

NOVARTIS AG  
Form 6-K  
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## SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

### FORM 6-K

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

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

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### Novartis AG

(Name of Registrant)

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(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:

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Yes:  No:

Enclosures:

1. NAVIGATOR trial investigators call for closer attention to glucose levels in cardiovascular and diabetes at-risk patients (Munich, Germany, August 31, 2004)
- 2.

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

FDA issues "approvable letter" for Certican® (Basel, 30 August 2004)

3. FDA Approves Zelnorm as the First Rx Therapy For Chronic Constipation (Basel, August 23, 2004)

4. *Prexige*® is first COX-2 selective inhibitor to significantly reduce gastrointestinal events without compromising cardiovascular safety compared to NSAIDs<sup>1,2</sup> (Basel, Switzerland, 20 August 2004)

5. Novartis completes Sabex acquisition (Basel, 16 August 2004)

6. Femara gains approval in Switzerland as only post-tamoxifen treatment for early breast cancer (Basel, 12 August 2004)

7. Novartis to launch new CHF 3 billion share buy-back program (Basel, 9 August 2004)

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**MEDIA RELEASE    COMMUNIQUE AUX MEDIAS    MEDIENMITTEILUNG**

**NAVIGATOR trial investigators call for closer attention to glucose levels in cardiovascular and diabetes at-risk patients**

*Data from this and other Diovan® (valsartan) studies, including VALIANT and Val-HeFT presented at the European Society Congress 2004*

**Munich, Germany, August 31, 2004** An analysis of more than 39,000 potential participants in the global NAVIGATOR (Nateglinide And Valsartan in Impaired Glucose Tolerance Outcomes Research) trial showed that an automatic assessment of glycemic status may improve unrecognized detection of type 2 diabetes and impaired glucose tolerance in people with heart disease or with risk factors for it.

Researchers found of those screened for the trial, one in four had undiagnosed type 2 diabetes, and a further 25-30 percent had previously unrecognized impaired glucose tolerance (IGT, also known as a pre-diabetes condition which frequently progresses to clinical diabetes). Type 2 diabetes and IGT are both risk factors for the development of cardiovascular disease.

"Physicians have long recognized cardiovascular disease as a common risk for people with both type 1 and type 2 diabetes; however, they are not aware of how frequently IGT and type 2 diabetes appear in people with heart disease or with risk factors for heart disease," said John McMurray, MD, Professor of Medical Cardiology, University of Glasgow, Scotland, UK and NAVIGATOR investigator.

"We're issuing this call for more vigilance on glycemic status. Although a high percentage of people we screened for NAVIGATOR tested positive for either IGT or type 2 diabetes, their previous medical records did not note these conditions," added Professor McMurray. "With nearly 800 sites in 39 countries, these findings suggest that this is not simply an issue in a few countries."

Commenting on the preliminary data from NAVIGATOR, Dr. Jörg Reinhardt, Head of Development, Novartis Pharma AG said, "Diovan has previously been associated with reducing new onset diabetes in a hypertensive high-risk population while Starlix has been proven to enhance early insulin secretion and reduce excessive post-meal blood glucose levels found in people with IGT and type 2 diabetes. Given the increasing prevalence of diabetes worldwide, the NAVIGATOR study takes on even greater importance in that it may demonstrate how these therapies can help millions of patients reduce their risk of developing clinical type 2 diabetes as well as cardiovascular disease. Novartis is pleased to be at the forefront of this pioneering research."

Though not expected to conclude until 2008, NAVIGATOR has already yielded data likely to prove useful to cardiologists and their patients. At its conclusion the trial will demonstrate whether the high blood pressure medicine *Diovan* or the oral anti-diabetic agent *Starlix*® (nateglinide) can reduce the incidence of CVD events and prevent people with IGT from progressing to clinical diabetes.

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**VALIANT study papers address critical issues for patients surviving heart attacks**

In addition to the news from NAVIGATOR, investigators from the VALIANT and Val-HeFT studies, also sponsored by Novartis, presented new data during the European Society of Cardiology Congress 2004:

New findings by Dr. Scott D. Solomon, Director of the Noninvasive Cardiac Laboratory at Brigham and Women's Hospital and Associate Professor of Medicine at Harvard Medical School, Massachusetts, USA, and colleagues demonstrate that Diovan produces a positive effect on the size and function of the heart's left ventricle in people who have survived a myocardial infarction or MI. The positive effect was equivalent to that of the angiotensin converting enzyme (ACE) inhibitor drug captopril.

A sub-study led by Dr. Lars Kober, MD, Department of Cardiology, Gentofte University Hospital, Copenhagen, Denmark, notes that patients with a form of irregular heart rhythm known as atrial fibrillation (AF), which can show up before or after a heart attack, have increased risk of additional complications and death. According to a sub-study of the Val-HeFT trial presented by Professor Aldo Maggioni, GISSI Group, coordinated by the Italian Association of Hospital Cardiologists (ANMCO) and the Istituto di Ricerche Farmacologie, Mario Negri, Milan, Italy, Diovan demonstrated an ability to reduce AF.<sup>1</sup> The new report poses the question of whether treatment can reduce AF in the post-MI population.

Novartis is focused on improving the care of patients with high blood pressure and heart disease through world-class research and unprecedented public health initiatives. The *Diovan* clinical trial program is one of the world's largest in cardiovascular research, involving approximately 50,000 patients including more than 9,500 patients with diabetes. Recently completed *Diovan* trials include VALUE in high blood pressure patients at risk for cardiovascular complications because of co-existing diseases or risk factors such as diabetes, history of stroke, and coronary artery disease; VALIANT in post-heart attack patients; and Val-HeFT in heart failure patients. Ongoing studies include the large outcomes NAVIGATOR trial and Val-MARC, a study on the effects of Diovan on C-reactive protein, an inflammatory marker for heart disease.

The fastest-growing high blood pressure drug on the market today, *Diovan* has been approved for first-line treatment of high blood pressure in more than 80 countries and in more than 50 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 U.S. and Switzerland, amongst other countries, *Diovan* is indicated for the treatment of heart failure in patients who cannot tolerate ACE inhibitors. On the basis of the results of VALIANT, Novartis has submitted marketing authorization applications to regulatory authorities around the world for a new indication for *Diovan* for use in patients at risk after having survived a heart attack. In addition to powerful double-digit blood pressure reductions and superior tolerability, patient persistency and patient compliance, *Diovan* has proven cardio-protective benefits beyond lowering blood pressure.

*Starlix*, a D-phenylalanine (amino acid) derivative, is a novel compound for the treatment of type 2 diabetes. *Starlix* was first approved in the U.S. in 2001 both as a monotherapy for drug-naïve patients with type 2 diabetes and also in combination with metformin, a leading oral antidiabetic agent. In 2003, the U.S. Food & Drug Administration approved the use of *Starlix* in combination with a thiazolidinedione (TZD) in patients with type 2 diabetes who are not adequately controlled after a therapeutic response to a TZD. *Starlix* is also approved in many countries around the world for the treatment of type 2 diabetes. In the EU, *Starlix* has been approved in combination therapy with metformin in type 2 diabetes patients inadequately controlled despite a maximally tolerated dose of metformin alone. Nateglinide is licensed to Novartis Pharma AG from Ajinomoto Co., Inc.

**References**

"Valsartan Reduces the Incidence of Atrial Fibrillation in the Patients with Heart Failure in the Val-HeFT trial." Abstract presented at ESC 2003.

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**About Novartis**

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

**Disclaimer**

The foregoing release contains forward-looking statements that can be identified by terminology such as "potential" "investigating", "new applications", or similar expressions, or by discussions regarding potential new indications or labeling for Diovan, Starlix, or regarding the long-term impact of a patient's use of either product. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results with Diovan or Starlix 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 Starlix will be approved for any additional indications or labeling in any market. In particular, management's ability to ensure satisfaction of the health authorities' further requirements is not guaranteed and management's expectations regarding commercialization of Diovan or Starlix could be affected by, among other things, additional analysis of Diovan or Starlix 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; 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.

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**Investor Relations Release**

**FDA issues "approvable letter" for Certican®**

**Basel, 30 August 2004** Novartis Pharma AG has received an "approvable" letter from the U.S. Food and Drug Administration (FDA) for *Certican* (everolimus) in combination with *Neoral* (cyclosporin for microemulsion) for the prevention of rejection episodes following heart or kidney transplantation.

The FDA has requested that Novartis provide "additional" information supporting a safe and effective dosing regimen for the combination of everolimus and cyclosporin. The FDA had previously issued an approvable letter for *Certican* in October 2003 with a request for additional clinical data on dosing regimens. Novartis submitted data in response to the first approvable letter in February 2004. However, the FDA still believes that additional clinical studies on dosing are necessary.

Already approved for use in Europe, *Certican* is a novel proliferation signal inhibitor with immunosuppressive and antiproliferative properties. It is the latest innovation in the 20-year history of Novartis leadership in transplantation medication. The new drug application to the FDA for *Certican* included data from one of the most extensive drug development programs conducted to date for a transplantation product.

"Everolimus has been shown in clinical trials to provide important benefits that would be of significant value to transplant patients and their health care providers," said Howard Eisen, M.D., Professor of Medicine at Temple University School of Medicine in Philadelphia.

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*All product names appearing in italics are trademarks of the Novartis Group*

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### Investor Relations Release

## FDA Approves Zelnorm as the First Rx Therapy For Chronic Constipation

### *4.5 Million Americans Suffer from Constipation Most of the Time*

**Basel, August 23, 2004** Novartis Pharma AG announced that the U.S. Food and Drug Administration (FDA) today approved a supplemental indication for its pro-motility agent Zelnorm® (tegaserod maleate) for the treatment of chronic idiopathic constipation in male and female patients less than 65 years of age.

The new indication is supported by safety and efficacy data from the two largest and longest randomized, double-blind, placebo-controlled, multi-national Phase III clinical trials ever conducted in chronic constipation. The two three-month trials included more than 2,600 male and female patients. In addition, one of the studies included a 13-month extension safety study of 840 patients. Zelnorm was found to significantly increase the frequency of complete spontaneous bowel movements as well as to provide relief of the multiple symptoms of chronic constipation that patients complain about most, including straining, hard stool, incomplete evacuation, infrequent defecation, bloating and abdominal discomfort.

"Chronic constipation has a tremendous impact on patients' lives, with nearly a million visits to emergency rooms every year, almost six million visits to doctors' offices, and thousands of hospitalizations," said Joerg Reinhardt, Head Development, Novartis Pharma AG. "We are very pleased the FDA has found Zelnorm safe and effective and has approved it for treatment of patients with chronic constipation. Novartis believes it will help bring relief to millions of patients."

Zelnorm has been available since July 2002 as the first and only prescription medication proven to provide women with the relief of abdominal discomfort or pain, bloating and constipation associated with irritable bowel syndrome (IBS). IBS with constipation and chronic idiopathic (meaning not due to other diseases or drugs) constipation are both lower gastrointestinal dysmotility disorders.

### **About Constipation**

Constipation, including that due to other diseases or drugs, is one of the leading gastrointestinal complaints in the United States, affecting nearly 18 percent of the population, or 37 million people. More than 4.5 million Americans report they are constipated most of the time. Chronic constipation, as a whole, accounts for more than 5.7 million constipation-related outpatient visits each year, with 990,994 to emergency rooms and 586,868 to hospital outpatient facilities. It leads to more than 282,000 in-patient hospitalizations with constipation as the primary diagnosis. Diagnosed cases of chronic constipation are evenly distributed across age groups and in both genders, although it is slightly more frequent in women.

### **A Need for New Therapies**

"Chronic constipation can have a huge impact on the sufferer's quality of life," says Larry Schiller, M.D., Attending Physician, Baylor University Medical Center, Dallas, Texas. "In addition, many chronic constipation patients have expressed dissatisfaction with the efficacy and tolerability of standard treatment options including fiber, osmotic laxatives or bulking agents. Zelnorm offers a new proven option for these patients."

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A recent survey with 557 patients found that 47 percent of patients with chronic constipation were not completely satisfied with currently available therapies due to the efficacy of these agents (82 percent) and the safety and side effects (16 percent). More than half (52 percent) of respondents felt that chronic constipation adversely impacted their quality of life.

In another survey of 311 primary care physicians, 98 percent reported that constipation was at least somewhat bothersome to their patients, with 95 percent describing constipation as having some impact on patients' quality of life. Furthermore, 60 percent of these physicians agreed that they do not have adequate products to treat patients with constipation, and 91 percent wished that better treatment options were available.

#### **About Zelnorm**

As a pro-motility agent, Zelnorm acts as an agonist at 5HT<sub>4</sub> (serotonin type 4) receptors in the GI tract and mimics the natural effects of serotonin by activating 5HT<sub>4</sub> receptors, which normalizes impaired motility in the GI tract, inhibits visceral sensitivity and stimulates intestinal secretion. Zelnorm treats dysmotility symptoms caused by chronic constipation and IBS with constipation.

Zelnorm is indicated for the short-term treatment of women with IBS whose primary bowel symptom is constipation. The safety and effectiveness of Zelnorm in men with IBS with constipation have not been established.

Zelnorm is also indicated for the treatment of patients less than 65 years of age with chronic idiopathic constipation. The effectiveness of Zelnorm in patients 65 years or older with chronic idiopathic constipation has not been established.

Overall, safety data is now available in more than 11,600 patients who have enrolled in clinical trials assessing Zelnorm's safety and efficacy in various GI conditions.

In chronic constipation studies, the incidence of adverse events with Zelnorm was similar to that of placebo. The only adverse event reported more often with Zelnorm 6 mg twice-a-day than placebo was diarrhea (6.6 percent vs. 3 percent). Diarrhea rarely led to discontinuation of the study (0.9 percent). Typically, diarrhea was transient, lasting two days, and generally resolved without rescue medication or interruption of treatment. Data from the trial that incorporated a 13-month extension study showed Zelnorm to be generally safe and well tolerated long term.

In IBS with constipation clinical trials, tolerability to Zelnorm was similar to placebo. The only adverse event reported notably more often with Zelnorm than with placebo was diarrhea (9 percent vs. 4 percent). The majority of patients reporting diarrhea had a single episode and in most cases, diarrhea occurred in the first week of treatment. Typically, it resolved with continued therapy. Serious consequences of diarrhea, including hypovolemia, hypotension and syncope, have been reported in the clinical studies (0.04 percent) and during marketed use of Zelnorm. In some cases, these complications have required hospitalization for rehydration.

Zelnorm was developed by Novartis and is also known in some countries as Zelmac. It is approved in more than 55 countries for IBS with constipation. Zelnorm also is approved for use in chronic constipation in 10 countries, including Mexico and Latin America. Zelnorm is being studied as a potential treatment for other important GI motility disorders, including gastroesophageal reflux disease (GERD) and dyspepsia.

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**Investor Relations Release**

***Prexige*<sup>®</sup> is first COX-2 selective inhibitor to significantly reduce gastrointestinal events without compromising cardiovascular safety compared to NSAIDs<sup>1,2</sup>**

*Landmark TARGET study shows up to 79% reduction of ulcer complications with Prexige versus established NSAIDs<sup>1</sup>*

*No increase in cardiovascular risk and more favorable blood pressure profile of Prexige versus NSAIDs<sup>2</sup>*

**Basel, Switzerland, 20 August 2004** Novartis Pharma AG announced today that results from a landmark trial showed that *Prexige*<sup>®</sup> (lumiracoxib), the structurally distinct and most selective COX-2 inhibitor, demonstrated a significant 79% reduction in the incidence of upper gastrointestinal (GI) ulcer complications without compromising cardiovascular (CV) safety.

The results were the basis for two papers published online in *The Lancet* on the findings of the landmark TARGET (Therapeutic Arthritis Research & Gastrointestinal Event Trial of lumiracoxib) study that further confirmed the safety benefit of *Prexige*<sup>1,2</sup>.

"The excellent GI and CV safety profile of *Prexige* demonstrated by the positive results of TARGET shows a favorable benefit/risk ratio for *Prexige*, even at multiples of the normal chronic dose. These findings may be linked to the different chemical and pharmacokinetic properties of *Prexige* which is the most selective COX-2 inhibitor," said Joerg Reinhardt, Head of Development, Novartis Pharma AG.

"With up to an estimated 16,500 GI-related deaths in the U.S. each year, these convincing data from 18,325 patients with osteoarthritis (OA) builds on the body of evidence suggesting that *Prexige* is effective while offering substantial GI safety benefits. TARGET fully supports the approved label in the UK and builds a strong basis for the ongoing European Mutual Recognition Process (MRP), which was recently started," Reinhardt said.

TARGET is the largest GI safety outcomes study performed to date and clearly demonstrates beneficial results specifically for the GI safety of *Prexige*. The TARGET data demonstrate that in patients not taking low-dose aspirin, *Prexige* had an overall statistically significant reduction of 79% versus the two comparator NSAIDs (non-steroidal anti-inflammatory drugs) naproxen and ibuprofen in the incidence of definite or probable upper GI ulcer complications (p<0.0001). *Prexige* significantly reduced the incidence of upper GI ulcer complications in those patients not taking aspirin by 83% versus ibuprofen and by 76% versus naproxen. For the overall population (patients taking and not taking low dose aspirin), *Prexige* significantly reduced the incidence of upper GI ulcer complications by 66% versus the two NSAIDs. For the smaller subgroup of patients taking aspirin, a numerical trend of 21% decrease of ulcer complications in favor of *Prexige* was observed compared to the NSAIDs<sup>1</sup>.

"TARGET was a very well-designed study and therefore yields robust results for *Prexige*, demonstrating an up to four-fold reduction in the incidence of GI ulcer complications compared to NSAIDs," said Chris Hawkey, Professor of Gastroenterology and Co-director of the Institute of Clinical Research, University of Nottingham and Chairman of the GI committee during the TARGET trial. "The benefit demonstrated by *Prexige* has not been shown by any other selective COX-2 inhibitor."

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In addition to GI tolerability, TARGET investigated CV safety. *Prexige* did not increase the CV risk (defined as the combined Anti-Platelet Trialist Collaboration [APTC] endpoint) compared to the two NSAIDs. The APTC endpoint included confirmed or probable non-fatal myocardial infarction (MI) including silent MI (ECG-detected), non-fatal stroke (ischemic or hemorrhagic) and cardiovascular death. For the APTC endpoint, no significant difference between *Prexige* and the comparator NSAIDs was observed in the overall population, or in the populations investigated separately for those taking or not taking low-dose aspirin. Furthermore, there was no significant difference in the incidence of MIs, congestive heart failure and other thrombotic events observed in the overall population groups studied between *Prexige* and naproxen or ibuprofen<sup>2</sup>.

"TARGET demonstrates that *Prexige* has a CV profile similar to conventional NSAIDs with a more favorable blood pressure profile. These very important results show that *Prexige* offers GI benefits to patients without compromising their CV safety," said Dr. Michael Farkouh, Director of the Cardiac Care Unit at New York University Medical Center and Chair of the TARGET Cardio-Cerebrovascular adjudication committee. "In TARGET, we found no difference in MIs, stroke or any of the other CV endpoints investigated between *Prexige* and ibuprofen or naproxen."

For the pre-specified endpoint combining serious GI and CV events, *Prexige* at up to four times the recommended dose for OA showed a significant 35% reduction (p=0.001) versus the NSAID groups<sup>1</sup>. Importantly, mean changes in systolic and diastolic blood pressure from baseline for patients taking *Prexige* were significantly smaller (p=0.0001) than for those taking NSAIDs (systolic +0.4 mmHg vs. +2.1 mmHg respectively; diastolic -0.1 mmHg vs. +0.5 mmHg respectively)<sup>1,2</sup>.

Serious GI or CV events are more frequent side effects in patients treated with NSAIDs and COX-2 selective inhibitors than serious hepatic events, as confirmed in TARGET with a more than ten times higher frequency of serious GI and CV events than hepatic events. In TARGET, there was no significant difference in serious hepatic events leading to jaundice between *Prexige* and the NSAID groups<sup>1</sup>. Of the approximately 9,000 patients using twice the maximum dose of *Prexige* for use in OA, six cases of jaundice were observed [0.07%], while two cases in the group using ibuprofen [0.05%] and one with naproxen [0.02%] at therapeutic doses with approximately 4,500 patients in each group. After discontinuation of therapy, all effects resolved fully. Less serious and transient hepatic enzyme elevations were recorded more often with *Prexige* compared to NSAIDs [2.6% versus 0.6% respectively], but were less frequent than seen with the most widely prescribed NSAID diclofenac [4%]<sup>8</sup>.

Recently completed studies with *Prexige* 100 mg daily in OA have shown hepatic enzyme elevations to be comparable to placebo at 13 weeks [0.25% 3xULN] (data on file).

#### **About TARGET**

TARGET was designed to answer questions about the overall safety of *Prexige*, building on the experience and shortcomings of previous GI outcomes trials of celecoxib (CLASS study) and rofecoxib (VIGOR study)<sup>3</sup>. In total, 18,325 patients participated in TARGET, randomized at more than 800 trial sites worldwide. The trial was designed to examine GI safety as the primary endpoint and CV safety as a secondary endpoint of *Prexige* 400 mg once daily two or four times the indicated dose for use in OA versus standard doses of ibuprofen 800 mg three times daily and naproxen 500 mg twice daily over 12 months. TARGET is also the first outcomes study designed to examine the impact of low-dose aspirin with *Prexige* on both GI and CV safety. In keeping with a "real-life" OA population, 24% of the randomized patients in TARGET included low-dose aspirin with their study medication for primary and secondary prevention of CV disease<sup>3</sup>.

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TARGET had several key differentiating features. The large size of the trial (>18,000 patients), a high retention rate at one year (60%), the choice of homogenous study population with OA and stratifying at randomization 24% of the patient population for low dose aspirin use (75-100 mg daily) all contributed to providing the power necessary to investigate the serious GI events that can occur with regular NSAID use in a representative OA population. The study design also permitted an assessment of the influence of low-dose aspirin on the GI benefit, a comparison with two NSAIDs with different anti-thrombotic properties, and a prospective investigation of key cardiovascular endpoints in patients taking, or not taking, concomitant low-dose aspirin. The TARGET study began in late 2001 and enrolled patients in the US, Europe, South America, Canada, South Africa and Asia. The TARGET protocol was reviewed by the US Food and Drug Administration (FDA), and study data were evaluated on an interim basis by an independent data and safety monitoring board.

#### **About *Prexige***

*Prexige* was developed for the treatment of the signs and symptoms of arthritis and management of pain. *Prexige* is the most selective cyclooxygenase-2 (COX-2) inhibitor with a non-sulfur containing structure distinct from existing selective COX-2 inhibitors<sup>4</sup>. *Prexige* has proven efficacy in an extensive phase III clinical trial program demonstrating rapid onset in acute pain with 400mg once daily (od) for short term use<sup>5</sup> and efficacy in OA with 100mg od (data on file) and 200mg od<sup>6</sup> and rheumatoid arthritis at 200mg od<sup>7</sup>.

Novartis has filed applications for regulatory approval throughout the world based on data from more than 40 pre-clinical and clinical studies in OA, rheumatoid arthritis, acute pain and primary dysmenorrhea involving more than 13,000 adult patients around the world. *Prexige* has been approved in 17 countries to date, including the United Kingdom, Australia and several countries in Latin America, including Argentina, Brazil and Mexico. Novartis have shared the TARGET data with all health authorities, including the UK Health Authority and the MHRA, and are currently initiating the Mutual Recognition Procedure (MRP) process in Europe.

#### **About Osteoarthritis**

Osteoarthritis (OA), the most common form of arthritis, is characterized by the breakdown of cartilage in joints, causing affected bones to rub against each other. This often leads to inflammation, pain and loss of movement. Globally, OA accounts for half of all chronic conditions in people age 65 and older, with an estimated 103 million Europeans and 20.7 million Americans affected. The economic impact of musculoskeletal diseases, including OA, is substantial, costing the US nearly \$65 billion annually in direct expenses, lost wages and production. Risk factors associated with OA include accidents, age, joint injuries due to sports, obesity or work-related activity.

#### **About Novartis**

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

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## Disclaimer

*The foregoing press release contains forward-looking statements that can be identified by terminology such as "may be", "suggesting", "builds a basis" or similar expressions, or by express or implied discussions regarding potential future regulatory filings, approvals or future sales of Prexige (lumiracoxib). 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 future regulatory filings will satisfy the FDA's and other health authorities' requirements regarding Prexige, that Prexige will be approved by the FDA or by any other country's health authorities for any indication, or that Prexige will reach any particular level of sales. In particular, management's expectations regarding Prexige could be affected by, among other things, uncertainties relating to clinical trials and product development, including additional clinical trials which must be conducted in the future in order to satisfy FDA's requirements; regulatory actions or delays or government regulation generally; the ability to obtain or maintain patent or other proprietary intellectual property protection; government, industry, and general public pricing pressures; and competition in general; as well as factors discussed in the Company's Form 20F 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 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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### Investor Relations Release

#### Novartis completes Sabex acquisition

*Provides strong growth opportunities in generic injectables market*

**Basel, 16 August 2004** Novartis AG announced today that its Sandoz generics business unit has completed the acquisition of Sabex Holdings Ltd., a leading Canadian generics pharmaceutical manufacturer in a USD 565 million cash transaction that officially closed on August 13. Sabex was acquired from the US private equity firm RoundTable Healthcare Partners, which had held a majority stake in the company.

The acquisition of Sabex establishes a new presence for Sandoz in Canada, the sixth largest generics market worldwide, and provides an attractive global growth platform in the fast-growing injectable generics business. Sandoz is focusing on strong organic growth complemented by strategic acquisitions to gain access to new geographic markets, therapeutic lines, formulations and production capabilities.

Sabex, which is based in Boucherville, Quebec, is a privately held generics manufacturer that offers a broad range of critical care and ophthalmic medicines as well as suppositories and other products covering more than 80 molecules.

#### Company Information

Sandoz, a Novartis company, is a world leader in generic pharmaceuticals and develops, manufactures and markets these medicines as well as pharmaceutical and biotechnological active ingredients. Decades of experience and profound know-how make Sandoz a renowned partner in the Franchises Pharmaceuticals, Biopharmaceuticals and Industrial Products. Altogether, Sandoz employs around 13,000 people worldwide and posted sales of USD 2.9 billion in 2003.

Novartis AG (NYSE: NVS) is a world leader in pharmaceuticals and consumer health. In 2003, the Group's businesses achieved sales of USD 24.9 billion and a net income of USD 5.0 billion. The Group invested approximately USD 3.8 billion in R&D. Headquartered in Basel, Switzerland, Novartis Group companies employ about 78,500 people and operate in over 140 countries around the world. For further information please consult <http://www.novartis.com>.

This release contains certain "forward-looking statements" relating to the Group's business, which can be identified by the use of forward-looking terminology such as "coming on stream", "will be", "to become", or similar expressions, or by express or implied discussions regarding strategies, plans and expectations. Such statements reflect the current plans or views of the Group with respect to future events and are subject to certain risks, uncertainties and assumptions. Management's expectations could be affected by, among other things, competition in general, and other risks referred to in Novartis AG's 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 described herein as anticipated, believed, estimated or expected.

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**MEDIA RELEASE    COMMUNIQUE AUX MEDIAS    MEDIENMITTEILUNG**

**Femara gains approval in Switzerland as only post-tamoxifen treatment for early breast cancer**

*Switzerland is first European country to approve use of Femara for post-menopausal women in extended adjuvant (post-tamoxifen) setting*

Basel, 12 August 2004 Femara® (letrozole) has been approved in Switzerland via fast track procedure for the extended adjuvant treatment of postmenopausal women with hormone receptor positive or unknown early breast cancer who have received post-surgery tamoxifen therapy for five years, Novartis announced today. This approval by the Swiss Agency for Therapeutic Products (Swissmedic) makes Switzerland the first European country to have approved the extended adjuvant indication. The term *extended adjuvant* describes the period following the current standard five years of adjuvant treatment with tamoxifen.

"Novartis is very pleased that the Swiss health authorities recognize the importance of Femara in helping to reduce the ongoing risk of breast cancer recurrence among postmenopausal women who have survived breast cancer," said Diane Young, MD, vice president, global head, Clinical Development, Novartis Oncology. "We continue to work diligently with health authorities to make this indication available as soon as possible in the European Union, the United States, and around the world."

Even years after breast cancer diagnosis and primary treatment, the ongoing risk of breast cancer recurrence and mortality remains significant. Approximately one-third of women with estrogen receptor-positive early breast cancer will experience a recurrence, and more than half of these recurrences occur later than five years after surgery, according to the Early Breast Cancer Trialists Group, Oxford, UK.

The approval for the use of Femara in the extended adjuvant setting was based on the landmark MA-17 study, results of which were initially published in the online edition of the *New England Journal of Medicine* in October 2003. Coordinated by the National Cancer Institute of Canada Clinical Trials Group at Queens University in Kingston, Ontario and supported by Novartis, the MA-17 study evaluated extended adjuvant treatment with Femara vs. placebo in nearly 5,200 postmenopausal women with early breast cancer.

Results from the final analysis of MA-17 were presented at the annual meeting of the American Society for Clinical Oncology (ASCO) in June 2004. The data showed that extended adjuvant treatment with Femara, following standard adjuvant tam-oxifen in postmenopausal women with early breast cancer, cut the risk of relapse by 42%.

At the median 2.5-year follow-up, a survival advantage had become apparent in those women whose cancer had already spread to lymph nodes at the time of diagnosis (node-positive). In this group of trial participants, which comprised approximately half of all patients in MA-17, deaths were reduced by a significant 39% vs. placebo. Patients with node-positive breast cancer are more likely to develop distant metastases and, therefore, may be at greater risk of dying from the disease.

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## Safety Data

The MA-17 study also included pre-planned sub-studies that assessed the effect of Femara on bone mineral density and lipid metabolism. While there was no significant difference between treatment groups in bone fractures, the authors noted more newly diagnosed cases of osteoporosis in women taking Femara vs. placebo (6.9% vs. 5.5%;  $P=0.04$ ).

Neither the core MA-17 protocol nor the lipid sub-study showed significant differences between the Femara and placebo groups in terms of cardiovascular events or lipid profiles.

## Femara

Femara, an aromatase inhibitor, is an oral once-a-day first-line treatment for postmenopausal women with hormone receptor positive or hormone receptor unknown locally advanced or metastatic breast cancer. It is also approved for the treatment of advanced breast cancer in postmenopausal women with disease progression following antiestrogen therapy, and as neo-adjuvant (pre-operative) therapy. Novartis has filed for the extended adjuvant indication in the European Union and in countries around the world. In the United States, the Food and Drug Administration has granted the filing for this indication a priority review, and a decision is expected shortly. Femara is currently available in more than 80 countries worldwide. Not all indications are available in every country.

## Contraindications and adverse events

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

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

## About Novartis

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

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

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*The foregoing release contains forward-looking statements that can be identified by terminology such as "continue to work", "to make... available," "will," "likely to," "may be," "is expected", or similar expressions, or by express or implied discussions regarding potential new indications for Femara or potential future sales of Femara, or regarding the long-term impact of a patient's use of Femara. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results with Femara to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Femara will be approved for any additional indications in any market. Nor can there be any guarantee regarding potential future sales of Femara. Neither can there be any guarantee regarding the long-term impact of a patient's use of Femara. In particular, management's expectations regarding commercialization of Femara could be affected by, among other things, additional analysis of Femara clinical data; new clinical data; unexpected clinical trial results; unexpected regulatory actions or delays or government regulation generally; the company's ability to obtain or maintain patent or other proprietary intellectual property protection; competition in general; 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 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 Release

#### Novartis to launch new CHF 3 billion share buy-back program

Basel, 9 August 2004 Novartis AG announced today that its Board of Directors has decided to launch a new share repurchase program for up to CHF 3 billion following the completion of a program initiated in 2002. The new program was approved by shareholders at the Annual General Meeting (AGM) in February 2004.

Novartis intends to repurchase the shares over an unspecified time via a second trading line on virt-x. The program will apply exclusively to Novartis registered shares listed on the SWX Swiss Exchange and not to Novartis American Depository Shares (ADSs) traded on the New York Stock Exchange.

In addition, the Board of Directors intends to propose at the next AGM in 2005 that the share capital of Novartis be reduced by an amount corresponding to the shares repurchased so far under this new program.

"Launching a new share buy-back program enables Novartis to continue returning surplus liquidity to shareholders, which is a result of our dynamic organic growth and robust free cash flow," said Daniel Vasella, Chairman and CEO of Novartis. "At the same time, we are maintaining a high degree of strategic flexibility and financial strength to seize appropriate opportunities."

Two earlier share buy-back programs were initiated in 1999 and 2001, both of which ended after the purchase of CHF 4 billion in shares in each program. Novartis completed its third share buy-back program on 6 August 2004 and bought back 69 779 000 shares for an amount of CHF 4 billion. A proposal will be put forward to shareholders at the Annual General Meeting in 2005 to cancel 22 839 000 shares, or 0.82% of the current share capital, after 46 940 000 shares were cancelled at the Annual General Meetings in 2003 and 2004.

The existing second trading line for Novartis registered shares will be maintained on virt-x for this new program. Novartis will be the exclusive buyer on this line and intends to repurchase its own shares for the purpose of subsequently reducing its share capital. Ordinary trading of Novartis registered shares under the Swiss security number 1 200 526 will not be affected and will continue as usual. A shareholder wishing to sell Novartis registered shares has the option of selling either via the ordinary trading channel or to Novartis via the second trading line for the purpose of the subsequent share capital reduction. Novartis has, however, at no point in time any obligation to purchase its own shares on the second trading line.

Shares purchased on the second trading line are subject to the Swiss federal withholding tax rate of 35% on the difference between the repurchase price of the Novartis registered share and its nominal value.

#### About Novartis

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The following applies, among others, to the United States of America and to US persons:

This offer is not made in the United States of America and to U.S. persons and may be accepted only by non-U.S. persons and BY PERSONS outside the United States. Offering materials with respect to this offer may not be distributed in or sent to the United States and may not be used for the purpose of solicitation of an offer to purchase or sell any securities in the United States.

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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: 02.09.2004

By: /s/ MALCOLM B. CHEETHAM

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Name: Malcolm B. Cheetham

*Title: Head Group Financial Reporting and Accounting*

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