

NOVARTIS AG  
Form 6-K  
October 05, 2004

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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 September 2004  
(Commission File No. 1-15024)

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### Novartis AG

(Name of Registrant)

Lichtstrasse 35  
4056 Basel  
Switzerland

(Address of Principal Executive Offices)

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

Form 20-F:  Form 40-F:

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

Yes:  No:

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Yes:  No:

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

Yes:  No:

Enclosures:

1. Bernard Fraisse Group to acquire Novartis Hettlingen production site (Basel, September 30, 2004)
2. Landmark ZENSAA trial shows Zelnorm® is effective in repeated treatment of Irritable Bowel Syndrome with Constipation (Basel, September 27, 2004)

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3. Largest study in gastrointestinal stromal tumor patients shows higher dose of Glivec® significantly improves progression-free survival (Basel, Switzerland, September 24, 2004)
  4. Novartis expands Diovan® production at Swiss manufacturing site (Basel, September 22, 2004)
  5. LAF237, first in a new class of oral antidiabetic agents, shown in phase II to provide clinically significant improvement in glycemic control (Munich, Germany, September 7, 2004)
  6. Novartis wins Lamisil Tablets® patent infringement lawsuit against Dr. Reddy's Laboratories (Basel, September 3, 2004)
  7. Novartis offers direct share purchase plan to investors in Switzerland, Liechtenstein, France and the United Kingdom (Basel, Switzerland, September 2, 2004)
  8. FDA defers decision on Omnitrope application (Vienna, September 2, 2004)
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Novartis honors researchers committed to advancing the understanding and treatment of diabetes (Basel, September 1, 2004)

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**MEDIA RELEASE    COMMUNIQUE AUX MEDIAS    MEDIENMITTEILUNG**

**Bernard Fraisse Group to acquire Novartis Hettlingen production site**

**Basel, September 30, 2004** Novartis announced today the sale of its pharmaceutical production site in Hettlingen, Switzerland, to Bernard Fraisse Group effective October 1, 2004. Terms of the deal were not disclosed.

"After reviewing our long-term strategy, we concluded that the Hettlingen facility will better prosper within a group that plans to develop the site in a new direction to optimize its long-term potential," said Andreas Rummelt, Head of Global Technical Operations, Novartis Pharma AG. "The agreement with Bernard Fraisse Group best serves the interests of Novartis and the Hettlingen employees."

Novartis will contract with Bernard Fraisse Group to manufacture products at the Hettlingen site for at least two years after the transfer of ownership. Products manufactured at this site include gels, ointments and drops such as Voltaren®, Dispatim®, Viscotears®, Gental® and Ultracortenol®.

Of the approximately 140 total staff at Hettlingen, about 25 job reductions are planned by Novartis before the hand-over. Employees affected will be offered outplacement services, severance packages or early retirement as appropriate.

Novartis has maintained strong relations with Bernard Fraisse Group since 2002 when the French company acquired a Novartis production site in Annonay, France. This transaction resulted in a substantial increase in production through orders from third parties and in the retention of most Novartis employees.

The Ophthalmics business unit reported a 25 percent increase in first-half 2004 sales, driven by the dynamic performance of the eye disease drug Visudyne®. Outsourcing the manufacturing of ophthalmic products will have no impact to the company's growth or strategic plan for Ophthalmics.

**About Novartis**

Novartis AG (NYSE: NVS) is a world leader in pharmaceuticals and consumer health. In 2003, the Group's business 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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**Investor Relations Release**

**Landmark ZENSAA trial shows Zelnorm® is effective in repeated treatment of Irritable Bowel Syndrome with Constipation**

*ZENSAA is largest trial to assess repeated treatment for IBS-C in Women<sup>1</sup>*

**Basel, September 27, 2004** Data presented at the 2004 United European Gastroenterology Week (UEGW) congress show Zelnorm® (tegaserod)\* is both effective and well-tolerated in the treatment of Irritable Bowel Syndrome with Constipation (IBS-C).<sup>2</sup>

Zelnorm 6 mg, twice daily, provided patients with statistically significant improvement of their overall IBS symptoms as well as for the specific endpoint of improvement in abdominal discomfort or pain relief.<sup>2</sup> ZENSAA (Zelnorm in Europe, North and South America and Africa) is the largest trial of a dysmotility disorder like IBS-C ever conducted, having included more than 2,600 patients.<sup>1,2</sup>

Highlights of ZENSAA include<sup>2</sup>:

Significant improvement with initial and repeated Zelnorm treatment for overall IBS and individual symptoms

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*Zelnorm* significantly decreased abdominal discomfort or pain during both the initial treatment and re-treatment periods (9.1% (p<0.00001) and 15.9% (p<0.0001), respectively)

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During the initial treatment period 33.7% of Zelnorm-treated patients experienced significant relief of overall IBS symptom relief during at least three weeks of the four-week treatment period compared with 24.2% of placebo-treated patients (p<0.0001)

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In the second four-week treatment period, with repeated treatment two out of three (60.5%) patients taking Zelnorm experienced significantly improved relief of their overall IBS symptoms for at least two weeks compared with 42.8% of patients taking placebo (p< 0.0001)

Notable improvements in productivity and health outcome measures with Zelnorm treatment

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More than three out of four Zelnorm-treated patients showed improvement in self-reported well-being (76.6% for Zelnorm-treated patients (p=0.013))

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Significant improvement in work productivity (reduced overall work impairment by 6.3% (p=0.0001)), including fewer sick days and a decrease in presenteeism was associated with *Zelnorm* treatment versus placebo

"These positive results illustrate what we've known about Zelnorm all along; it has the distinction of treating the multiple dysmotility symptoms associated with IBS to the satisfaction of both physicians and patients," said Joerg Reinhardt, Head of Development, Novartis Pharma AG. "Because Zelnorm holds the promise of treating the tens of thousands of underserved people who now suffer from IBS-C, we remain committed to bringing Zelnorm to market in the European Union."

Designed in line with the recommendations of the European Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Evaluation Agency (EMA), ZENSAA was set up to assess initial and repeated Zelnorm treatment, as well as the effect on quality of life measures for women suffering from the multiple dysmotility symptoms of IBS-C.



"The debilitating effects of IBS-C impact all aspects of a patient's quality of life – physical, social, emotional and ability to work," said lead investigator Professor Jan Tack, Associate Professor and Associate Head of Clinic, Department of Gastroenterology, University of Leuven, Belgium. "The exact trial design of ZENSAA, its broad scope and the volume of patients leave no doubt about the effectiveness of tegaserod in treating IBS with Constipation."

The trial was also designed to mirror clinical practice as closely as possible within the clinical trial setting. The positive results from the ZENSAA trial will be used to support the upcoming EMEA filing of Zelnorm for the treatment of IBS-C in the European Union.

#### **More About ZENSAA<sup>1</sup>**

In this study, the adverse events profile of Zelnorm was similar to placebo, with the exception of diarrhea. Diarrhea was more frequent in patients taking Zelnorm (3.8%) vs placebo (0.6%) in treatment period 1. For tegaserod treated patients, diarrhea rarely led to discontinuation (0.9%). There was a low incidence of serious adverse events in both treatment periods (0.1% in Period 1 and 0.6% in Period 2) for Zelnorm-treated patients.

ZENSAA was a randomized, double-blind, placebo-controlled, multi-centre trial of 2,660 women with IBS-C. The trial was conducted in 262 centres in 24 countries including the U.K., Germany, France, Italy, Spain, the U.S., New Zealand, Canada, Mexico and South Africa. The first treatment period comprised 2,135 patients taking 6 mg of Zelnorm twice daily and 525 patients taking placebo (4:1 ratio). Treatment was discontinued in all patients after a four-week period, followed by two to 12 weeks without treatment. Patients were then re-randomized after their symptoms recurred. In the second treatment period, 488 patients were given Zelnorm and 495 given placebo (1:1 ratio).

The data were evaluated at the end of the trial. The primary efficacy endpoints were satisfactory relief of abdominal discomfort/pain and overall IBS relief for three of the four weeks of treatment, also referred to as the 75% rule.<sup>3</sup> The study data were also assessed using the 50% rule, satisfactory relief for two of the four weeks of treatment, for abdominal discomfort/pain and overall IBS relief.<sup>2</sup>

ZENSAA was designed to assess the efficacy, safety and tolerability of Zelnorm during both short-term (4 week) treatment and re-treatment at recurrence of symptoms; daily and weekly symptom evaluation; quality of life including work productivity; and overall patient-reported satisfaction with treatment. For the work productivity measures, at the end of the trial, treatment with Zelnorm reduced absenteeism (work missed due to symptoms) by 2.6% vs. placebo (p= 0.0042) and reduced "presenteeism" (loss productivity while at work) by 5.4% (p=0.0001).

#### **About Irritable Bowel Syndrome with Constipation (IBS-C)**

Irritable Bowel Syndrome with constipation (IBS-C) is a chronic, recurrent dysmotility disorder characterized by the multiple symptoms of abdominal pain and discomfort, bloating, and constipation.<sup>4,5,6</sup> Serotonin (5HT), a naturally occurring chemical in the body that regulates motility and pain perception in the intestinal system, is thought to play an important role in the normal activities of the GI tract. Serotonin is believed to influence the movement of food and waste through the body.<sup>7,8,9</sup> There is currently no effective treatment available in Europe for the multiple dysmotility symptoms of IBS. Traditional treatment for the condition has included a constellation of symptom-specific approaches, which may worsen concurrent symptoms.

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### **About Zelnorm**

Zelnorm (tegaserod), a pro-motility agent, is the first in a newer class of medications known as serotonin-4 receptor agonists (5HT<sub>4</sub> agonists) specifically developed to treat the multiple symptoms associated with dysmotility disorders like IBS-C. By activating 5HT<sub>4</sub> receptors in the gastrointestinal tract, Zelnorm normalizes delayed motility and reduces sensitivity of the intestinal tract.<sup>10,11,12,13</sup> In clinical studies, significantly more patients experienced a general relief of symptoms when treated with Zelnorm, such as a decrease in abdominal pain, bloating and constipation.<sup>14,15,16,17,18</sup> In most patients, the onset of relief occurred within just one week<sup>16</sup>. The medicine has been shown to be well tolerated and shows a profile of side effects similar to that of placebo with the exception of diarrhea. The majority of patients reporting diarrhea had a single episode and in most cases, diarrhea occurred in the first week of treatment. Typically, diarrhea resolved with continued therapy.<sup>1,13,14,15,16</sup>

Zelnorm, discovered and developed by Novartis, is approved for the treatment of IBS in more than 50 countries including Australia, Switzerland, Canada, the United States, Mexico, China and Brazil. Zelnorm is also approved for the treatment of Chronic Constipation in more than 10 countries including the United States and Mexico. Zelnorm is being studied as a potential treatment for other important gastrointestinal disorders, such as gastroesophageal reflux disease (GERD) and dyspepsia (heartburn). For more information about IBS please visit <http://www.IBSMediacentre.com>.

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 "holds the promise", "potential treatment" or similar expressions, or by express or implied discussions regarding potential future regulatory approvals, additional indications or sales of Zelnorm. Such forward-looking statements reflect the current views of the Company with respect to future events and are subject to certain risks, uncertainties and assumptions. There can be no guarantee that Zelnorm will be approved in the EU or in any additional countries; or that Zelnorm will be approved for the treatment of any additional indications; or regarding potential future revenues from Zelnorm. In particular, management's expectations could be affected by, among other things, uncertainties relating to unexpected regulatory actions or delays; government regulation generally; new clinical data; unexpected clinical trial results; the 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 Securities and Exchange Commission of the United States. 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 UEGW**

United European Gastroenterology Week (UEGW) was first held in Athens in 1992. UEGW was designed by the United European Gastroenterology Federation to be a regular, scientifically-oriented, multi-disciplinary gastroenterology meeting held in Europe. UEGW takes place 25-29 September 2004 in Prague, Czech Republic. The meeting showcases several abstracts and hundreds of lectures on the latest advances in GI research, medicine and technology.

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**MEDIA RELEASE    COMMUNIQUE AUX MEDIAS    MEDIENMITTEILUNG**

**Largest study in gastrointestinal stromal tumor patients shows higher dose of Glivec® significantly improves progression-free survival**

**Basel, Switzerland, September 24, 2004** Patients in a study taking an 800 mg daily dose of Glivec (imatinib)\* for treatment of certain forms of gastrointestinal stromal tumor (GIST) had significantly longer progression-free survival compared to the patients taking the standard 400 mg daily dose, according to results published today in *The Lancet*.

The results showed that doubling the daily dose of Glivec may improve progression-free survival of patients with KIT (CD117)-positive inoperable and/or metastatic\*\* GIST. At a median follow-up of 760 days, patients receiving 800 mg per day experienced five months longer progression-free survival compared to patients receiving the 400 mg daily dose.

"The introduction of Glivec has dramatically improved the prognosis of patients diagnosed with advanced KIT-positive GIST," said Jaap Verweij, Head of The Division of Experimental Chemotherapy, Department of Medical Oncology, Erasmus University Medical Center, Rotterdam, The Netherlands, the principal investigator and lead author of this publication. "While further research is needed to establish the impact of a higher starting dose on patients' survival, the prolonged progression-free survival seen in this study represents benefit to patients."

The international, randomized, Phase III intergroup study was conducted by the EORTC (European Organization for Research and Treatment of Cancer), ISG (Italian Sarcoma Group) and the AGITG (Australasian Gastrointestinal Trials Group). A total of 946 patients with advanced and/or metastatic KIT-positive GIST received either a 400 or 800 mg dose of Glivec per day (400 mg twice daily). Patients who experienced any disease progression on the 400 mg daily dose were allowed to increase to 800 mg per day to regain control of the disease. At the time of the analysis (May 2004), a total of 412 patients had completed treatment in the trial, which had progression-free survival as the primary endpoint.

Patient treatment with 800 mg of Glivec per day significantly increased progression-free survival compared to treatment with 400 mg per day. Although side effects were more common and more severe with the higher dose, the majority of patients did not require a dose reduction. Treatment in both groups was fairly well-tolerated.

**About GIST**

GIST is the most frequent form of gastrointestinal cancer, a life-threatening disease highly resistant to traditional treatment with chemotherapy and radiation. Surgery is considered the best way to initially treat GIST. However, many GISTs cannot be surgically removed because they are too large or have already spread to other parts of the body before diagnosis. When surgery is performed, cells from the original GIST may remain behind or the cancer may return in another site within the body. Experts believe that GIST may be more prevalent than previously believed, affecting approximately 15 people per 1 million per year. In the past, GIST was considered to be untreatable if doctors could not remove the tumor by surgery or if it had spread to other parts of the body.

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In GIST, a specific mutation causes a cellular enzyme, known as KIT, to be switched "on" all the time. KIT is an enzyme (called a "tyrosine kinase") responsible for sending growth and survival signals inside the cell. If it is "on," the cell stays alive and grows or proliferates. The overactive, uncontrolled mutant KIT enzyme triggers the runaway growth of GIST tumor cells. This insight into the way GISTs develop has already helped to identify new treatments for this sarcoma.

#### **About Glivec**

Glivec is indicated in the EU, US and more than 45 other countries worldwide for the treatment of patients with KIT (CD 117)-positive unresectable (inoperable) and/or metastatic malignant GIST. In Japan, Glivec is approved for the treatment of patients with KIT (CD117)-positive GIST.

Glivec is also approved for first-line treatment of adult patients with Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) in chronic phase, in the EU, US and Japan and a number of other countries. It is also approved in some countries (including the EU and Switzerland) for the treatment of certain pediatric patients with CML. In addition, Glivec is approved in over 80 countries for the treatment of adult patients with Ph+ CML in blast crisis, accelerated phase or in chronic phase after failure of interferon-alpha therapy.

#### **Contraindications and adverse events**

The most common undesirable effects experienced during Glivec treatment in GIST are: headache, nausea, vomiting, diarrhea, dyspepsia, myalgia, muscle spasm and cramps, joint swelling, dermatitis, eczema, rash, edema, fluid retention, neutropenia, thrombocytopenia or anemia.

In the first-line study (IRIS), the safety profile with Glivec was similar to that of previous Phase II studies in other CML patients. The majority of patients treated with Glivec experienced adverse events at some time. Most events were of mild to moderate grade and treatment was discontinued for adverse events only in 2% of patients in chronic phase, 3% in accelerated phase and 5% in blast crisis. The most common side effects included nausea, superficial edema, muscle cramps, skin rash, vomiting, diarrhea, hemorrhage, fatigue, headache, joint pain, cough, dizziness, dyspepsia and dyspnea, as well as neutropenia and thrombocytopenia.

Glivec is contraindicated in patients with known hypersensitivity to imatinib or any of its excipients. Women of childbearing potential should be advised to avoid becoming pregnant while taking Glivec.

The foregoing release contains forward-looking statements that can be identified by terminology such as "improve," "may", "may prolong," "significantly increased" or similar expressions, or by express or implied discussions regarding potential future revenue from Glivec. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results with Glivec to be materially different from any future results, performance or achievements expressed or implied by such statements. In particular, management's expectations regarding Glivec could be affected by, among other things, additional analysis of Glivec 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 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.

\*In the U.S.: Gleevec® (imatinib mesylate)

\*\*Metastatic patients are patients whose tumors have spread to other parts of the body

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Further information on Novartis Oncology and Glivec can be found at [www.novartisoncology.com](http://www.novartisoncology.com) or [www.glivec.com](http://www.glivec.com).

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

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**MEDIA RELEASE    COMMUNIQUE AUX MEDIAS    MEDIENMITTEILUNG**

**Novartis expands Diovan® production at Swiss manufacturing site**

**Basel, September 22, 2004** Novartis has completed a CHF 60 million expansion of its manufacturing facility in Schweizerhalle, Switzerland, to increase production capacity for the blockbuster anti-hypertensive Diovan® (valsartan).

"The expansion of this important Swiss production site is due to growing patient demand for our range of Diovan products," said Andreas Rummelt, Head of Global Technical Operations, Novartis Pharma AG. "The ongoing development of new strengths and combinations, as well as the clinical development of new treatment options, underscores the need to be flexible and ready to support future growth. This expansion also highlights our continued commitment to investment in Switzerland."

More than 600 Novartis employees are currently based at the Schweizerhalle plant near Basel and approximately 25 new positions will be added as part of this expansion. The company has invested more than CHF 1 billion in its production facilities in Switzerland since the creation of Novartis in 1996, contributing to the growth of Novartis as well as creating jobs and stimulating economic growth in the Basel region.

Diovan, which belongs to the class of blood pressure-lowering medicines called angiotensin II receptor blockers (ARBs), is the world's leading ARB and the second largest selling antihypertensive agent. Co-Diovan, a leading combination product for high blood pressure, provides patients who need additional blood pressure control greater flexibility beyond that provided with Diovan or the product's second active ingredient, the anti-hypertensive agent hydrochlorothiazide, alone. Diovan offers powerful double-digit blood pressure reductions and superior tolerability, patient persistency and patient compliance. In addition, Diovan has proven cardio-protective benefits beyond lowering blood pressure.

Discovered and developed by Novartis in Switzerland, Diovan is approved and available in more than 80 countries for the first-line treatment of hypertension, and for heart failure in more than 50 countries. In the United States and Switzerland, among other countries, Diovan is indicated for the treatment of heart failure in patients who cannot tolerate ACE inhibitors, another type of anti-hypertensive treatment.

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 "will be" or similar expressions, or by express or implied discussions regarding potential future sales of Diovan. Such forward-looking statements reflect the current views of the Company with respect to future events and are subject to certain risks, uncertainties and assumptions. There can be no guarantee regarding potential future revenues from Diovan. In particular, management's expectations could be affected, among other things, by uncertainties relating to unexpected regulatory actions or delays; government regulation generally; new clinical data; unexpected clinical trial results; the 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 Form 20-F on file with the Securities and Exchange Commission of the United States. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those described herein as anticipated, believed, estimated or expected. Novartis is providing the information in this press release as of this date and does not undertake any obligation to update any forward-looking statements contained in this press release as a result of new information, future events or otherwise.

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**MEDIA RELEASE COMMUNIQUE AUX MEDIAS MEDIENMITTEILUNG**

**LAF237, first in a new class of oral antidiabetic agents, shown in phase II to provide clinically significant improvement in glycemic control**

*Researchers conclude LAF237 positively influences both insulin production and utilization in type 2 diabetes*

**Munich, Germany, September 7, 2004** The investigational drug LAF237, the first in a new class of oral anti-diabetes agents, significantly improved glycemic control in patients with type 2 diabetes who were not adequately controlled by metformin alone, an improvement that was sustained for up to a year while taking LAF237, according to data presented at the European Association for the Study of Diabetes (EASD) annual meeting.

"Although most oral antidiabetic agents are initially effective in achieving acceptable glycemic control in patients with type 2 diabetes, control is seldom maintained in the long term, even with combination therapy," explained study author Professor Bo Ahrén of Lund University, Sweden. "The finding that LAF237 can achieve acceptable hemoglobin A1c reduction and maintain it for up to a year is very encouraging."

Several other studies presented during the meeting suggest that LAF237, a member of an innovative class of diabetes treatments known as DPP-4 inhibitors, works to address the insulin/glucose imbalance that is the underlying defect of type 2 diabetes. Researchers reported that LAF237 increases insulin secretion while suppressing the release of glucagon in patients with diabetes. Additionally, researchers in a small study of people with type 2 diabetes concluded that the compound improved function of the insulin-producing beta cells in the pancreas.

LAF237 works in a different manner than other therapies used to treat type 2 diabetes. It increases levels of specific hormones found in the gut (incretin hormones) called glucagon-like peptide (GLP)-1 and gastric inhibitory polypeptide (GIP), by blocking the action of dipeptidyl peptidase (DPP)-4, an enzyme that normally inactivates them. GLP-1 and GIP are secreted from the intestine in response to food and stimulates insulin production by the beta cells of the pancreas. GLP-1 also reduces the secretion of glucagon, a hormone that signals the liver to produce glucose. In this way, LAF237 helps to address the imbalance between insulin supply and demand, one of the underlying causes of type 2 diabetes.

**Long-term study results**

In this phase II study, 42 patients were given oral LAF237 plus metformin once daily and 29 patients received placebo plus metformin. Hemoglobin A1c (HbA1c) levels were measured over the course of 52 weeks. In patients treated with LAF237 plus metformin, the HbA1c levels decreased significantly and those levels were maintained up to 52 weeks. In the patients who continued on metformin alone, glycemia control deteriorated over time. At study end, there was an average difference of 1.1% between the two groups (p<0.0001). Glucose levels measured after 8-12 hours of fasting and 1-2 hours after eating a meal were also reduced in patients taking metformin plus LAF237 versus continued therapy with metformin alone.

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LAF237 was found to be well tolerated, with 76.2% of patients in the LAF237 plus metformin arm and 89.7% of patients in the metformin plus placebo arm completing the 52-week investigation. The metformin plus LAF237 group reported a slightly higher percent of patients with at least one adverse event (69%) compared to the metformin plus placebo group (58.6%). However, suspected drug-related adverse events were 4.8% and 6.9% respectively. Four patients in the metformin plus LAF237 group discontinued due to an adverse event. Three patients assigned to receive the combination of metformin plus LAF237, although these events were mild and did not lead to discontinuations.

#### **Mechanistic studies**

Results from three additional smaller studies that highlight the drug's unique mechanism of action were also presented at the EASD meeting. This research demonstrated the effect LAF237 has on levels of GLP-1 and GIP and subsequently beta cell function and glucagon secretion. Specifically, LAF237 imitates the body's own regulatory system, providing an effect on insulin secretion and glucagon suppression similar to that of the body's normal physiology.

In one study, patients with type 2 diabetes not previously treated with oral agents received either LAF237 (100mg twice daily, n=9) or placebo (n=11) for 28 days to assess the impact of LAF237 on beta cell function. Results demonstrated that LAF237, by increasing the active forms of GLP-1 and GIP, improved beta cell function in terms of enhanced insulin secretion in response to glucose challenge.

In a 28-day, randomized, placebo-controlled, double-blind crossover trial of 12 patients with type 1 diabetes treated by insulin pump therapy, LAF237 suppressed glucagon secretion following a meal, indicating that GLP-1 acts on glucagon secretion independent of insulin effects. In a separate double-blind four-way crossover study involving 16 healthy male subjects, LAF237 reduced GLP-1 and GIP secretion in response to glucose administration. Larger follow-up studies to confirm these findings are ongoing.

"The more we learn about LAF237, the more promise this treatment appears to hold," said Dr. Jörg Reinhardt, Head of Development, Novartis Pharma AG. "Clinically, we're seeing meaningful endpoints in sustainable reductions of hemoglobin A1c levels, and when we closely examine how the drug works, we see it closely mirrors the body's own natural, physiological mechanism to balance out insulin supply and demand. This effect, combined with LAF237's oral administration, good tolerability, and the lack of weight gain seen among patients is exciting and encouraging to the Novartis research team as we continue the compound's phase III development program."

The development of new diabetes treatments like DPP-4 inhibitors is critically important given the World Health Organization's estimate that the number of people with diabetes in Europe will rise from approximately 33.3 million in 2000 to more than 48 million in 2030. In 2000 alone, approximately 609,000 deaths in Europe were attributed to diabetes.

The phase III clinical trial program of LAF237 is currently ongoing, with first regulatory submissions expected in 2006. The development of LAF237 is driven by Novartis' cardiovascular and metabolic business franchise. A worldwide leader in cardiovascular care and in the treatment of a variety of metabolic disorders, the cardiovascular and metabolic business franchise currently markets the diabetes treatment Starlix® (nateglinide), the anti-lipidemia therapies Lescol®/Lescol®XL (fluvastatin) and the hypertensive therapies Diovan® (valsartan) and Co-Diovan® (valsartan and hydrochlorothiazide).

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The foregoing release contains forward-looking statements that can be identified by terminology such as "investigational", "first in a new class", "suggest", "long-term", "follow-up studies... are ongoing", "the more promise this treatment appears to hold", "continue", "will rise", "expected" or similar expressions, or by discussions regarding potential approvals to market LAF237 or regarding the long-term impact of a patient's use of LAF237. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results with LAF237 to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that LAF237 will be approved for sale in any market. In particular, management's expectations regarding LAF237 could be affected by, among other things, additional analysis of LAF237 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.

#### **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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### Investor Relations Release

#### Novartis wins Lamisil Tablets® patent infringement lawsuit against Dr. Reddy's Laboratories

**Basel, September 3, 2004** Novartis announced today that it has prevailed in its US patent infringement lawsuit with Dr. Reddy's Laboratories Limited of Hyderabad, India, regarding Novartis' widely prescribed oral antifungal agent Lamisil Tablets® (terbinafine hydro-chloride). *Lamisil* is the leading prescription treatment to effectively treat onychomycosis, a fungal infection that commonly affects the toes or fingernails.

Dr. Reddy's Laboratories has withdrawn its challenge to a *Lamisil* patent held by Novartis, conceding that it is valid, enforceable and had been infringed by Dr. Reddy's Laboratories.

"While generics play an important and legitimate role in offering cost-effective therapeutic alternatives, strong patent protection remains essential to fostering continuous innovation that advances medical treatment for patients," said Dr. Daniel Vasella, Chairman and CEO of Novartis.

Under the terms of the consent judgment in the US District Court for the Southern District of New York, Dr. Reddy's Laboratories will not manufacture, use, sell or import into the United States a generic version at least until the patent expiration date of December 2006 and any pediatric exclusivity extension (six months) issued by the US Food and Drug Administration (FDA) for the patent.

Novartis has a strong patent position for *Lamisil* that relies on an abundance of evidence showing terbinafine hydrochloride to be a distinctive molecule with a unique mode of action. Chemically and therapeutically, terbinafine is unique in its class in the treatment of onychomycosis. An estimated 35 million Americans suffer from onychomycosis, a fungal infection that aggressively discolors, thickens, and destroys the nail plate of the toenails or the fingernails.

#### About Novartis

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This release contains certain forward-looking statements relating to the Company's business, which include express or implied representations regarding future patent protection of *Lamisil Tablets*. Such statements reflect the current views of the Company with respect to future events and are subject to certain risks, uncertainties and assumptions. There can be no guarantee that success in this patent challenge will mean that the Company will be successful in defending itself against these suits in the future. In particular, management's expectations could be affected by, among other things, the 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 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.

*All product names appearing in italics are trademarks of Novartis AG or its affiliated companies.*

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### Investor Relations Release

#### Novartis offers direct share purchase plan to investors in Switzerland, Liechtenstein, France and the United Kingdom

*Convenient investor plan is first of its kind among Swiss companies*

**Basel, Switzerland, September 2, 2004** Novartis announced today that it will offer a Direct Share Purchase Plan (DSPP) to investors in Switzerland, Liechtenstein, France and the United Kingdom, marking the first time such a program has been offered by a Swiss company. The plan enables investors to minimize transaction costs to acquire Novartis Registered Shares and to hold shares free of charge in a Share Deposit Account.

"Novartis is pleased to offer this innovative program to investors in these four countries," said Dr. Daniel Vasella, Chairman and CEO of Novartis. "Our new Direct Share Purchase Plan offers current and potential investors an inexpensive way to invest in Novartis Registered Shares. We are proud to be the first Swiss company, and among the first European companies, to offer such a plan to investors."

The DSPP is a way for long-term investors to more easily acquire and hold Novartis Registered Shares without paying high commissions and deposit fees. Additional features of the plan include automatic reinvestment of dividends in additional Novartis shares, low purchase and sale transaction fees, and share safekeeping. Direct share purchase programs are popular in the United States though not yet well known in Europe. Novartis introduced a DSPP for investors of Novartis American Depositary Shares in the United States in 2001.

The new DSPP is available only to residents of Switzerland, Liechtenstein, France and the United Kingdom. Investors participating in the DSPP may invest up to CHF 200,000 per calendar year in additional Novartis Registered Shares and/or apply their dividends from Novartis AG for the acquisition of further Novartis Registered Shares. The plan extends solely to Novartis Registered Shares (Securities Number 1200526, ISIN No. CH0012005267), and investors cannot acquire any other securities through the Direct Share Purchase Plan.

The DSPP is operated by Novartis in cooperation with S A G SIS Aktienregister AG, which manages the Plan on behalf of Novartis. Credit Suisse is the designated broker. It replaces the existing Novartis Share Deposit Plan managed by S A G, which ended on August 31, 2004. Shareholders who already hold Novartis Registered Shares under the existing Share Deposit Plan will have their share plans automatically transferred to the new DSPP.

More information about the Novartis Direct Share Purchase Plan is available at [www.novartis.com/investors](http://www.novartis.com/investors) or [www.sag.ch/dspp/novartis](http://www.sag.ch/dspp/novartis).

#### 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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**Important legal notice**

The information published by Novartis in the above media release, on the Novartis website or any other document related to the Novartis Direct Share Purchase Plan does not constitute a solicitation or offer, or recommendation, to buy or sell Novartis shares, to effect any transaction, or to conclude any legal act of any kind whatsoever.

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 US persons and may be accepted only by non-US 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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### Investor Relations Release

#### FDA defers decision on Omnitrope application

**Vienna, September 2, 2004** Sandoz has received notice from the US Food and Drug Administration (FDA) that the agency is unable to reach a decision on whether to approve an application for the marketing of the recombinant DNA human growth hormone Omnitrope.

According to the FDA letter issued to Sandoz, the agency has completed its review of Omnitrope and did not identify any deficiencies in the application. However, the agency stated it had been unable to reach a final decision on the application due to uncertainty regarding scientific and legal issues.

"We appreciate the constructive consultations held with the agency, and believe we have submitted complete and thorough data to support marketing approval for Omnitrope," said Dr. Alexander Berghout, Head of Clinical Development and Regulatory Affairs, Biopharmaceuticals, Sandoz. "We believe it is important for patients and healthcare providers that cost-effective follow-on biologics like Omnitrope become available as safe and effective therapeutic alternatives."

Sandoz acknowledges that the approval of most follow-on biologics in the US will require new legislation to ensure that the FDA has the authority to fulfill its mission of ensuring the safety and efficacy of every approved medicine. The company supports a transparent public process to help identify an appropriate regulatory pathway for follow-on biologics with an emphasis on ensuring patient safety while protecting the legitimate intellectual property rights of innovator companies.

"Technologies to make medicines, particularly biologics, have progressed rapidly during the last 20 years," Dr. Berghout said. "It is critical that advancements be made in regulatory requirements to improve patient access to high-quality, cost-effective alternatives to branded products that have lost patent protection."

Sandoz believes that rigorous scientific criteria should be applied with the highest standards, but without unnecessary or unethical duplication of pre-approval studies or clinical trials and without wasting resources that are needed to invest in continuous innovation. Generics and follow-on proteins are an important part of the tool kit that physicians must use to provide high-quality and cost-effective healthcare for their patients.

#### 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 its pharmaceuticals, biopharmaceuticals and industrial products franchises. Sandoz employs around 13,000 people worldwide and posted sales of USD 2.9 billion in 2003.

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**MEDIA RELEASE    COMMUNIQUE AUX MEDIAS    MEDIENMITTEILUNG**

**Novartis honors researchers committed to advancing the understanding and treatment of diabetes**

**Basel, September 1, 2004** Four physician-scientists were recognized today by Novartis for significant and innovative research, clinical practice advances and educational efforts in diabetes. The recipients of the sixth annual Novartis Award in Diabetes will be honored at the time of 40th Annual Meeting of the European Association for the Study of Diabetes (EASD) in Munich, Germany on September 7, 2004.

The recipients of the Long-Standing Achievement award are Professor Ele Ferrannini from the University of Pisa, Italy and Dr. Robert S. Sherwin of Yale University, United States. The Young Investigator award, for scientists age 45 or younger, will be presented to Dr. Paola Fioretto of the University of Padova, Italy and Dr. Michael Roden of the University of Vienna Medical School, Austria.

"Diabetes is a growing, global epidemic, affecting more than 200 million children and adults worldwide, and this number is expected to double by 2030", said Professor Eberhard Standl, Physician-in-Chief, Third Medical Department, Diabetes and Metabolism, Endocrinology and Angiology at the Academic Hospital Munich-Schwabing in Germany and chair of the Award's selection panel. "The esteemed researchers singled out today are working on truly ground-breaking science that may result in improved treatments and have already uncovered better ways to manage the disease."

**The Long-Standing Achievement Awards recipients**

With a research focus on the role of adipose (fat tissue) on diabetes, Ele Ferrannini, Chief of the Metabolism Unit of the National Research Council of Clinical Physiology in Pisa and a Professor of Internal Medicine at the University of Pisa School of Medicine is recognized for the significant research conducted throughout his career. In the search for new and better treatments, Dr. Ferrannini has made important contributions to understanding the connection between the inability to respond to insulin and the breakdown of glucose in the liver of people with diabetes. Dr. Ferrannini and his research team have also made fundamental contributions to understanding the origin and development of high blood pressure in people with diabetes and the relationship between insulin resistance and the body's resulting compensatory insulin production.

Robert Sherwin is the C.N.H. Long Professor of Medicine at Yale University. Professor Sherwin's role in the development of insulin pump therapy represents a crucial advance in diabetes patient care. While studying the effect of continuous insulin infusion on the liver's response to glucose, he proposed that continuous subcutaneous (under the skin) infusion via a small pump would provide a relatively safe method of insulin delivery in people with diabetes. Some of Prof Sherwin's other work involved helping to develop the most widely accepted method for measuring the body's cells sensitivity to insulin, a procedure known as the euglycemic hyperinsulinemic clamp technique.

**The Young Investigator Award recipients**

Paola Fioretto, an Assistant Professor in the Department of Medical and Surgical Sciences at the University of Padova, is a recognized expert in the field of diabetic nephropathy (damage to the kidney cells), the leading cause of kidney failure in people with type 1 and type 2 diabetes. Dr. Fioretto has also explored the link between the normalizing of blood sugar levels resulting from successful pancreas transplantation and its effects on lesions within the kidney caused by diabetic nephropathy.

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Michael Roden is an Associate Professor of Medicine at the Division of Endocrinology and Metabolism, Department of Internal Medicine III, University of Vienna Medical School and Head of the Internal Medical Department, Hanusch Hospital. Dr. Roden's clinical interests include the study of the roles of insulin and glucagon in the production and turnover of glycogen in the liver and the mechanism by which free fatty acids cause insulin resistance. The results of Dr. Roden's studies provide new insights into how fatty acids cause insulin resistance in human muscle tissue.

"Novartis honors these four outstanding recipients for their personal and professional commitment to diabetes," said Dr. Jörg Reinhardt, Head of Development, Novartis Pharma AG. "Like these physician-scientists, Novartis is committed to diabetes care and is conducting research in promising new treatment areas, including incretin hormones."

Recipients will be presented with a monetary prize by the selection panel members at a presentation dinner during the time of EASD.

#### **Novartis commitment to diabetes**

This international award is one of many activities that Novartis is supporting to help increase both the awareness of and urgency for innovation in diabetes research, education and clinical practice. Novartis is constantly exploring new approaches for the treatment of type 2 diabetes, including the novel insulin secretion agent, *Starlix*® (nateglinide), which 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. Nateglinide is licensed to Novartis Pharma AG from Ajinomoto Co., Inc.

Novartis has also launched a phase III program for LAF237, an investigational, potential first-in-class, oral DPP-4 inhibitor that in phase II clinical trials has demonstrated significant clinical efficacy in improving glycemic control.

#### **About Novartis**

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**Disclaimer**

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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: October 4, 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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