

NOVARTIS AG  
Form 6-K  
February 02, 2005

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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 January 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:

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. Novartis Venture Fund invests USD 28 million in new capital in 2004 (Basel, Switzerland, January 28, 2005)
2. First results of major study show that Femara® provides a disease free survival advantage vs. tamoxifen in adjuvant treatment of early breast cancer (Basel, Switzerland, 26 January 2005)

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3. Novartis and Schering AG finalize commercialization agreement for novel oral angiogenesis inhibitor PTK787 (Basel, Switzerland, January 25, 2005)
  4. Novartis shows dynamic momentum in industry-leading pipeline (Basel, Switzerland, January 20, 2005)
  5. Novartis grants marketing rights for antihypertension medicines Cibacen and Cibadrex in most EU markets (Basel, Switzerland, January 20, 2005)
  6. Novartis receives positive CHMP opinion recommending EU approval for Aclasta® to treat Paget's disease of the bone (Basel, Switzerland, 20 January 2005)
  7. Novartis providing over USD 2 million in immediate emergency aid for victims of Southeast Asian disaster (Basel, Switzerland, January 6, 2005)
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**MEDIA RELEASE    COMMUNIQUE AUX MEDIAS    MEDIENMITTEILUNG**

**Novartis Venture Fund invests USD 28 million in new capital in 2004**

*Six new companies added to portfolio, three companies complete IPOs*

*Total investments exceed USD 250 million in 132 companies since 1996, creating 1,700 new jobs*

**Basel, January 28, 2005** The Novartis Venture Fund invested USD 28 million in a broad portfolio of entrepreneurial health sciences businesses in 2004, including USD 8.5 million in six new companies, three of which are located in the US and three in Europe.

Despite a relatively slow economy, most companies in the portfolio performed well in 2004. Eyetech Pharmaceuticals Inc., Idenix Pharmaceuticals and Theravance Inc. successfully completed their initial public offerings (IPOs) last year and CombinatoRx Inc. filed its IPO, creating new opportunities for the Fund to realize returns on its investments which can then be re-invested in new start-up companies.

"We are most proud that the Fund, since it was first established in 1996, has helped generate more than 1,700 new jobs," said Dr. Daniel Vasella, Chairman and CEO of Novartis. "We believe funding these start-up businesses will stimulate innovation, contribute to medical advances, and further establish a platform for economic growth and job creation."

According to its 2004 activity report, the Novartis Venture Fund has invested in 132 companies over its eight-year history with a total commitment of USD 250 million. The six new companies receiving funds in 2004 include Amphora Discovery of Research Triangle Park, North Carolina; Covalys BioSciences AG of Witterswil, Switzerland; Evolva SA of Basel, Switzerland; PTC Therapeutics of South Plainfield, New Jersey; Symetis AG of Zurich, Switzerland; and Tepha Inc. of Cambridge, Massachusetts.

"Some of our portfolio companies have already finalized agreements and collaborative arrangements with important pharmaceutical companies," said Dr. François L'Eplattenier, Chairman of the Novartis Venture Fund. "We are pleased to see this development since we believe in the importance of cross-fertilization between innovative and dynamic start-up companies and major pharmaceutical companies as a key factor in overcoming the existing innovation gap."

The Novartis Venture Fund is based on the conviction that economic growth and the creation of new jobs can be achieved in the long run only if new entrepreneurial initiatives develop and promising new ideas become business reality. The present equity portfolio consists of 69 private and six public companies.

**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 a 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 about 81,400 people and operate in over 140 countries around the world. For further information please consult <http://www.novartis.com>.

The Novartis Venture Fund Activity Report 2004, which summarizes the activities of the Fund and presents profiles of its portfolio companies, can be downloaded from the Novartis Venture Fund website <http://www.venturefund.novartis.com> or ordered from the following address:

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**INVESTOR RELATIONS RELEASE**

**First results of major study show that Femara® provides a disease free survival advantage vs. tamoxifen in adjuvant treatment of early breast cancer**

*Data show at 26 months already a significant overall benefit in disease free survival across all postmenopausal women with early hormone receptor-positive breast cancer (19%,  $p = 0.003$ ); especially reducing spread to distant sites of the body (27%;  $p = 0.0012$ )*

*Femara demonstrated the most significant advantage in disease free survival vs. tamoxifen in women at greatest risk of recurrence*

*Femara is now the only treatment shown to significantly reduce risk of recurrence both as initial therapy post-surgery and also following standard tamoxifen*

*Novartis will file for adjuvant use with global regulatory authorities in mid-2005*

**Basel, 26 January 2005** Adjuvant use of Femara® (letrozole) in postmenopausal women with hormone receptor-positive early breast cancer demonstrated a significant 19% reduction in risk of relapse ( $p = 0.003$ ); especially reducing the risk that the cancer would spread to other parts of the body (distant metastases) by 27%, compared with the reductions offered by tamoxifen ( $p = 0.006$ ) according to an international study presented today by the International Breast Cancer Study Group. The data, from the Breast International Group (BIG) 1-98 trial result from a head-to-head comparison of Femara with tamoxifen in more than 8 000 women treated at a median follow-up of only 26 months.

The BIG 1-98 trial demonstrated a particularly strong disease free survival advantage for patients at the highest risk of breast cancer recurrence in the adjuvant (post-surgery) setting, such as those with node-positive early breast cancer (cancer that already spread to lymph nodes at the time of diagnosis), and those who have received prior chemotherapy. These women are more likely to develop distant metastases and, therefore, may be at greater risk of dying from their disease. Disease free survival, the primary efficacy endpoint in this study, was defined as the time from randomization to recurrence (including recurrence restricted to the breast after breast conserving treatment, whichever occurred first), metastasis, appearance of a second primary tumor, or death from any cause.

"The biggest fear of women who have battled breast cancer is that their breast cancer might return," said PD Dr. Beat Thürlimann, MD, Scientific Secretary General, Therapy of Early Breast Cancer Senology Center of Eastern Switzerland, Kantonsspital St. Gallen. "Convincing results from this very large study show that letrozole helps more women remain cancer free when compared to tamoxifen."

**Study details**

Postmenopausal women with early breast cancer in 27 countries enrolled in this phase III, randomized, double-blind, controlled clinical trial, supported by Novartis.

There was a statistically significant reduction of 17% in the risk of systemic failure (the time from randomization to systemic recurrence, appearance of a second non breast malignancy, or death without recurrence, whichever occurred first) ( $p = 0.02$ ). There was a 14% reduction in risk of death in favor of Femara that was not significant. Patients will continue to be monitored to track disease status, survival and long-term tolerability.

These positive data complement those of the landmark MA-17 trial for the use of Femara in the extended adjuvant setting. Femara is the only aromatase inhibitor shown to be effective in both the adjuvant and extended adjuvant settings. The term *extended adjuvant* describes the period following standard adjuvant treatment with tamoxifen. Femara is approved for extended adjuvant treatment of early breast cancer in 20 countries worldwide.

"This is exciting news for breast cancer patients and Novartis. Femara is the only hormonal therapy that has been shown to significantly reduce the risk of breast cancer recurrence in postmenopausal women with early breast cancer after standard tamoxifen therapy, known as the extended adjuvant setting. Now we have the first evidence that Femara also offers a significant disease free survival advantage over tamoxifen in the adjuvant setting in this population," said Diane Young, MD, Vice President and Global Head, Clinical Development, Novartis Oncology.

In this trial, patients treated with Femara had significant reductions in vaginal bleeding, hot flushes, and endometrial cancer when compared to tamoxifen. Hypercholesterolemia, grade 3-5 stroke and other cardiovascular events were more common in Femara. As expected with estrogen deprivation therapy, the number of women reporting new bone fractures to date was 5.8% on Femara and 4.1% on tamoxifen. Grade 3-5 thromboembolic events were more common in tamoxifen treated patients. In patients whose breast cancer did not recur, more deaths due to stroke were reported in Femara treated patients than tamoxifen treated patients (7 vs. 1) as well as cardiac causes (26 vs. 13). These events combined with all deaths from causes other than recurrence of breast cancer were not statistically significant. The median age of women who died without experiencing a previous cancer event was 70 compared with a median age of 61 of all women in the study. Further analysis of these preliminary data is ongoing. In the interim, routine assessments of bone mineral density and cholesterol levels with active treatment when necessary should be considered. Overall, more patients in the study died on tamoxifen than Femara. 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 minimize 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. Results from the ongoing arms of the study, which are expected to determine which treatment is more effective, monotherapy or sequential therapy, and if sequential therapy, which sequence is more effective, are expected in 2008.

#### **About Femara**

Femara is a leading once-a-day oral aromatase inhibitor that 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 antiestrogen therapy, and as neo-adjuvant (pre-operative) therapy. Femara is approved for extended adjuvant treatment of early breast cancer in postmenopausal women who have completed adjuvant tamoxifen therapy in 20 countries worldwide. Femara is currently available in more than 80 countries worldwide. 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 are hot flushes, arthralgia/arthritis and myalgia. Other commonly reported adverse reactions are: nausea, fatigue, anorexia, appetite increase, peripheral oedema, headache, dizziness, vomiting, dyspepsia, constipation, diarrhea, alopecia, increased sweating, rash, myalgia, bone pain, arthritis/arthralgia, and weight increase.

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

### For more information

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

### About Novartis

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**INVESTOR RELATIONS RELEASE**

**Novartis and Schering AG finalize commercialization agreement for novel oral angiogenesis inhibitor PTK787**

*Companies will partner on promotion and further development of the product for metastatic colorectal cancer in North America, Europe and Japan*

*In a separate agreement Novartis also obtains exclusive rights to expand development of PTK787 to age-related macular degeneration and potentially other ophthalmic diseases*

**Basel, January 25, 2005** Novartis Pharma AG announced today that it has executed a commercialization agreement with Schering AG, Germany, for the investigational agent PTK787, known by Schering AG as ZK222584. PTK787 is an oral angiogenesis inhibitor, which Novartis and Schering AG have been jointly researching and co-developing since 1995.

Under the commercialization agreement, the companies will partner on promotion and further development of the product all oncology indications including metastatic colorectal cancer in all major markets. The value of the agreement to Schering and Novartis is designed to be equal based on the co-promotion terms and territory allocations. Novartis will lead North American co-promotion activities and Schering will lead European co-promotion activities with both companies sharing co-promotion activities equally in Japan. Novartis will exclusively promote the product in Asia (excluding Japan) and Middle East. Schering will exclusively promote PTK787 in Latin America, Africa and Australia.

PTK787 is currently in phase III clinical trials for metastatic colorectal cancer. Initial results are expected in the second quarter of 2005, and filing planned for the second half of 2005. Two phase III trials have enrolled approximately 2,000 patients with metastatic colorectal cancer at more than 200 centers around the world.

"This agreement will further optimize the commercialization and future development activities for this potential breakthrough cancer medicine. Our collaboration has enabled us to effectively move PTK787 through clinical trials and now working closely together in the world's major regions should allow us to most effectively reach physicians and patients once the medicine is commercialized," said David Epstein, CEO of Specialty Medicines and president of Novartis Oncology.

In a separate agreement with Schering, Novartis has obtained exclusive rights to develop PTK787 for the treatment of "wet" age-related macular degeneration (AMD). Under the agreement, Novartis will obtain full global and exclusive developmental and commercialization rights to PTK787 in ophthalmics. Novartis will pay an upfront fee, milestone payments and royalties on ophthalmics sales. Additional details of the agreement were not disclosed.

"The wet AMD market is expected to show strong market growth over the next 10 years, fueled by increased patient diagnosis and referrals with the entry of new competitors," said Epstein. "With PTK787, we are excited to explore the full potential of this next-generation compound and continue to lead innovation in the treatment of retinal diseases."



### Phase III Study for Treatment of Colorectal Cancer

PTK787 is currently in Phase III development for metastatic colorectal cancer, with first results expected in Q2 2005 from the CONFIRM I trial, which is evaluating the safety and potential efficacy benefit of once-daily oral treatment with PTK787 in combination with the FOLFOX-4 regimen compared to FOLFOX-4 alone in previously untreated patients with metastatic colorectal cancer. A second trial, CONFIRM 2 is evaluating the safety and potential survival benefit of once-daily oral treatment with PTK787 in combination with the FOLFOX-4 regimen compared with FOLFOX-4 alone in patients with metastatic colorectal cancer who have progressed after irinotecan-based chemotherapy. The CONFIRM trials started in January 2003 and enrollment was completed in July 2004.

According to the World Health Organization, in 2000 there were almost 940,000 cases of colorectal cancer worldwide, almost 65% of which were in the more developed countries. The Colorectal Cancer Network reports that in the United States only lung cancer is responsible for more cancer-related deaths.

### Contraindications and Adverse Events

PTK787 treatment has been generally well tolerated in more than 1,000 patients with up to 24 months of uninterrupted treatment and the side effects that have been observed are generally mild to moderate. The most frequently reported adverse events were nausea, fatigue, vomiting, and dizziness and the majority of these were mild to moderate. In the Phase I/II trial, the adverse event profile for the group of patients treated with PTK787 in combination with FOLFOX-4 was generally similar to that reported for the FOLFOX-4 regimen alone. PTK787 should not be administered to women who are pregnant or lactating or to anyone not practicing adequate contraception.

The foregoing release contains certain forward-looking statements that can be identified by terminology such as "will participate," "potentially," "will lead," "will," "expected," "will obtain," "will pay," "to explore the full potential," or similar expressions, or by discussions regarding the potential that PTK787 will be approved for marketing, or regarding any potential revenues from PTK787. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results with PTK787 to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that PTK787 will be approved for sale in any market. In particular, management's expectations regarding commercialization of PTK787 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; 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 RELEASE**

**Novartis shows dynamic momentum in industry-leading pipeline**

*75 projects in development, including 43 new molecular entities*

*Key late-stage projects progressing on track*

*New data on five of ten top-priority compounds presented*

*AMN107 Phase I data reveal hematological response in over 50% of Gleevec-resistant patients*

*FTY720 Phase II MS data show strong efficacy as potentially first oral therapy*

*QAB149 Phase IIb data underscore efficacy in asthma and COPD*

*First SPP100 Phase IIb/III data confirm efficacy in high blood pressure*

*ICL670 set for US/EU submission based on response in 20 mg & 30 mg doses*

*New Phase III data expected on six compounds and five key submissions in 2005*

**Basel, January 20, 2005** At a Research & Development review today, Novartis provided an update on its industry-leading pipeline, announcing robust progress in 75 development projects that aim to address unmet medical needs.

In addition to these 75 projects in clinical development, which includes 52 in phase II, III or registration and 43 new molecular entities (NMEs), Novartis announced that it has more than 64 candidates in advanced pre-clinical testing. Key areas of development are oncology and cardiovascular diseases, with promising compounds in both primary care and specialty medicines.

"Innovation is the core of our strategy, and our strong investments of USD 3.5 billion in pharmaceutical R&D in 2004 rank among the highest in the industry. In the US alone, our investments have allowed us to bring 13 new medicines to patients over the past four years, the highest number of any pharmaceutical company," said Dr. Daniel Vasella, Chairman and Chief Executive Officer.

"We continue to focus on novel medicines. Six of our 10 highly innovative compounds in mid-to-late-stage development are potential first-in-class medicines, and I am pleased that the expertise of our scientists, improved processes and advanced technologies have contributed to maintaining a leading position in R&D productivity," Dr. Vasella said.

**Pipeline highlights**

Novartis has been consistently ranked by industry experts as having one of the best pipelines, highlighted by several innovative compounds. These include SPP100 (hypertension), QAB149 (asthma and COPD) and FTY720 (multiple sclerosis and transplantation) as well as LAF237 (type 2 diabetes) and PTK787 (cancer). Many of these projects have the potential to become a new standard of care and the first to market in

their respective classes.

The priority development projects include:

### **Oncology & Hematology**

**AMN107** is an investigational oral compound being studied in the small subset of advanced chronic myeloid leukemia (CML) patients who do not respond or stop responding to *Gleevec/Glivec* and have no treatment options available. The compound is a signal transduction inhibitor that selectively inhibits specific proteins called tyrosine kinases, including BCR-ABL and some mutant forms of this protein, that cause white blood cells to grow and divide uncontrollably. AMN107 has been shown in preclinical studies to be the most selective BCR-ABL inhibitor to date and more potent than *Gleevec*. Phase I data showed hematological responses of over 50% in *Gleevec*-resistant patients in advanced disease stages (accelerated or blast phases). Phase II trials are expected to start in the first half of 2005.

**PTK787** (vatalanib) is an oral angiogenesis inhibitor in Phase III development for metastatic colorectal cancer. First Phase III results for PTK787, which is being developed with Schering AG, are expected in Q2 2005 from the CONFIRM1 trial in colorectal cancer. Enrollment was completed in 2004 for both the CONFIRM1 and the CONFIRM2 trials, which aim to show that PTK787 has the potential to set a new standard of care in metastatic colorectal cancer. Novartis plans to initiate an adjuvant colon cancer trial in 2005 pending positive CONFIRM1 data. A broad Phase I/II program is underway to identify additional indications for further development, including prostate, non-small cell lung (NSCLC), breast, pancreatic and ovarian cancers as well as glioblastoma and hematological malignancies.

**ICL670** (deferasirox) offers the potential to revolutionize the treatment of iron overload, providing a once-daily oral formulation to replace the cumbersome infusion therapy *Desferal*. Iron overload is a cumulative, potentially life-threatening condition that may result from repeated blood transfusions required to treat certain types of anemias, including sickle cell disease, thalassemia and myelodysplastic syndromes. It is estimated that, of the more than 250,000 people worldwide who require frequent blood transfusions, and as many as 100,000 people may require an iron chelator to avoid dangerous iron overload. ICL670 is expected to increase treatment compliance of this debilitating and life-threatening condition, leading to better health outcomes. Phase III data showed efficacy in the group of patients that received 20-30 mg/kg doses. Based on the results, submission in the US and EU with Orphan Drug Status is planned for the first half of 2005.

### **Cardiovascular & Metabolism**

**LAF237** (vildagliptin) is a first-in-class incretin enhancer for the treatment of type 2 diabetes. It has been shown in Phase II trials to be effective in lowering blood-sugar (HbA1c) levels. Phase III development as a monotherapy and in combination with other medicines remains on track. Phase III data are expected at the end of 2005. Submission is planned for early 2006.

**SPP100** (aliskiren) is the first in a new class of antihypertension agents called renin inhibitors that offers a once-daily treatment with efficacy and safety comparable to angiotensin-receptor blockers (ARBs), another class of high blood pressure treatments. In contrast to other antihypertensive agents, SPP100 lowers renin enzyme activity in the bloodstream, so it may have the potential to better protect against heart attacks (myocardial infarction) and kidney disease. Phase IIb/III data confirmed efficacy as a monotherapy and suggested benefits of combination with ARBs. Phase III trials are ongoing in the US, EU and Japan. Additional Phase III data are expected in Q3 2005. The first regulatory submission is planned for early 2006.

## Neuroscience

**FTY720**, an oral immunomodulator with a novel mechanism of action, has shown excellent efficacy in multiple sclerosis (MS) in a Phase II study. FTY720 has the potential to become the first efficacious oral therapy for MS, a condition estimated to affect more than one million people worldwide. Data from the Phase II study showed a significant reduction in the relapse rate and in the number of brain lesions detected by MRI scan as well as a longer time to first relapse. The vast majority of patients are continuing in the extension phase. One-year data are expected in mid-2005. Phase III studies are planned to start in mid-2005.

## Transplantation

**FTY720** is also being developed for transplantation. Phase III data remain on track for completion in 2005. US and EU submissions are expected in early 2006.

## Respiratory diseases

**QAB149** is a once-daily long-acting beta-2 agonist for asthma and Chronic Obstructive Pulmonary Disease (COPD) that offers a quick onset of action and true 24-hour control. New Phase IIb data showed strong efficacy in both asthma and COPD and confirmed safety at high doses. QAB149 is being developed first as a monotherapy for the bronchodilator market. Treatments like QAB149 are expected to maintain substantial market share in a rapidly growing asthma/COPD market. Phase III studies are planned to start in 2005. Regulatory submissions are planned for 2007. Several options for combination products are currently being evaluated in parallel.

**Xolair** is on track for EU regulatory approval in 2005. This novel agent offers a breakthrough in treating asthma, particularly as a unique add-on therapy for adults and adolescents with severe persistent asthma who remain inadequately controlled with conventional medicines. Clinical data have shown *Xolair* offers substantial improvements in disease control and reduces clinically significant exacerbation rates. *Xolair* is being developed in collaboration with Genentech and Tanox.

## Bone and joint treatment

**Aclasta**<sup>(1)</sup> (zoledronic acid) has the potential to become the gold standard in treating osteoporosis. Having shown superior efficacy in Phase III studies in Paget's disease, a condition marked by abnormal bone growth, the single once-yearly bisphosphonate infusion has the potential to provide unsurpassed compliance and excellent bone protection. *Aclasta* has received priority review status in the US for Paget's disease, and a decision is expected in March 2005. EU approval is expected in the first half of 2005. Submission for postmenopausal osteoporosis is expected in 2007 following completion of ongoing Phase III trials.

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(1)

Zoledronic acid (5 mg) is authorized to be marketed under the name Aclasta in Europe and is awaiting US approval of the name.

**AAE581** is an oral once-daily compound aiming to be the first cathepsin K inhibitor for treating osteoporosis. Well-tolerated and efficacious in Phase II trials, AAE581 has been shown to inhibit bone resorption and may have a positive effect on bone formation. Phase II trials are on schedule, and biomarker data are expected in Q4 2005. Phase III trials are planned to start in Q1 2006.

### Infectious diseases

**LDT600** (telbivudine) is a once-daily tablet treatment for hepatitis B virus (HBV) infection, a disease estimated to affect about 400 million people worldwide. Phase II clinical data have shown efficacy exceeding lamivudine, the global market leader for hepatitis B therapeutics. The ongoing international Phase III GLOBE clinical trial, which includes China, is designed to evaluate telbivudine head-to-head against lamivudine. Patient enrollment was completed ahead of schedule in April 2004. Novartis holds a 57% investment in Idenix, and both companies plan to submit US, EU and international marketing applications for telbivudine beginning in Q4 2005 and extending into 2006.

### Ophthalmics

**Lucentis** is a recombinant antibody fragment designed as a new treatment for "wet" AMD (age-related macular degeneration), an eye condition that can cause vision loss. Developed with Genentech, which retains the right to develop and market the product in North America, Lucentis binds and inactivates VEGF (vascular endothelial growth factor), a protein that plays a role in angiogenesis (the formation of new blood vessels). Data from two Phase III trials are expected in 2005. Submission for EU approval is planned for 2006.

A total of 12 development projects were added to the portfolio, while 16 left the portfolio through approval or launch (5 projects) as well as through termination or for being put on hold (11 projects). Among the terminated projects is **TCH346** in Parkinson's disease and amyotrophic lateral sclerosis (ALS) after Phase II studies did not demonstrate efficacy.

Novartis expects the EU Mutual Recognition Procedure (MRP) for **Prexige**, a novel anti-inflammatory medicine being developed for osteoarthritis, to resume in mid-2005 after the European Medicines Agency (EMA) completes a review of the COX-2 inhibitor class. Data from the landmark TARGET safety outcomes study in August 2004 demonstrated a significant 79% reduction in the incidence of upper gastrointestinal (GI) ulcer complications without compromising cardiovascular (CV) safety. The TARGET study showed that **Prexige** had a cardiovascular profile similar to conventional non-steroidal anti-inflammatory drugs (NSAIDs).

Discussions are underway with the FDA on requirements for a new cardiovascular safety study. Additional studies are already underway to support the 100 mg dose for treating osteoarthritis. However, submission for US approval is not expected before 2007.

### Promising early-stage projects

A priority of Novartis R&D efforts is to expedite "proof-of-concept" trials in humans through a "translational medicine" approach to better assess a compound's clinical potential by collecting biomarker data as early as possible.

Novartis highlighted a group of nine early-stage compounds currently in Phase I/II that offer significant potential based on the results of proof-of-concept testing. The richness of the early-stage pipeline illustrates the replacement power of the Novartis pipeline and demonstrates the continuing high performance of the research organization.

Among the priority early-stage projects is **LBM642**, a novel agonist of both PPAR-alpha and PPAR-gamma (peroxisome proliferator-activated receptor) for the treatment of metabolic syndrome, a group of risk factors that include obesity, insulin resistance, elevated cholesterol and high blood pressure. LBM642 was shown to be more efficacious in lipid lowering than fenofibrate in a first proof-of-concept trial. Proof-of-concept data in diabetes are expected in mid-2005.

Other early-stage projects include **ACZ885**, which offers a new mechanism for treating rheumatoid arthritis; **AEE788**, an anti-cancer agent with promise in many solid tumors; **valopicitabine** (also known as NM283), a novel therapy for hepatitis C infection being developed by Idenix, for which Novartis has an exclusive right to in-license; and **AEB071**, a first-in-class immunomodulator with potential in transplantation.

#### **Important submissions planned for 2005**

In 2005, Novartis anticipates making submissions for at least three new molecular entities for regulatory approval as well as making a series of applications for new indications of products already on the market, including the following:

**PTK787** in the US for colorectal cancer (pending Phase III results of CONFIRM1 trials)

**ICL670** in the US and EU as the first oral treatment for chronic iron overload

**LDT600** in the US for the treatment of hepatitis B

**Femara** in the US and EU for a new indication for treating women with breast cancer in the early adjuvant (post-surgery) setting (pending initial data from the BIG 1-98 trial expected to be presented at the St. Gallen Breast Cancer Conference in January)

**Visudyne** in the US for the occult form of age-related macular degeneration (AMD)

Seven major projects are currently in registration, including *Aclasta* for the treatment of Paget's disease in the US and EU, the novel asthma medicine *Xolair* in the EU following approval in the US in mid-2003 and *Zelnorm/Zelmac* for treating irritable bowel syndrome (IBS) in the



EU. Regulatory decisions are expected in 2005.

### Strategic alliances complement pipeline

Novartis has more than 100 alliances with biotechnology and academic institutions looking for a major pharmaceutical company partnership. At the same time, Novartis recognizes the value of scientific advances that are made by partners and seeks to source the best technologies and early-stage compounds. Novartis has a culture designed to build fair, effective and mutually beneficial alliances.

Our alliance strategy in 2004 focused on two key components to strengthen our pipeline: development of research alliances and the in-licensing of new compounds.

A key focus of in-licensing was the acquisition of three compounds to complement internal cardiovascular/metabolism programs. **D-4F**, a novel apoA-I (apolipoprotein A-I) mimetic, was acquired from the US biotechnology company BruinPharma. ApoA-I is the major protein component of HDL and is considered a promising target for atherosclerosis therapy since it has been associated with beneficial effects on cardiovascular disease. Phase I development of D-4F has been initiated. An exclusive agreement was signed with Xenon Pharmaceuticals to develop and commercialize compounds from their **Stearoyl-CoA Desaturase-1 (SCD1)** program, which is in pre-clinical development. This program is complementary with Novartis programs targeting type 2 diabetes and the metabolic syndrome, which are conditions characterized by risk factors including obesity, insulin resistance, elevated cholesterol and high blood pressure. An agreement was also signed with Torrent Pharmaceuticals to develop its **AGE** (Advanced Glycosylation End-products) breaker compound in heart disease and diabetes-related vascular events, which is also in pre-clinical development.

Complementing internal discovery efforts in oncology, Novartis selected **VX-322**, a protein kinase inhibitor from Vertex in 2004, and also acquired from Vernalis the exclusive rights to the UK biotechnology company's development program for **Hsp90**, a target implicated in a number of different cancers.

Novartis also recently acquired all rights to Triad's pre-clinical **p38map** kinase program, which may deliver a promising oral therapeutic for inflammatory diseases. Novartis will be responsible for full development and commercialization of all compounds covered under Triad's intellectual property.

New alliances included **Morphosys** (development of therapeutic antibodies), **Cellzome** (identification of critical molecular pathways and interactions), **Infinity Pharmaceuticals** (expanding the chemical universe for new drug discovery), and the **Broad Institute** of MIT and Harvard (discovering the basic genetic causes of type 2 diabetes).

#### **Disclaimer**

This release contains certain forward-looking statements relating to the Company's business, which can be identified by the use of forward-looking terminology such as "pipeline", "potential", "set for", "2005 newsflow", "aim to", "potential", "expected", "plans to", "planned", "being developed", "aiming to", "early-stage projects", "anticipates", "promising", "may deliver", or similar expressions, or by express or implied discussions regarding potential new products, potential new indications for existing products, or regarding potential future revenues. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that any of the development projects described in this release will succeed, that any new products will be brought to market, or that any new indications will be approved for any of our existing products. Similarly, there can be no guarantee that Novartis, or any present or future product, will achieve any particular level of revenue. In particular, management's expectations could be affected by, among other things, additional analysis of 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; as well as factors discussed in the Company's Form 20-F filed with the US Securities and Exchange Commission. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those described herein as anticipated, believed, estimated or expected. Novartis is providing the information in this press release as of this date and does not undertake any obligation to update any forward-looking statements contained in this press release as a result of new information, future events or otherwise.

#### **About Novartis**

Novartis AG (NYSE: NVS) is a world leader in pharmaceuticals and consumer health. In 2004, the Group's businesses achieved sales of USD 28.2 billion and 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 81,400 people and operate in over 140 countries around the world. For further information please consult <http://www.novartis.com>.

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**INVESTOR RELATIONS RELEASE**

**Novartis grants marketing rights for antihypertension medicines Cibacen and Cibadrex in most EU markets**

**Basel, January 20, 2005** Novartis has signed an agreement to grant the Swedish specialty pharmaceuticals company Meda AB the exclusive rights to the antihypertension medicines Cibacen® and Cibadrex® in most European markets.

The agreement, which was signed in January 2005, provides Meda the exclusive rights to the existing trademarks, pharmaceutical registrations and patents in most European markets in exchange for a cash payment of USD 135 million.

The divestiture allows Novartis to focus further on its mission of introducing innovative new medicines for cardiovascular conditions as well as medicines in other targeted therapeutic areas. At the same time, this transaction ensures that patients and physicians have access to a trusted therapy.

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**MEDIA RELEASE    COMMUNIQUE AUX MEDIAS    MEDIENMITTEILUNG**

**Novartis receives positive CHMP opinion recommending EU approval for Aclasta® to treat Paget's disease of the bone**

*First positive regulatory opinion for Aclasta as a single infusion of zoledronic acid 5 mg, to treat debilitating metabolic bone disorder*

**Basel, Switzerland, 20 January 2005** Novartis Pharma AG announced that the Committee for Medicinal Products for Human Use (CHMP) has issued a positive opinion for Aclasta® (zoledronic acid 5 mg solution for infusion) for the treatment of Paget's disease of the bone. The CHMP is recommending that the European Commission grant a Marketing Authorization for Aclasta for the treatment of Paget's disease in all 25 European Union (EU) countries as well as Norway and Iceland. A decision by the European Commission is expected later this year and would mark the first approval of Aclasta globally.

"Aclasta is the first treatment that after just one single infusion provides an extended remission period of one year or more in many Paget's patients," said Joerg Reinhardt, Head of Development, Novartis Pharma AG. "The CHMP positive opinion marks the achievement of the first regulatory milestone for Aclasta. We are currently investigating Aclasta as a once-yearly osteoporosis treatment in a comprehensive clinical development program involving several thousand patients worldwide."

The CHMP opinion is based on the review of data from pivotal clinical studies in patients with Paget's disease of the bone. Patients treated with Aclasta received a single 5 mg intravenous (IV) infusion of zoledronic acid administered over at least 15 minutes, rather than a current standard oral bisphosphonate treatment, risedronate. Data showed that a single infusion of Aclasta more effectively and rapidly normalized the biochemical markers of bone turnover in patients and provided a longer lasting remission of Paget's disease in comparison to risedronate. Aclasta, in clinical trials, was found to be generally safe and well tolerated.

**More about Aclasta**

Bisphosphonates are well established as the standard of care for metabolic bone diseases such as Paget's disease. As a bisphosphonate, Aclasta works by preventing bone from further breakdown or damage while restoring the balance between bone resorption and formation. Aclasta is unique in that after a single infusion, it provides lasting therapeutic effects for 12 months or longer in most patients. Aclasta quickly and effectively restores normal bone turnover in patients with Paget's disease.

The development of Aclasta is supported by an extensive clinical development program. The HORIZON (Health Outcomes and Reduced Incidence with Zoledronic acid ONce yearly) 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. The

HORIZON program includes studies in postmenopausal osteoporosis for reduction of spine and hip fractures, the prevention of new clinical fractures following a hip fracture in men and women, male osteoporosis, corticosteroid-induced osteoporosis, prevention of postmenopausal osteoporosis and the treatment of osteogenesis imperfecta in children. Worldwide, over 10,000 patients in more than 300 trial centers globally are enrolled in the HORIZON program, one of the most comprehensive drug evaluation programs ever undertaken in the area of metabolic bone diseases.

#### **About Paget's disease**

Paget's disease of the bone (*osteitis deformans*) is a painful and chronic disorder of bone metabolism, the biochemical process which controls the normal breakdown and formation of bone. In Paget's disease, accelerated breakdown and formation of bone produces new bone that is disorganized and weaker than normal. Paget's disease can affect any part of the skeletal system, most commonly the skull, the spine and the bones of the arms, legs and pelvis. In some patients Paget's disease remains asymptomatic; however in many patients the disease causes pain, fractures and deformities that can seriously impede a patient's ability to perform routine activities of daily living.<sup>(1)</sup> Complications of Paget's disease, the most common bone disease after osteoporosis, can include fractures and deformities, such as bowing of the limbs and if the disease affects the skull, hearing loss.

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#### References:

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Hosking, D. et al. Paget's disease of bone: diagnosis and management. *BMJ* 1996;312:491-494.

Frequently the symptoms of Paget's disease are misinterpreted as symptoms of arthritis, leading to inadequate treatment of the disease. An accurate diagnosis of Paget's disease of the bone is most commonly performed through blood tests measuring serum alkaline phosphatase (SAP) levels as well as X-rays to determine the site and extent of bone damage.

The foregoing press release contains forward-looking statements that can be identified 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 any current or future regulatory filings will satisfy the CHMP's and other health authorities' requirements regarding Aclasta, that Aclasta will be approved by any European Union's health authorities for any indication, or that Aclasta will be brought to market in the US or any other country, or will reach any particular level of sales. 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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**MEDIA RELEASE    COMMUNIQUE AUX MEDIAS    MEDIENMITTEILUNG**

**Novartis providing over USD 2 million in immediate emergency aid for victims of Southeast Asian disaster**

*Support includes direct financial assistance to relief organizations and donation of essential medicines, including key malaria treatment and antibiotic drugs*

*Employees encouraged to make personal contributions to nationally recognized relief organizations to be matched with company funds*

**Basel, January 6, 2005** Through its local organizations in countries throughout the region, Novartis is providing over USD 2 million in immediate emergency aid for victims of the recent natural disaster in Southeast Asia. The support, which began immediately in the wake of the tragedy, includes both direct financial aid to relief agencies working in the region as well as donations of essential medicines, including a key malaria treatment and a range of antibiotic drugs.

"It was with huge dismay that we learned about the destructive force of the tsunamis following the quake in Southeast Asia, which has brought such immense suffering," said Dr. Daniel Vasella, Chairman and CEO of Novartis. "I would like to express our deepest sympathy for all the people concerned and also to assure them of our support. Our experience of providing support in the wake of natural disasters primarily through our local companies has again proven successful, ensuring that we can get aid to the people fast and efficiently."

Novartis companies in the countries affected provided local authorities, hospitals and other institutions with aid and support immediately after the tsunami struck. In Thailand, Indonesia and Malaysia, for example, extensive drug donations were made to local hospital organizations, the Red Cross and the Red Crescent organizations. Where necessary and appropriate, aid was also provided in the form of direct financial donations. In Sri Lanka, where the Novartis Foundation for Sustainable Development has strong contacts with a local partner organization, funds were donated in support of its work for the flood victims.

Novartis employees are also being encouraged to make cash contributions to nationally-recognized relief organizations such as the International Disaster Relief Funds of the Red Cross/Red Crescent societies or UNICEF. These employee donations will then be matched by the company.

Finally, Novartis will work with local authorities and aid organizations to identify several projects where assistance can be provided on a longer-term basis to ensure that there is sustainable support for people impacted by this tragic natural disaster.

**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 81,000 people and operate in over 140 countries around the world. For further information please consult <http://www.novartis.com>.

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