, MARINA. Common ocular adverse side effects that occurred more frequently in the Lucentis arms than in the control group were mild to moderate and included conjunctival hemorrhage, eye pain, increased intraocular pressure and vitreous floaters. Serious ocular adverse events that occurred more frequently in the Lucentis-treated arms were uncommon and included endophthalmitis (approximately 1 percent). Among non-ocular serious adverse events, the frequency of cerebral vascular events was equal across all three arms. The frequency of myocardial infarctions was slightly higher in patients treated with 0.5 mg of Lucentis than in the other two arms, although this difference was not statistically significant.

#### **About MARINA**

Earlier this year, Novartis announced positive preliminary one-year Phase III data on Lucentis from this study of 716 patients with wet AMD. In addition to meeting the study's primary efficacy endpoint of maintaining vision in patients with wet AMD,

25 percent (59/238) of patients treated with 0.3 mg of Lucentis and 34 percent (81/240) treated with 0.5 mg of Lucentis improved vision by a gain of 15 letters or more compared to approximately 5 percent (11/238) of patients in the sham control group as measured by the ETDRS eye chart.

Nearly 40 percent (188/478) of Lucentis-treated patients achieved a visual acuity score of 20/40 or better at 12 months compared to 11 percent (26/238) in the control group.

At 12 months, patients treated with Lucentis gained an average of seven letters in visual acuity compared to study entry, while those in the control group lost an average of 10.5 letters.

The majority of patients treated with Lucentis (74.8 percent in the 0.3 mg group and 71.3 percent in the 0.5 mg group) experienced a letter improvement of zero or more at one year compared to 28.6 percent in the sham control group.

An analysis of the one-year data showed that adverse events were similar to those seen in earlier trials of Lucentis. Common side effects occurring more frequently in the Lucentis arms than in the control group were mild to moderate and included conjunctival hemorrhage, eye pain and vitreous floaters. Serious ocular adverse events occurring more frequently in Lucentis-treated patients were uncommon (<1 percent) and included uveitis and endophthalmitis. There appeared to be no imbalance in serious non-ocular adverse events.

#### **About Lucentis**

Lucentis (ranibizumab) is a humanized monoclonal antibody fragment designed to bind and inhibit VEGF-A, a protein that is believed to play a critical role in angiogenesis (the formation of new blood vessels). Consequently Lucentis blocks new blood vessel growth and leakiness which leads to wet AMD disease progression and vision loss.

Lucentis is being developed by Genentech and the Novartis Ophthalmics Business Unit. Genentech retains commercial rights for Lucentis in North America (United States, Canada and Mexico). Novartis has exclusive commercialization rights for the rest of the world.

### **About Visudyne**

Visudyne therapy is a two-step procedure involving the intravenous administration of the drug into the patient's arm. A non-thermal laser light is then shone into the patient's eye to activate the drug. Once activated, Visudyne affects abnormal blood vessels, resulting in a cessation of growth of blood vessels in the eye and a stabilization of the corresponding vision loss. Visudyne therapy does not appear to damage normal retinal vessels.

### **About AMD**

AMD is a major cause of painless central visual loss and is a leading cause of blindness for people over the age of 50. It affects over 25 million people worldwide. AMD occurs in two forms: dry and wet. The dry form is associated with atrophy of the central retina or macula, that is required for fine vision used for activities such as reading, driving or recognizing faces. The wet form is caused by growth of abnormal blood vessels also known as choroidal neovascularization (CNV) or ocular angiogenesis under the macula. These vessels leak fluid and blood and cause scar tissue that destroys the macula. These changes result in a deterioration of sight over a period of months to years.

### **About angiogenesis**

Genentech is a leader in research and product development in the area of angiogenesis, the process by which new blood vessels are formed. In 1989 Napoleone Ferrara, M.D., and a team of scientists at Genentech conducted seminal work in the field, which resulted in the identification and cloning of a gene termed Vascular Endothelial Growth Factor (VEGF), now known as VEGF-A. The VEGF protein plays a critical role in angiogenesis, and serves as one of the key contributors to physiological or pathological conditions that can stimulate the formation of new blood vessels. The process of angiogenesis is normally regulated throughout development and adult life, and the uncontrolled growth of new blood vessels is an important contributor to a number of pathologic conditions, including wet AMD.

### **About Novartis Ophthalmics**

With worldwide headquarters in Basel, Switzerland, the Novartis Ophthalmics Business Unit is a global leader in research, development and manufacturing of leading ophthalmic pharmaceuticals that assist in the treatment of age-related macular degeneration, eye inflammation, glaucoma, ocular allergies and other diseases and disorders of the eye. Novartis Ophthalmics products are available in more than 110 different countries. Novartis Ophthalmics products are made in Switzerland, France, the United States and Canada. For more information, visit [www.novartisophthalmics.com](http://www.novartisophthalmics.com) or [www.us.novartisophthalmics.com](http://www.us.novartisophthalmics.com).

### **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 4.1 billion in R&D. Headquartered in Basel, Switzerland, Novartis Group companies employ about 91,700 people and operate in over 140 countries around the world. For further information please consult <http://www.novartis.com>.

**Novartis Global Investor Relations**

**Karen J. Huebscher, Ph.D.** +41 61 324 84 33

**International office**

Katharina Ambühl +41 61 324 53 16

Nafida Bendali +41 61 324 35 14

Richard Jarvis +41 61 324 43 53

Silke Zentner +41 61 324 86 12

e-mail: [investor.relations@novartis.com](mailto:investor.relations@novartis.com)

Fax: +41 61 324 84 44

[www.novartis.com](http://www.novartis.com)

**North American office**

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John Menditto +1 212 830 24 44

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**- Investor Relations Release -**

**Novartis announces leadership of new vaccines and diagnostics business**

**Basel, November 3, 2005** Novartis announced today that it has designated Dr. Joerg Reinhardt, currently Global Head of Pharma Development, to become CEO of a new Novartis division that will combine Chiron Corporation's (NASDAQ: CHIR) vaccines and diagnostics business, pending regulatory and shareholder approvals. In this new role,

Dr. Reinhardt will report directly to Dr. Daniel Vasella, the Chairman and CEO of Novartis.

The biopharmaceuticals business of Chiron will be integrated into the Pharma division of Novartis under the leadership of Thomas Ebeling, CEO of this division.

We are confident that Dr. Reinhardt's technical experience and leadership skills will enable us to maximize the potential of these two new growth platforms to further meet customer demand and address public health needs by driving innovation while increasing vaccine quality and production," said Dr. Daniel Vasella, Chairman and CEO of Novartis.

Dr. Reinhardt has spent 23 years at Novartis, most recently as head of its pharmaceutical development activities, which have been widely recognized as one of the most successful in the industry resulting in a full product pipeline. In that position, he has overseen the company's clinical, pharmaceutical, chemical and biotechnological product development, drug safety assessment and regulatory affairs. Under Dr. Reinhardt's leadership, Novartis has achieved an outstanding record in development quality, speed and productivity.

Dr. James S. Shannon, who now holds the position as Head of Clinical Development & Medical Affairs, has been named to succeed Dr. Reinhardt as Head of Pharmaceutical Development at Novartis Pharma AG. Dr. Shannon has guided the Diovan® clinical trial program, which is one of the largest clinical programs in the industry with over 50,000 patients, and has also been responsible for the development of the LAF237 and SPP100 programs, which are two of the most promising late-stage compounds with blockbuster potential in the Novartis pipeline. Dr. Shannon joined Sandoz in 1994 and played an integral role in the merger that formed Novartis. In the past, Dr. Shannon has led functions such as Regulatory Affairs and Global Project Management.

**More about the proposed transaction**

Novartis announced on October 31 that it has entered into a definitive merger agreement with Chiron Corporation to acquire all of the remaining publicly held shares of Chiron it does not currently own. Novartis has made an offer to acquire the remaining approximately 113 million fully diluted shares of Chiron for USD 45.00 per share in cash, or approximately USD 5.1 billion.

Chiron's Board of Directors, based upon the unanimous recommendation of Chiron's independent

directors, who were charged with acting solely on behalf of Chiron shareholders other than Novartis, have approved the Merger Agreement and recommended that Chiron shareholders vote to approve the merger.

Following approval of the proposed transaction by shareholders and regulatory authorities, Novartis will gain entry to the global vaccines market, which is expected to experience accelerating growth, more than doubling in sales in the next five years to over USD 20 billion in 2009 from about USD 9.6 billion in 2004, according to industry surveys. This acquisition also provides Novartis with access to a blood testing business, which offers strong near-term growth opportunities and potential for access to the emerging growth segment of molecular diagnostics.

Chiron, headquartered in Emeryville, California, has approximately 5,400 associates worldwide and is comprised of activities in vaccines, blood testing and biopharmaceuticals, had overall sales of USD 1.7 billion in 2004 and pro-forma net income of USD 152 million.

### **About Novartis**

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

### **Disclaimer**

This communication is for information purposes only. It shall not constitute an offer to purchase, sell or exchange or the solicitation of an offer to purchase, sell or exchange any securities of Novartis or Chiron. The distribution of this news release may, in some countries, be restricted by law or regulation. Accordingly, persons who come into possession of this document should inform themselves of and observe these restrictions.

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 "should", "can", "intends", "to become", "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; 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.

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**Novartis Global Investor Relations**

**Karen J. Huebscher, Ph.D.** +41 61 324 84 33

**International office**

|                  |                  |
|------------------|------------------|
| Katharina Ambühl | +41 61 324 53 16 |
| Nafida Bendali   | +41 61 324 35 14 |
| Richard Jarvis   | +41 61 324 43 53 |
| Silke Zentner    | +41 61 324 86 12 |

e-mail: [investor.relations@novartis.com](mailto:investor.relations@novartis.com)

Fax: +41 61 324 84 44  
[www.novartis.com](http://www.novartis.com)

**North American office**

|                    |                  |
|--------------------|------------------|
| <b>Ronen Tamir</b> | +1 212 830 24 33 |
| Nina Malik         | +1 925 551 59 64 |
| John Menditto      | +1 212 830 24 44 |
| Jill Pozarek       | +1 212 830 24 45 |

e-mail: [investor.relations@novartis.com](mailto:investor.relations@novartis.com)

Fax: +1 212 830 24 05  
[www.novartis.com](http://www.novartis.com)

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**Novartis International AG**  
CH-4002 Basel  
Switzerland

**Novartis Corporation**  
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New York, NY 10020  
USA

**- Investor Relations Release -**

**Exjade®, a breakthrough once-daily oral iron chelator, receives first approval worldwide in the US**

*Exjade offers new alternative to burdensome standard therapy in children and adults who require blood transfusions for chronic anemias*

*Approval makes iron chelation more accessible to patients suffering from diseases such as thalassemia, sickle cell and myelodysplastic syndromes*

**Basel, November 3, 2005** Novartis announced today the first approval worldwide for Exjade® (deferasirox) – the first and only once-daily oral iron chelator – by the US Food and Drug Administration. Exjade has been approved for the treatment of chronic iron overload due to blood transfusions in adults and children age two and older.

Exjade is the only iron chelator administered as a drink (the tablets are dispersed in a glass of orange juice, apple juice or water), compared to the current standard of care, which often requires a subcutaneous infusion lasting eight to 12 hours per night, for five to seven nights a week for as long as the patient continues to receive blood transfusions or has excess iron within the body. As a result, many patients may have stopped or avoided iron chelation therapy, thus risking the toxic effects of iron overload.

The approval of Exjade is expected to greatly enhance the acceptance of iron chelation therapy, especially for children, and offer a new alternative to the burdensome continuous infusion therapy.

The approval of Exjade is an advance for people like me, who have been having blood transfusions and iron chelation for most of our lives, said Jasmine Williams, who has sickle cell disease and participated in a clinical trial of Exjade. With Exjade I won't have to worry about using my needle and pump. I just have to drink my medicine and not think about it again until the next day. Exjade has really made a difference in my life.

Iron overload is a potentially life-threatening and unavoidable consequence of frequent blood transfusions used to treat certain types of rare chronic blood disorders, including thalassemia and sickle cell disease, as well as other rare anemias and myelodysplastic syndromes. Signs of iron overload may be detected after transfusion of about 20 units of blood. If left undiagnosed or untreated, the excess iron in the body is likely

to lead to damage to the liver, heart and endocrine glands. The body has no inherent mechanism to remove excess iron, so iron chelation is used as an effective treatment for transfusion-related iron overload.

We believe Exjade is a significant breakthrough that will fill an important gap in protecting

patients from the cumulative toxicity of iron overload by making iron chelation therapy much more acceptable. Until now, patients may have avoided the potentially life-saving benefits of iron chelation because the standard therapy can be difficult to use, said David Epstein, CEO of Specialty Medicines and President of Novartis Oncology.

Exjade was approved after being granted priority review by the FDA and also after the Blood Products Advisory Committee to the FDA voted unanimously to give Exjade a positive recommendation for approval. Designated an orphan drug in the US, Switzerland, Australia, and the EU, Exjade has also been granted a priority review in Switzerland, Canada, Australia and New Zealand. Additional regulatory submissions have been made around the world.

### **Filing data**

The Exjade filings were based on the results of a clinical trials program that included a Phase III trial, which showed that after one year Exjade produced reductions in liver iron concentration (LIC).

The clinical trials, which included more than 1,000 adults and children, were part of the largest prospective global clinical trials program ever implemented for an investigational iron chelator. LIC is an indicator for body iron content in patients receiving blood transfusions. It is a measure of iron accumulation in the liver. The studies demonstrated that Exjade, at 20-30 mg/kg/day, led to the maintenance or reduction of iron burden in transfused patients with thalassemia and sickle cell disease as well as other rare anemias and myelodysplastic syndromes. In the clinical studies, Exjade was generally well tolerated, with the most frequently reported adverse events being nausea, vomiting, diarrhea, abdominal pain, skin rash and increases in serum creatinine. As with deferoxamine (Desferal®), cases of ocular and auditory disturbances have been reported.

Mild, non-progressive increases in serum creatinine, mostly within the normal range, occur in about one-third of Exjade treated patients. These are dose-dependent, often resolve spontaneously and can sometimes be alleviated by reducing the dose. Serum creatinine should be assessed before initiating therapy and should be monitored monthly thereafter to determine if dose modification or discontinuation is necessary. Liver function should be monitored monthly and if there is an unexplained, persistent, or progressive increase in serum transaminase levels Exjade should be interrupted or discontinued.

### **About iron chelation**

In iron chelation, an agent binds to iron in the body and tissues and helps remove it through the urine and/or feces. The goal of iron chelation therapy is to remove the amount of iron administered in transfusions and, as required, to reduce the existing iron burden. In many patients the need for transfusions may be life-long. To date, only deferoxamine is globally available for the first-line treatment of transfusion related iron overload. While deferoxamine is effective, due to its burdensome administration, many patients do not undergo iron chelation therapy, exposing themselves to the dangers of iron overload. Novartis believes the approval of Exjade will not only help patients currently receiving iron chelation, but also extend the benefits of iron chelation to those not currently undergoing therapy.

The foregoing release contains forward-looking statements that can be identified by terminology such as significant breakthrough/breakthrough, will fill an important gap, first, is expected, is likely, potentially, greatly enhance, or similar expressions, or by express or implied discussion 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 (Desferal®) please contact your local Novartis affiliate.

**More Information For Health-Care Providers:**

Some clinical trials with Exjade are ongoing. To learn more about Exjade clinical trials, health-care providers can call +44 (0) 1506 814899 or +1-800-340-6843 in the US

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**International office**

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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: December 1, 2005

By: /s/ Malcolm B. Cheetham

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

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