

NOVARTIS AG  
Form 6-K  
September 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 August 2005

(Commission File No. 1-15024)

---

**Novartis AG**

(Name of Registrant)

Lichtstrasse 35

4056 Basel

Switzerland

(Address of Principal Executive Offices)

---

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F:

Edgar Filing: NOVARTIS AG - Form 6-K

Form 20-F:  Form 40-F:

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

Yes:  No:

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

Yes:  No:

Indicate by check mark whether the registrant by furnishing the information contained in this form is also thereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934.

Yes:  No:

---

Enclosures:

1. Aclasta® superior to risedronate for Paget's disease of the bone in head-to-head study published by *The New England Journal of Medicine* (Basel, August 31, 2005)
2. Femara® granted FDA priority review for new indication as adjuvant treatment for postmenopausal women with early breast cancer (Basel, August 29, 2005 )
3. Novartis acquires rights to develop and commercialize new treatment for hyperphosphatemia in kidney dialysis patients (Basel, August 18, 2005)
4. Novartis receives FDA approval for Diovan® (valsartan) to reduce cardiovascular death in heart attack survivors at high risk (Basel, August 4, 2005)

**Investor Relations**

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

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

**- Investor Relations Release -**

**Aclasta® superior to risedronate for Paget's disease of the bone in head-to-head study published by *The New England Journal of Medicine***

*Single 15 minute infusion of Aclasta found more effective, faster acting and longer-lasting than 2 month course of standard oral therapy*

**Basel, August 31, 2005** A head-to-head study published in *The New England Journal of Medicine (NEJM)*(1) showed that a single dose of Aclasta® (zoledronic acid 5mg solution for infusion) in patients with Paget's disease offers superior efficacy, a longer period of remission and more rapid onset of action compared to the oral bisphosphonate risedronate.(1)

Two identical double-blind, active-controlled trials in patients with Paget's disease compared a single 15-minute IV infusion of Aclasta\* to oral risedronate (30 mg per day for 60 days) in 357 patients with Paget's disease, from 76 centers in ten countries. Affecting 4 million people worldwide(2), Paget's disease is the second most prevalent bone disease after osteoporosis and is a chronic, often painful and potentially debilitating bone disorder marked by the malfunction of the body's regular bone-building process.(3) Patients may experience bone pain, skeletal deformity, pathological fractures, secondary arthritis, neurological complications and deafness.

At six months, 96% of Aclasta patients showed a therapeutic response, compared to 74% of patients treated with risedronate (p<0.001). Aclasta patients also showed a shorter median time to first therapeutic response (64 versus 89 days). Additionally, serum alkaline phosphatase (SAP) levels – a key marker for bone turnover – were normalized in 89% of Aclasta patients, compared with 58% of risedronate patients. The superior response rates with Aclasta were independent of age, gender, baseline SAP levels and previous therapy for Paget's disease.

This study provides for a new and effective option for patients with Paget's disease by demonstrating that a single dose of Aclasta is more effective than the current standard of care – both in time to first response and in normalizing the bone turnover process for longer periods, said lead study author Ian Reid, MD, University of Auckland, New Zealand. The convenient infusion of zoledronic acid eliminates the need for patients to comply with the strict daily regimen required by oral medications.

Overall, the number of patients with adverse events were similar in the Aclasta and risedronate groups. The most common adverse events with Aclasta were mild to moderate flu-like symptoms such as muscle aches and low grade fever relating to the infusion, the majority of which

occurred

within three days of infusion and usually resolved within four days. After three days, adverse events were comparable between the two groups.(1)

---

\*Aclasta is the trademark of zoledronic acid 5mg in Europe and the rest of the world. The US tradename is under review.

For those patients that responded at the end of six months and entered into the post-trial follow-up for a further six months, there was a loss of therapeutic response in only one out of 113 Aclasta-treated patients, compared with 21 out of 82 risedronate-treated patients.

Based on the results of these studies, Aclasta was licensed for the treatment of Paget's disease in all 25 European Union member states, as well as Norway and Iceland, in April 2005. Canadian regulatory authorities approved Aclasta in June 2005. Aclasta was launched in Germany, the first EU launch market, in May 2005 and is expected to be launched in other European countries during 2005 and 2006. The US Food and Drug Administration issued an approvable letter for this product for the treatment of Paget's disease of the bone in March 2005. Novartis is working with the US regulatory agency to gain approval for this indication.

Aclasta is being studied worldwide in a series of independent, multi-national and multi-center clinical trials program called HORIZON (Health Outcomes and Reduced Incidence with Zoledronic acid ONce Yearly). This clinical development program is the first of its kind to study a single-dose regimen with Aclasta for sustained benefits in the treatment of Paget's disease as well as a once-yearly dosing for osteoporosis. It also includes studies in postmenopausal osteoporosis for prevention of spine and hip fractures, the prevention of clinical fractures following a hip fracture in men and women, male osteoporosis, corticosteroid-induced osteoporosis, prevention of osteoporosis and the treatment of osteogenesis imperfecta in children. Approximately 10,000 patients are enrolled in more than 400 trial centers worldwide. The HORIZON program is one of the most comprehensive drug evaluation programs ever undertaken in the area of metabolic bone diseases.

### **About Paget's Disease**

Paget's disease is a chronic skeletal disorder which may result in bone pain, fractures and deformities that can impede patients' ability to perform routine activities of daily living such as walking and prolonged standing.(4) Paget's disease can be difficult to diagnose and may often be left untreated as not all patients experience noticeable symptoms.(4) For more information, visit [www.myhealthybones.com](http://www.myhealthybones.com).

The foregoing press release contains forward-looking statements that can be identified by the use of forward-looking terminology such as "may", "is being studied", or by express or implied discussions regarding potential future regulatory filings, approvals or future sales of Aclasta (zoledronic acid). 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 Aclasta will be approved for any additional indication, that Aclasta will be brought to market in the US or any additional countries, or will reach any particular level of sales. In particular, management's expectations regarding the approval and commercialization of Aclasta could be affected by, among other things, additional analysis of clinical data; new clinical data; unexpected clinical trial results; unexpected regulatory actions or delays in 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; as well as the additional factors discussed in Novartis AG's Form 20-F filed with the US Securities and Exchange Commission. Should one or more of these risks or uncertainties



materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those described herein as anticipated, believed, estimated or expected. Novartis is providing this information as of this date and does not undertake any obligation to update any forward-looking statements contained in this document as a result of new information, future events or otherwise.

## About Novartis

Novartis AG (NYSE: NVS) is a world leader in pharmaceuticals and consumer health. In 2004, the Novartis group of companies' businesses achieved sales of USD 28.2 billion and a pro forma net income of USD 5.8 billion. The group invested approximately USD 4.2 billion in R&D. Headquartered in Basel, Switzerland, Novartis group companies employ approximately 83,700 people and operate in over 140 countries around the world. For further information, please consult <http://www.novartis.com>.

---

## References

- (1). Reid IR, Miller P, Lyles K *et al.* A single infusion of zoledronic acid improves remission rates in Paget's disease: a randomized controlled comparison with risedronate. *N Engl J Med* 2005; **353**: 898-908
- (2). Mattson Jack (EPI database)
- (3). Ankrom MA, Shapiro JR. Paget's disease of bone (osteitis deformans). *J Am Geriatr Soc* 1998;**46**:1025-33
- (4). Hosking, D. et al. Paget's disease of bone: diagnosis and management. *BMJ* 1996;**312**:491-494

###

## 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**

**Femara® granted FDA priority review for new indication as adjuvant treatment for postmenopausal women with early breast cancer**

*Enhanced efficacy in subgroups at potentially higher risk for breast cancer recurrence in which existing therapies have not demonstrated benefit*

**Basel, August 29, 2005** Novartis announced today that the US Food and Drug Administration has granted priority review to Femara® (letrozole) in the adjuvant (post-surgery) treatment of postmenopausal women with hormone receptor-positive early breast cancer.

The FDA grants priority review to products that could potentially offer a significant improvement compared to marketed products in the treatment, diagnosis or prevention of a disease. Novartis asked for consideration for priority review based on enhanced efficacy in high risk subgroups for which existing therapies have not demonstrated benefit. Specifically, Femara showed significantly improved efficacy compared with tamoxifen in women with node-positive disease and those who received chemotherapy treatment. Femara also demonstrated a significantly reduced risk of distant metastases compared with tamoxifen.

If approved for this new indication, Femara will become the only breast cancer treatment approved in the US to significantly reduce the risk of recurrence for both the adjuvant setting and in extended adjuvant treatment following standard tamoxifen therapy. The supplemental new drug application for use of Femara in the adjuvant setting was submitted in June 2005. Novartis has submitted marketing applications for this indication globally.

This priority review acknowledges the potential for Femara to represent a significant advance in treating postmenopausal women with early breast cancer immediately following surgery, said Diane Young, MD, vice president and global head of Clinical Development at Novartis Oncology.

The FDA submission is based on data from the Breast International Group (BIG) 1-98 study, a Phase III, randomized, double-blind study that compared the safety and efficacy of adjuvant Femara vs. tamoxifen in more than 8,000 postmenopausal women with hormone receptor-positive early breast cancer.

The overall results of BIG 1-98 demonstrated that at a median follow-up of 26 months, Femara prolonged disease-free survival by reducing risk of recurrence by an additional 21% (p=0.002) over the reduction offered by tamoxifen. Women who were treated with Femara experienced a 27% reduction in the risk that their cancer would spread to other parts of the body (distant metastases) compared with tamoxifen (p=0.001), a clinically relevant finding since women who develop distant metastases may be at greater risk of dying from their disease. Femara also provided

a 14% reduction in the risk of death, although this did not reach statistical significance (p=0.155).

In two separate pre-planned subset analyses, Femara also reduced the risk of cancer returning by 29% among patients whose initial cancer had already spread to the lymph nodes at the time of diagnosis (node-positive breast cancer) and by 30% in those who had received chemotherapy, two groups that are at increased risk of recurrence. Additionally, in node-positive patients and in patients who received adjuvant chemotherapy, the risk of distant metastases was reduced by more than 30% with Femara compared to tamoxifen.

### **About BIG 1-98**

BIG 1-98 is the only clinical trial designed to incorporate both a head-to-head comparison of Femara with tamoxifen during the first five years following breast cancer surgery and a sequencing of both agents to determine the most effective approach to minimizing the risk of recurrence. Patients were randomized to the following arms: tamoxifen for five years, Femara for five years, tamoxifen for two years followed by Femara for three years, and Femara for two years followed by tamoxifen for three years. BIG 1-98 was conducted by the International Breast Cancer Study Group (IBCSG) with many independent centers and was supported by Novartis.

The adverse events in the BIG 1-98 study were consistent with published data on both Femara and tamoxifen. In the BIG 1-98 study, the two treatments were generally well tolerated and the safety profile in the two treatment arms overall was similar. Arthralgia/arthritis, bone fractures and osteoporosis were significantly more common with Femara treatment than with tamoxifen. Hot flashes/flushes, night sweats, vaginal bleeding, thromboembolic events and endometrial proliferative disorders were significantly more frequent in the tamoxifen arm.

Overall, more deaths were reported on tamoxifen (n=192) than on Femara (n=166). More patients on tamoxifen (n=154) than on Femara (n=111) died after a recurrence from cancer- and non-cancer-related causes. In patients whose breast cancer did not recur, more deaths due to cardiac causes were reported in the Femara arm than in the tamoxifen arm. In the trial, the number of all cardiovascular events was overall lower in the Femara arm than in the tamoxifen arm (9.7% vs. 10.5%). Irrespective of causality, the following adverse events occurred in both the Femara and tamoxifen groups: thromboembolic events, angina pectoris, myocardial infarction and cardiac failure. In the tamoxifen arm, there was a modest median decrease from baseline of 10-15% over 5 years in total serum cholesterol, compared with no change (0-7% median decrease) in the Femara arm.

The frequency of bone fractures and osteoporosis on both treatments was low, but the numbers were higher in the Femara arm (fractures: 5.7%; osteoporosis 2.0%) compared to tamoxifen (fractures 4.0%; osteoporosis: 1.1%). Endometrial proliferative disorders were reported more often for tamoxifen (1.8%) than for Femara (0.3%).

## About Femara

Femara is a leading once-a-day oral aromatase inhibitor currently available in more than 90 countries worldwide. Femara is approved for extended adjuvant treatment of early breast cancer in postmenopausal women who have completed standard adjuvant tamoxifen therapy in 57 countries worldwide, including Europe as well as the United States. In addition, it is indicated for first-line treatment of postmenopausal women with hormone receptor-positive or hormone receptor-unknown locally advanced or metastatic breast cancer and for the treatment of advanced breast cancer in postmenopausal women with disease progression following anti-estrogen therapy, and as neo-adjuvant (pre-operative) therapy. Not all indications are available in every country.

## Contraindications, warnings and adverse events

In previous clinical trials, the most common adverse events experienced with Femara have been hot flashes/flushes, arthralgia/arthritis and myalgia. Other commonly reported adverse reactions are: nausea, fatigue, anorexia, appetite increase, peripheral edema, headache, dizziness, vomiting, dyspepsia, constipation, diarrhea, alopecia, increased sweating, rash, bone pain, weight increase, osteoporosis and bone fracture.

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

The foregoing release contains forward-looking statements that can be identified by terminology such as will become, significantly reduce, potential, are expected, significant advance, potentially offer, or similar expressions, or by express or implied discussions regarding potential new indications, marketing approvals, or future sales of Femara. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results with Femara to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Femara will be approved for any additional indications in any market, nor that it will reach any particular sales levels. In particular, management's expectations regarding commercialization of Femara could be affected by, among other things, additional analysis of Femara clinical data; new clinical data; unexpected clinical trial results; unexpected regulatory actions or delays or government regulation generally; the company's ability to obtain or maintain patent or other proprietary intellectual property protection; competition in general; increased government, industry, and general public pricing pressures; and other risks and factors referred to in the Company's current Form 20-F on file with the U.S. Securities and Exchange Commission. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those anticipated, believed, estimated or expected. Novartis is providing the information in this press release as of this date and does not undertake any obligation to update any forward-looking statements contained in this press release as a result of new information, future events or otherwise.

## For more information

Additional information regarding Femara or Novartis Oncology can be found on the websites [www.femara.info](http://www.femara.info) or [www.novartis oncology.com](http://www.novartis oncology.com).

Additional media information can be found at [www.novartis oncologyvpo.com](http://www.novartis oncologyvpo.com).



**About Novartis**

Novartis AG (NYSE: NVS) is a world leader in pharmaceuticals and consumer health. In 2004, the Group's businesses achieved net sales of USD 28.2 billion and pro forma net income of USD 5.6 billion. The Group invested approximately USD 4.2 billion in R&D. Headquartered in Basel, Switzerland, Novartis Group companies employ about 83,700 people and operate in over 140 countries around the world.

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

###

© 2001 Novartis AG, [Legal Disclaimer](#)

**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 acquires rights to develop and commercialize new treatment for hyperphosphatemia in kidney dialysis patients**

**Basel, August 18, 2005** Novartis announced today that it has signed an agreement with SeBo GmbH of Germany to acquire the global rights for a novel oral phosphate binder in development for the treatment of elevated serum phosphate levels (hyperphosphatemia) in late- or end-stage renal disease patients.

Under the terms of the agreement, which were not disclosed, Novartis has obtained the rights to develop, manufacture and commercialize this compound for patients with chronic kidney disease or patients already on dialysis. The compound is currently in Phase I clinical development.

This novel compound complements the expertise in kidney disease that we have established through our leadership in transplantation and has the potential to offer dialysis patients a new, more potent and convenient oral treatment option to help them manage the effects of dialysis and chronic kidney disease, said Thomas Ebeling, CEO of Novartis Pharma AG. In our transplantation and immunology business, we are committed to providing patients with new and safe treatment options to help them live longer, healthier and more productive lives before and after organ transplantation.

Patients with chronic kidney disease, as well as those already on dialysis, have reduced phosphate excretion, which leads to elevated serum phosphate levels (hyperphosphatemia). This condition may lead to increased calcium-phosphate deposits that cause arteriosclerosis, which in turn raises the risk for coronary heart disease and stroke as well as bone disease.

Currently available treatments for hyperphosphatemia do not reliably achieve treatment standards set by kidney specialists to help patients effectively manage their disease. As a result, a need remains for novel, more efficient, convenient and tolerable treatment options that lower phosphate without raising calcium levels in the serum to values that are accepted by physicians in order to improve patient well being and possibly survival.

We are strengthening our leading position in transplantation by expanding our focus to also offer therapeutic solutions for transplantation precursor diseases, such as chronic kidney disease, to patients and physicians, said Giacomo Di Nepi, Head of the Transplantation and Immunology Business Unit of Novartis Pharma AG.



At least 90% of dialysis patients receive chronic treatment for hyperphosphatemia, while an estimated 80% of patients with chronic kidney disease are also treated for this condition.

Approximately 800,000 patients are estimated to have end-stage renal disease in Europe and the US, with the vast majority of them requiring dialysis. An equal number of patients are estimated to have late-stage chronic kidney disease and could eventually require dialysis.

Phosphate is primarily derived from dietary sources and is absorbed in the intestine. Hyperphosphatemia is generally caused by renal insufficiency when the kidneys are no longer able to filter excessive amounts of phosphate out of the blood. Elevated phosphate levels in the blood can lead to several serious conditions that include soft tissue calcification, kidney failure and heart disease. Another potential condition is hyperplasia of parathyroid glands with secondary hyperparathyroidism (HPT), which leads to bone disease. Acute hyperphosphatemia can also lead to hypocalcemia with tetany, seizures and arrhythmias.

The Novartis Transplantation and Immunology Business Unit is committed to helping the transplant community by developing and offering an innovative range of therapeutic products for use in the prevention of transplant organ rejection. Novartis is a global leader in this field of medicine, having helped to revolutionize organ transplantation over two decades ago by introducing Sandimmune® (cyclosporin).

The foregoing press release contains forward-looking statements that can be identified by the use of forward-looking terminology such as "in development", "potential", or similar expressions, or by express or implied discussions regarding the potential development, regulatory approvals and commercialization of the oral phosphate binder which is the subject of this release. 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 this product will be approved for sale in any market, or that this product will achieve any particular level of sale. Any such commercialization can be affected by, among other things, uncertainties relating to product development and clinical trials, including unexpected clinical trial results; unexpected regulatory actions or delays or government regulation generally; the ability to obtain or maintain patent or other proprietary intellectual property protection; competition in general; government, industry, and general public pricing pressures; as well as factors discussed in the Company's Form 20-F filed with the Securities and Exchange Commission. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those described herein as anticipated, believed, estimated or expected. Novartis is providing this information as of this date and does not undertake any obligation to update any forward-looking statements contained in this document as a result of new information, future events or otherwise.

**About Novartis**

Novartis AG (NYSE: NVS) is a world leader in pharmaceuticals and consumer health. In 2004, the Group's businesses achieved sales of USD 28.2 billion and pro forma net income of USD 5.6 billion. The Group invested approximately USD 4.2 billion in R&D. Headquartered in Basel, Switzerland, Novartis Group companies employ about 83,700 people and operate in over 140 countries around the world. For further information please consult <http://www.novartis.com>.

###

© 2001 Novartis AG, [Legal Disclaimer](#)

**Investor Relations**

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

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

**- Investor Relations Release -**

**Novartis receives FDA approval for Diovan® (valsartan) to reduce cardiovascular death in heart attack survivors at high risk**

*First-in-class approval for powerful high blood pressure agent follows authorizations across EU and worldwide for both heart attack survivors and people with heart failure*

**Basel, August 4, 2005** Novartis announced today that the US Food and Drug Administration (FDA) approved Diovan® (valsartan), the most prescribed ARB (angiotensin receptor blocker) worldwide, for a new indication to reduce cardiovascular death in patients at high risk (with left ventricular failure or left ventricular dysfunction) following a heart attack. The FDA also expanded the drug's heart failure labeling. Diovan can now be prescribed in a broader range of heart failure patients and is no longer limited to those intolerant of ACE inhibitors.

Diovan is now the only agent in its class across the world indicated to treat high blood pressure, high-risk heart attack survivors and people with heart failure. The US approval follows shortly after marketing authorizations were granted for Diovan in 14 EU member states and other countries around the world to treat people who survived a recent heart attack and people with heart failure.

Every day, more than 3,000 patients suffer a heart attack in the United States.(1) While we've made significant advances in recent years, death following a heart attack remains unacceptably high, said Marc Pfeffer, MD, PhD, professor of medicine at Harvard Medical School, interim chair of medicine at Brigham and Women's Hospital, Boston, and the chair of the VALIANT (VALsartan In Acute myocardial INfarcTion) trial, the study that led to the FDA's approval. VALIANT was a tremendous scientific undertaking involving more than 14,000 patients in 24 countries. We are proud it has resulted in the approval of a new treatment to help improve the survival of patients at high risk following a heart attack.

High blood pressure, a disease which affects one billion people globally JNC-VII (2), greatly increases the risk of suffering a heart attack or developing heart failure. People who have suffered a heart attack are at greater risk of repeat attacks or death and may also progress to heart failure. In fact, within six years, nearly one-third of heart attack survivors will be disabled with heart failure, a progressive condition in which the heart's muscle weakens after injury from other cardiovascular conditions such as a heart attack or high blood pressure.

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

Millions of patients already rely on Diovan to help them get to goal and maintain healthier blood pressure goals. Now, based on results from one of the largest megatrial programs in the ARB class, Diovan has demonstrated additional benefits that can address the needs of an even broader spectrum of cardiovascular patients, said Joerg Reinhardt, Head of Development, Novartis

Pharma AG. We remain committed to developing the full clinical potential of this agent.

### **Approvals based on landmark VALIANT trial**

The approvals of Diovan to reduce cardiovascular death in high-risk heart attack survivors are based on the results of VALIANT, one of the largest, long-term studies ever conducted in people who have suffered a heart attack. VALIANT was a rigorous comparison of Diovan vs. captopril (an ACE inhibitor) vs. the combination of both in 14,703 patients at high risk for death following a heart attack. In the VALIANT trial Diovan was reported to improve survival and reduce cardiovascular events including recurrent heart attack and hospitalizations for heart failure in these patients. There were no differences observed in overall mortality among the treatment groups. The results of VALIANT were published in the peer-reviewed journal, the *New England Journal of Medicine*, and presented at the American Heart Association Scientific Sessions in November 2003. (3)

### **About Diovan**

Novartis remains on the forefront of cardiovascular medicine, through development of innovative products like Diovan, one of the most prescribed antihypertensives in the world today. Diovan is available as a powerful first-line treatment for high blood pressure in more than 90 countries, for the treatment of heart attack survivors in nearly 50 countries and in 70 countries for the treatment of people with heart failure. Additional marketing authorization applications are pending for the treatment of post-heart attack and heart failure.

For high-risk heart attack patients, Diovan recently completed the EU Mutual Recognition Procedure (MRP) in 14 countries for the treatment of clinically stable patients with symptomatic heart failure or asymptomatic left ventricular systolic dysfunction after a recent myocardial infarction. In the US, Diovan is indicated to reduce cardiovascular mortality in clinically stable patients with left ventricular failure or left ventricular dysfunction following myocardial infarction.

For heart failure, Diovan also completed an EU type II variation application in 14 countries for the treatment of people with symptomatic heart failure when ACE inhibitors can not be used, or as add-on therapy to ACE inhibitors when beta blockers can not be used. In the US, Diovan is indicated for the treatment of heart failure (NYHA class II-IV).

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

The foregoing release contains forward-looking statements that can be identified by terminology such as potential, are pending or similar expressions, or by express or implied discussions regarding potential new indications or labeling and marketing approvals for Diovan or Co-Diovan or regarding potential future sales of Diovan or Co-Diovan. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results with Diovan or Co-Diovan to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Diovan or Co-Diovan will be approved for any additional indications or labeling in any other market. Nor can there be any guarantee regarding potential future sales of Diovan or Co-Diovan. In particular, management's expectations regarding commercialization of Diovan or Co-Diovan could be affected by, among other things, additional analysis of Diovan or Co-Diovan clinical data; new clinical data; unexpected clinical trial results; unexpected regulatory actions or delays or government regulation generally; the company's ability to obtain or maintain patent or other proprietary intellectual property protection; competition in general; industry, government, and general public pricing pressures; and other risks and factors referred to in the Company's current Form 20-F on file with the US Securities and Exchange Commission. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those anticipated, believed, estimated or expected. Novartis is providing the information in this press release as of this date and does not undertake any obligation to update any forward-looking statements contained in this press release as a result of new information, future events, or otherwise.

#### **About Novartis**

Novartis AG (NYSE: NVS) is a world leader in pharmaceuticals and consumer health. In 2004, the Group's businesses achieved sales of USD 28.2 billion and pro forma net income of USD 5.6 billion. The Group invested approximately USD 4.2 billion in R&D. Headquartered in Basel, Switzerland, Novartis Group companies employ about 83,700 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**

**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)



**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: September 1, 2005

By: /s/ MALCOLM B. CHEETHAM

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