

NOVARTIS AG  
Form 6-K  
July 06, 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 dated June 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:

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. Sandoz to strengthen Danish market position and Nordic operations with acquisition of Astra Zeneca's generics subsidiary in Denmark (Vienna, June 30, 2004)
- 2.

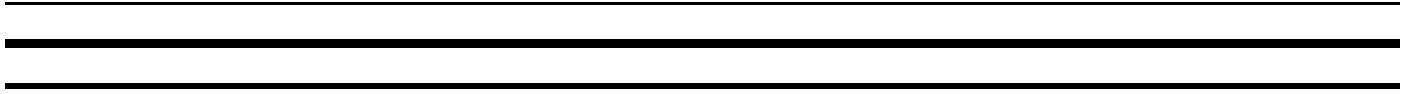
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U.S. FDA grants priority review for Femara for new indication as first ever post-tamoxifen treatment for early breast cancer in postmenopausal women (Basel, June 29, 2004)

3. Leading European agency recognises clinical and cost-effectiveness of steroid-free Elidel cream for treating eczema (Basel, 28 June, 2004)
  4. Sandoz Inc. launches AB-Rated Levothroxine (Princeton, New Jersey, ,23 June, 2004)
  5. The VALUE trial complements the long-term cardioprotective profile of Diovan (Paris, 14 June, 2004)
  6. Novartis unveils promising new clinical data of key pipeline projects at the Goldman Sachs Healthcare Conference in Laguna Niguel (Laguna Niguel, 8 June, 2004)
  7. Femara® Is First Hormonal Therapy To Significantly Reduce Spread Of Early Breast Cancer To Other Parts Of The Body After Standard Tamoxifen Treatment In Postmenopausal Women (Basel, 8 June, 2004)
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8. Positive results of first phase II study in new class of oral diabetes drugs (Basel, 7 June, 2004)
9. Sandoz makes major entry into generic injectables field with acquisition of fast-growing Sabex Holdings Ltd. of Canada (Vienna, June 7, 2004)



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**Investor Relations Release**

**Sandoz to strengthen Danish market position and Nordic operations with acquisition of Astra Zeneca's generics subsidiary in Denmark**

*Strategic acquisition of Durascan makes Sandoz number two player in local generics market and provides operational hub for entire Nordic region*

Vienna, June 30, 2004 Sandoz today announced the acquisition of Durascan, the generic subsidiary of Astra Zeneca in Denmark, in a transaction aimed at claiming the number two position in the Danish generics market and establishing a new operational hub in the Nordic region. Financial details of the transaction were not disclosed.

With net sales of €25 million in 2003, Durascan has a broad portfolio of generic medicines that provide growth opportunities for Sandoz throughout the Nordic region. In addition, Durascan provides Sandoz with state-of-the-art quality assurance and logistics facilities, making it an attractive operational platform to fuel regional growth.

"The acquisition of Durascan provides Sandoz with a leadership position in the Danish generics market and a platform to increase our presence in the Nordic region with its strong and highly competitive generics environment," said Christian Seiwald, CEO of Sandoz. "It is perfectly in line with our strategy to grow organically, while seeking selected regional or therapeutic acquisitions."

**Company Information**

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

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

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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 "aimed at," "provide growth opportunities," "operational platform to fuel," "a platform to increase," "strategy to grow," or similar expressions, or by express or implied discussions regarding strategies, plans and expectations. Such statements reflect the current plans or views of the Company with respect to future events and are subject to certain risks, uncertainties and assumptions. Many factors could cause the actual results, performance or achievements of the Company to be materially different from any future results, performances or achievements that may be expressed or implied by such forward-looking statements. There can be no guarantee that the transactions that are the subject of this release will lead to the commercialization of any new products in any market, or that any such products will reach any particular sales levels. Any such commercialization or sales could be affected by, among other things, new clinical data; unexpected 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; increased government pricing pressures; competition in general, and other risks referred to in Novartis AG's Form 20-F on file with the US Securities and Exchange Commission. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those described herein as anticipated, believed, estimated or expected. The Company 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**

**U.S. FDA grants priority review for Femara for new indication as first ever post-tamoxifen treatment for early breast cancer in postmenopausal women**

*Agency expected to give decision before end of year*

Basel, June 29, 2004 Novartis Oncology announced today that its supplementary New Drug Application for Femara® (letrozole) has been granted priority review by the U.S. Food and Drug Administration (FDA) for an indication in the extended adjuvant treatment of early breast cancer in postmenopausal women who have completed standard adjuvant (post-surgery) tamoxifen therapy.

The FDA grants priority review to products that appear to represent a significant advance for serious or life-threatening diseases. The application was filed at the end of April 2004. The priority review establishes an action date no later than six months after the filing date. Femara received its first approval for this new indication from the Mexican health authorities earlier this month. Novartis Oncology has also submitted marketing applications for this new indication in the European Union, Canada and Switzerland among other countries.

"We are pleased the FDA recognizes the potential for Femara to fulfill an important unmet medical need of postmenopausal women to reduce their risk of recurrence of breast cancer following completion of therapy with tamoxifen," said Diane Young, MD, vice president, global head, Clinical Development, Novartis Oncology.

In women with early breast cancer, adjuvant therapy with tamoxifen has not been shown to provide additional benefit after five years and, traditionally, most women have not received treatment after completion of adjuvant tamoxifen therapy. More than half of the recurrences of breast cancer occur after the completion of standard adjuvant therapy with tamoxifen. Recurrence of breast cancer after initial treatment places patients at greater risk of developing distant metastases and of dying of the disease.

There is currently no post-tamoxifen therapy available for the approximately 100,000 women who complete tamoxifen therapy in the United States each year. Upon completion of tamoxifen therapy, many of these women are potential candidates for treatment with Femara.

The filing for this new indication was based on data from the landmark MA-17 trial. MA-17 is the first study that has provided clinical evidence to support the use of a medication, Femara, to reduce the risk of breast cancer recurrence during this extended adjuvant (post-tamoxifen) period. Coordinated by the National Cancer Institute of Canada Clinical Trials Group at Queens University in Kingston, Ontario and supported by Novartis, the MA-17 study evaluated extended adjuvant treatment with Femara vs. placebo in over 5,100 postmenopausal women with early breast cancer. Interim results from MA-17 received an expedited review from the *New England Journal of Medicine* and were published in October 2003. Updated results of the study were presented earlier this month at the annual meeting of the American Society of Clinical Oncology held in New Orleans.

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## About Femara

Femara, an aromatase inhibitor, is an oral once-a-day first-line treatment for postmenopausal women with hormone receptor positive or hormone receptor unknown locally advanced or metastatic breast cancer. It is also approved for the treatment of advanced breast cancer in postmenopausal women with disease progression following antiestrogen therapy, and as neo-adjuvant (pre-operative) therapy. Femara is currently available in more than 80 countries worldwide. Not all indications are available in every country.

## Femara Contraindications and Adverse Events

In the interim MA-17 analysis, the most common adverse events were hot flashes, sweating, edema, hypercholesterolemia, headache, arthralgia, myalgia, fatigue, constipation and dizziness, in greater than 10% of patients in either arm of the study. Of these, hot flashes, arthralgia, and myalgia were more common in those receiving Femara than placebo ( $P < 0.05$ ). Vaginal bleeding was more common in those taking placebo ( $P = 0.01$ ). The MA-17 researchers noted a trend toward newly diagnosed cases of osteoporosis in women taking Femara vs. placebo (5.7 vs. 4.5%;  $P = 0.07$ ) and, at two years there was a mean decrease in bone mineral density in the hip from baseline as compared to placebo (3.0 vs. 0.4%;  $P = 0.048$ ).

Femara is contraindicated in patients with known hypersensitivity to Femara or any of its excipients. Femara is generally well tolerated and adverse reaction rates in the first-line study in which Femara was compared with tamoxifen were similar with those seen in second-line studies. The most commonly reported adverse events for Femara vs. tamoxifen were bone pain (22% vs. 21%), hot flashes (19% vs. 16%), back pain (18% vs. 19%), nausea (17% vs. 17%), dyspnea or labored breathing (18% vs. 17%), arthralgia (16% vs. 15%), fatigue (13% vs. 13%), coughing (13% vs. 13%), constipation (10% vs. 11%), chest pain (6% vs. 6%) and headache (8% vs. 6%). Femara may cause fetal harm when administered to pregnant women. The incidence of peripheral thromboembolic events, cardiovascular events, and cerebrovascular events was 3-4% in each treatment arm.

The foregoing release contains forward-looking statements that can be identified by terminology such as "landmark," "first ever," "potential," "appear to represent a significant advance" or similar expressions, or by express or implied discussions regarding potential new indications for Femara or potential future sales of Femara, or regarding the long-term impact of a patient's use of Femara. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results with Femara to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Femara will be approved for any additional indications in any market. Nor can there be any guarantee regarding potential future sales of Femara. Neither can there be any guarantee regarding the long-term impact of a patient's use of Femara. In particular, management's expectations regarding commercialization of Femara could be affected by, among other things, additional analysis of Femara clinical data; new clinical data; unexpected clinical trial results; unexpected regulatory actions or delays or government regulation generally; the company's ability to obtain or maintain patent or other proprietary intellectual property protection; competition in general; 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. 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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**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 78,500 people and operate in over 140 countries around the world. For further information please consult <http://www.novartis.com>.

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

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**MEDIA RELEASE COMMUNIQUE AUX MEDIAS MEDIENMITTEILUNG**

**Leading European agency recognises clinical and cost-effectiveness of steroid-free Elidel cream for treating eczema**

Basel, 28 June 2004 Patient groups and clinicians today praised a decision by the National Institute for Clinical Excellence (NICE), the influential UK authority responsible for evaluating the cost-effectiveness of medicines, recommending the use of Elidel Cream (pimecrolimus) for treating certain cases of atopic eczema (AE). The decision means that patients and clinicians will continue to benefit from a steroid-free therapy.

The Final Appraisal Determination (FAD) released by NICE earlier today recommends that Elidel should be used for the treatment of moderate AE on the face and neck in children aged 2-16, where the disease has not been controlled by topical corticosteroids and there is a risk of adverse effects from further steroid use.

The decision comes after doctors and patients challenged a preliminary recommendation issued by NICE on 5 April 2004, which questioned whether Elidel should be made available on the National Health Service (NHS). In today's FAD, NICE said it had been persuaded by clinical experts that Elidel was a useful treatment option for moderate facial AE in children.

Dr. Tom Poyner, Vice Chair of the Primary Care Dermatology Society, said: "This is good news for general practitioners who can now continue to prescribe Elidel for some patients with atopic eczema. Some patients and parents, as well as healthcare professionals, experience problems and have concerns when using topical steroids on the face. This decision now allows GPs to continue to offer Elidel as an effective alternative to steroid treatment."

Margaret Cox, Chief Executive of the National Eczema Society, said: "Eczema can be an extremely distressing condition for children and parents, especially if it appears on the face. Patients go through real physical and emotional problems that can interfere with schooling and study, and impairs family and social relationships. The final NICE decision means that many patients and clinicians will now have access to another effective treatment for atopic eczema on the NHS."

The decision on Elidel should be issued by NICE to the NHS in England and Wales within the next 10 weeks. This decision will then form the guidance for clinical practice within the NHS. Full details of the Final Appraisal Determination can be found on the NICE website at <http://www.nice.org.uk>.

**About Elidel**

Elidel, developed by Novartis, is the only steroid-free prescription cream and is currently available in more than 80 countries. It is licensed for the short-term and intermittent long-term treatment of mild to moderate atopic eczema, to prevent the progression of flare-ups in both children and adults. Clinical studies have shown that Elidel does not cause skin atrophy, sometimes seen with long-term topical corticosteroid use.

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Elidel may be used on all skin surfaces, including delicate areas such as the face, neck and skin folds, with no limits on duration or volume of use. The active ingredient is pimecrolimus, which is derived from ascomycin, a natural substance produced by the fungus *Streptomyces hygroscopicus var. ascomyceticus*. Pimecrolimus selectively blocks the production and release of cytokines from T-cells. These cytokines in the skin cause the inflammation, redness and itching associated with eczema.

#### **About Atopic Eczema**

Atopic eczema (also known as atopic dermatitis) is a chronic, persistent disease in which the skin is typically dry, rough and scaly. Patients suffer from intermittent "flare-ups" in which the skin becomes red, swollen and itchy, creating an uncontrollable urge to scratch and resulting in broken, oozing and bleeding skin.

The prevalence of eczema has increased steadily in the last 30 years, possibly because of environmental and lifestyle changes. Between 10 and 20% of children will have the disease at some time in their lives, while 1-3% of adults are affected.

This release contains certain "forward-looking statements", relating to the Group's business, which can be identified by the use of forward-looking terminology such as "will continue to benefit", "will now have access", "should be used", "continue to offer", "should be issued", "will . . . form", "may be used", or similar expressions, or express or implied discussions regarding potential future sales of Elidel. Such statements reflect the current views of the Group with respect to future events and are subject to certain risks, uncertainties and assumptions. There can be no guarantee that Elidel will reach any particular sales levels. In particular, management's expectations could be affected by, among other things, 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 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.

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

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**Investor Relations Release**

**SANDOZ INC. LAUNCHES AB-RATED LEVOTHYROXINE  
Generic Treatment for Hypothyroidism Provides Lower Cost Alternative for Patients**

*PRINCETON, NEW JERSEY, June 23, 2004* Sandoz Inc., a Novartis company and one of the leading generic pharmaceutical companies in the world, announced today it began commercially shipping its version of generic Levothyroxine Sodium tablets. On June 23, 2004, the United States Food and Drug Association (FDA) approved the Sandoz Levothyroxine Sodium tablets as AB-rated (bioequivalent) to both Synthroid® and Levoxyl®. The Sandoz product is now shipping to all classes of trade, including retail chain drugstores, wholesalers and distributors, and managed care customers.

Levothyroxine is indicated for the treatment of hypothyroidism. The Sandoz tablets are manufactured in all 12 dosage strengths: 25, 50, 75, 88, 100, 112, 125, 137, 150, 175, 200 and 300 mcg. Sandoz becomes the first generic pharmaceutical company to launch AB-rated versions of Synthroid® and Levoxyl® with an approval for all dosage strengths.

John Sedor, President and CEO of Sandoz North America, stated, "We are extremely pleased to launch our version of Levothyroxine Sodium tablets. This product is fully substitutable for Synthroid® and Levoxyl®. Patients deserve a lower cost alternative in their treatment for hypothyroidism. Sandoz is pleased to provide this high quality, fully bioequivalent product. Additionally, our product maintains 25-months of expiration dating. This longer expiration dating is excellent news for our customers and patients as it ensures greater product availability when needed."

Sandoz Levothyroxine Sodium tablets were developed through a partnership between Sandoz Inc. and MOVA Pharmaceutical Corporation, who will manufacture this product for Sandoz.

Sales of Synthroid® for 2003 were USD 818M and sales of Levoxyl® for 2003 were USD 256M, according to IMS data.

The thyroid gland regulates metabolism and organ function. Hypothyroidism is a condition whereby the thyroid gland fails to produce enough thyroid hormone. According to the American Association of Clinical Endocrinologists, an estimated 13 million Americans have thyroid disorders, with more than half undiagnosed. Those most likely afflicted with a thyroid condition are women and the elderly. Treatment replaces the deficient thyroid hormone.

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. In the U.S., Sandoz Inc., is one of the largest prescription generic pharmaceutical companies. The company produces more than 200 products each year. Sandoz products range across many therapeutic drug categories including anti-infectives, anti-arthritis, cardiovasculars, gastrointestinal agents and psychotherapeutics. More information about Sandoz U.S. operations can be found at <http://www.us.sandoz.com>.

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*This release contains certain "forward-looking statements" relating to the Group's business, which can be identified by the use of forward-looking terminology such as "shipping to all classes of trade", or similar expressions, or by express or implied discussions regarding potential availability of Levothyroxine, or potential revenues for sales of Levothyroxine. Such statements reflect the current plans or views of the Group with respect to future events and are subject to certain risks, uncertainties and assumptions. There can be no guarantee of the future availability of Levothyroxine, or that that Sandoz or the Novartis Group will attain any particular level of revenue from Levothyroxine. In particular, management's expectations could be affected by, among other things, potential litigation with manufacturers of branded versions of Levothyroxine, uncertainties regarding production, regulatory actions or delays or government regulation generally, pricing pressures, competition in general, and other risks referred to in Novartis AG's Form 20-F on file with the U.S. Securities and Exchange Commission. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those described herein as anticipated, believed, estimated or expected.*

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Synthroid® is a registered trademark of Abbot Laboratories, and Levoxyl® is a registered trademark of King Pharmaceuticals.

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**Investor Relations Release**

**The VALUE trial complements the long-term cardioprotective profile of Diovan**

Paris, 14 June, 2004 Novartis announced today at the European Society of Hypertension meeting and simultaneously published online in *The Lancet*, the results of VALUE (Valsartan Antihypertensive Long-term Use Evaluation Trial) a prospective, double-blind, randomised, active-controlled study conducted at 934 clinical sites in 31 countries. VALUE was a study of a Diovan® (valsartan)-based regimen vs. an amlodipine-based regimen in 15,245 high blood pressure patients at risk for cardiovascular complications because of co-existing diseases or risk factors such as diabetes, history of stroke, and coronary artery disease. The trial was designed to test, for the same level of blood pressure control, whether a Diovan-based treatment regimen would be more effective than an amlodipine-based treatment regimen in reducing cardiac mortality and morbidity in these high risk patients.

The VALUE trial complements the long-term cardioprotective profile of Diovan and suggests potential new benefits in lowering the incidence of new onset diabetes with Diovan in hypertensive patients at high cardiovascular risk. The study highlights the need for both aggressive blood pressure lowering as well as cardiac and metabolic protective regimens in this patient population. There was no difference with respect to the incidence of the primary endpoint of cardiac mortality and morbidity between the two treatment groups (10.6% [n=810] for the Diovan regimen vs. 10.4% [n=789] for the amlodipine regimen; p=0.49), no statistically significant difference between the Diovan and amlodipine treatment groups in death from heart attack (0.86% [n=66] vs. 0.84% [n=64] respectively; p=0.81) and no statistically significant difference between the Diovan and amlodipine treatment groups in all-cause death (11.0% [n=841] vs. 10.8%, [n=818]; p=0.45). The two treatment regimens effectively lowered blood pressure. Despite unintended blood pressure differences especially early in the trial in favour of amlodipine-based regimen, there was no statistically significant difference in the primary composite cardiac morbidity and mortality endpoint. However, these unintended differences make interpretation of the secondary endpoints difficult.

The Diovan-based regimen was associated with a reduction in new onset of diabetes by 23% vs. the amlodipine-based regimen (13.1% [n=690] vs. 16.4% [n=845]; p<0.001). "Since hypertension regimens studied in previous trials may increase the risk of diabetes and as amlodipine is known to be neutral on glucose metabolism, this finding in VALUE is especially significant at a time when the prevalence of the condition continues to increase throughout the developed world," said Stevo Julius, MS, ScD, VALUE lead investigator and Professor, Internal Medicine and Physiology, Frederick G.L. Huetwell Professor of Hypertension, University of Michigan, Ann Arbor.

In VALUE, the rate of hospitalisation for congestive heart failure was 4.6% [n=354] with the Diovan-based regimen vs. 5.3% [n=400] with the amlodipine-based regimen (p=0.12, not significant). The rate of stroke was 4.2% [n=322] vs. 3.7% [n=281] with the Diovan and amlodipine-based regimen respectively (p=0.08, not significant). The rate of heart attack was 4.8% [n=369] with the Diovan-based regimen vs. 4.1% [n=313] for the amlodipine-based regimen (p=0.02). Both treatment regimens were well tolerated though more patients discontinued the amlodipine-based regimen due to side effects (14.5%) than they did in the Diovan group (13.4%; p=0.045, significant).

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While the VALUE trial demonstrated better blood pressure control compared to certain other large-scale studies, 40 percent of patients in this high risk population did not achieve the predefined blood pressure goal (less than 140/90 mm Hg). This highlights the need for earlier and more aggressive dose titrations as well as add-on therapies with proven combination regimens that can get high risk cardiovascular patients to goal and protect them from adverse cardiovascular outcomes.

"VALUE together with Val-HeFT and VALIANT reinforce the clinical benefit of Diovan in treating high cardiovascular risk patients. The additional finding that Diovan may be associated with the reduction in the onset of diabetes in a population at high risk is very exciting. The long-term benefits and clinical implications of this finding are being investigated in the ongoing NAVIGATOR trial which is fully enrolled and expected to report in 2008," said Joerg Reinhardt, Head of Development, Novartis Pharma AG.

#### **About VALUE**

Patients in VALUE were men and women aged 50 or older with high blood pressure and additional cardiovascular risk factors or cardiovascular disease. The mean age of patients was 67.2 years. Co-existing risk factors and diseases for patients at the start of the study included coronary heart disease (45.8% of patients), type 2 diabetes (31.7%), and history of stroke or transient ischaemic attack (19.8%).

The vast majority of VALUE patients (92.3% of the study population) had already been treated with antihypertensive medications prior to the start of the trial. Patients were randomised to once-daily treatment with either Diovan 80 mg or amlodipine 5 mg, with no wash-out period. The blood pressure goal was <140/90 mmHg. In both groups, if additional control was needed, patients were titrated up to Diovan 160 mg (the maximum recommended dose at the time of the study start) or the maximum dose of amlodipine (10 mg), depending on their blood pressure. If still not at goal, hydrochlorothiazide was added first at 12.5 mg, then 25 mg. If still more blood pressure reduction was needed, physicians were free to add other types of antihypertensive drugs, with the exception of calcium channel blockers (CCBs), angiotensin II receptor blockers (ARBs), or angiotensin-converting-enzyme (ACE) inhibitors. Patients with heart failure or certain types of renal disease were allowed to take ACE inhibitors during the course of the study. Provisions were made for faster up-titration of study drugs at the physician's discretion.

Patients in the Diovan-based group were half as likely (15% vs. 33%) to experience the most frequently reported side effect, peripheral oedema. Adverse events reported more frequently in the Diovan-based group vs. the amlodipine-based group respectively included dizziness and headache.

#### **About high blood pressure**

High blood pressure is a public health crisis, affecting one billion people worldwide, or one-sixth of the world population. In spite of available effective treatments, nearly 70% of those with high blood pressure do not have it adequately controlled. Uncontrolled high blood pressure leads to life-threatening health problems such as heart attack, heart failure and other potentially fatal events.

Novartis is focused on improving the care of patients with high blood pressure and heart disease through world-class research and unprecedented public health initiatives. The Diovan clinical trial programme is one of the world's largest in cardiovascular research, involving approximately 50,000 patients including more than 9,500 patients with diabetes. Besides VALUE, recently completed Diovan trials include VALIANT in post-heart attack patients and Val-HeFT in heart failure patients. Ongoing studies include NAVIGATOR in pre-diabetes patients at high risk for cardiovascular disease and Val-MARC, a study of the effects of Diovan on C-reactive protein, an inflammatory marker for heart disease.

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Diovan is the fastest growing branded antihypertensive on the market today and is available in more than 80 countries for the treatment of hypertension. Diovan is also available in 56 countries for use in heart failure. On the basis of the results of VALIANT, Novartis has submitted marketing authorisation applications to regulatory authorities around the world for a new indication for Diovan for use in patients at risk after having survived a heart attack. In addition to powerful double-digit blood pressure reductions and superior tolerability, patient persistency and patient compliance, Diovan has proven cardioprotective benefits beyond lowering blood pressure.

The foregoing release contains forward-looking statements that can be identified by terminology such as "long-term," "suggests," "potential new," "may increase," "may be," "long-term benefits," "implications," "potentially," or similar expressions, or by discussions regarding potential new indications or labelling for Diovan, or regarding the long-term impact of a patient's use of Diovan. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results with Diovan to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Diovan will be approved for any additional indications or labelling in any market. In particular, management's expectations regarding Diovan could be affected by, among other things, additional analysis of Diovan clinical data; new clinical data; unexpected clinical trial results; unexpected regulatory actions or delays or government regulation generally; the company's ability to obtain or maintain patent or other proprietary intellectual property protection; competition in general; 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 materialise, 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 unveils promising new clinical data of key pipeline projects at the Goldman Sachs Healthcare Conference in Laguna Niguel**

*Zelnorm* New European landmark trial confirms long-term safety and demonstrates efficacy as intermittent therapy in patients with Irritable Bowel Syndrome

*LAF237* 52 week data show durability of glucose lowering effect as monotherapy and in combination with metformin

*Enablex* Excellent safety profile confirmed with no QTc prolongation, data submitted to FDA

*Prexige* TARGET study completed, data to be submitted to authorities in Q3

*Zoledronic acid* 15 minute infusion more efficacious than daily oral treatment with current gold standard in Paget's disease

Laguna Niguel, 8 June 2004 Novartis unveiled new data on key developmental projects today at the Goldman Sachs Healthcare Conference in Laguna Niguel. The company, which has gained market share and turned in above-market growth for the past nine quarters, announced clinical trial results for some late-stage pipeline compounds and in-market products.

James Shannon, Global Head of Clinical Development, commented, "We are pleased that our development activities are delivering strong data for key drugs including the European landmark trial data for *Zelnorm*, the durability of efficacy over 52 weeks shown with LAF237 and the safety profile of *Enablex*. We have made excellent progress in the first months of 2004 and our key projects are on track to meet our milestones in the 2004 to 2005 timeframe."

Top line results were revealed of a new landmark trial, involving more than 4 500 patients, which focused on the effect of *Zelnorm* (irritable bowel disease) after four weeks of treatment and again after a further four weeks of treatment in patients whose symptoms recurred. The results were highly statistically significant on both primary variables, overall relief of IBS symptoms and abdominal pain and discomfort. The data again confirmed efficacy, safety and tolerability, allowing for resubmission in the EU in 2004. In addition to this new data, *Zelnorm* for the use in chronic constipation was also discussed at the conference. This data is under review at the FDA, having been filed in October 2003. An FDA Advisory Committee is scheduled for 14 July.

**LAF 237**, an oral DPP4 inhibitor in Phase III, is the first in a highly attractive new class of compounds for type 2 diabetes. Most recent results of three-month and one-year phase II clinical studies showed a statistically and clinically significant sustained dose dependent reduction in HbA1c, both as monotherapy and in combination with metformin. In a Phase II trial (Study 2204), patients who were part of the metformin plus LAF237 treatment arm sustained an HbA1c level that was on average 1.1 percent lower than the group on metformin plus placebo at the end of 52 weeks of treatment. Glucose levels measured after 8-12 hours of fasting and those measured 1-2 hours after eating a meal were also reduced in patients taking metformin plus LAF237 versus continued therapy with metformin alone. The phase III clinical program for LAF237 is ongoing and filing is expected in 2006.

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Further information was provided on two products under regulatory review, *Prexige* and *Enablex*. It was announced that the TARGET trial was completed for *Prexige* (COX II inhibitor for osteoarthritis, rheumatoid arthritis, and pain) and is currently being analyzed. Data from the TARGET trial, as well as data on the use of the medicine for osteoarthritis at a 100mg dose, will be supplied to regulatory authorities in the US and EU. Novartis confirmed that the MRP procedure in the EU is expected to start in the third quarter 2004 with resubmission in the US latest in early 2006. The QTc study on *Enablex* (overactive bladder) conducted in Q1 2004 illustrated the overall highly beneficial safety profile of *Enablex* by demonstrating that there is no increase in QT/QTc intervals underscoring the potential benefit of its M3 selectivity. The data address the question raised in the US approvable letter as part of the FDA's new QTc standards to evaluate anti-cholinergics drugs. Data have been supplied to the FDA in June for the US resubmission.

**Zoledronic Acid** (postmenopausal osteoporosis and Paget's disease) is currently the most advanced of several new Novartis drugs for osteoporosis. Data show that one 15-minute infusion of the intravenous bisphosphonate zoledronic acid more rapidly reduced the biochemical markers of bone turnover in patients with Paget's and also produced greater sustained efficacy at six months than was seen with the oral treatment risedronate (95% vs. 75% response rate respectively). This data was generated as part of the Zoledronic Acid HORIZON Clinical Development Program with approximately 10,000 patients worldwide, in more than 200 trial centers on four continents, one of the most comprehensive drug evaluation programs ever undertaken in the area of metabolic bone diseases. The Paget's file has been submitted to the CHMP in Europe in April and will be submitted to the FDA in Q4 2004.

The extensive mega-trial program for *Diovan*, the number one ARB worldwide and the fastest growing top antihypertensive, was also discussed. This program is designed to document the medicine's efficacy, tolerability, cardio-protection and enhanced compliance. The next clinical results from the VALUE trial, evaluating morbidity and mortality in high risk patients with at least one additional risk factor for cardiovascular events, will be released at the European Society of Hypertension conference in June. Novartis recently launched a broad cardiovascular category management program, the most aggressive and comprehensive program ever introduced to educate and motivate patients to treat their elevated blood pressure, with more than 50,000 patients already enrolled.

Further outstanding new data from the MA-17 trial with *Femara* also were presented. They showed that *Femara* is the first hormonal therapy to significantly reduce distant metastases, or spreading of the cancer to other parts of the body, by 40% in postmenopausal women with early breast cancer in the extended adjuvant setting. *Femara* also reduced recurrence by 42% irrespective of nodal status and overall mortality by 39% vs. placebo in postmenopausal women with early breast cancer that had already spread to the lymph nodes by the time of diagnosis (called node-positive breast cancer). These data were the basis for global filings for the use of *Femara* in the extended adjuvant treatment of breast cancer in April 2004. Data from the BIG 198 trial in early adjuvant use of *Femara* vs. tamoxifen will become available in late 2004.

Novartis continues to excel in its development activities and was recently ranked number one by Center Watch in its relationships with European investigators. A total of 79 development projects fill the pipeline, of which 61 are in Phases II and III or in registration. They include 17 projects in cancer and 11 in cardiovascular medicine, two of Novartis' key growth areas. The number of projects in clinical development grew 44% between 2000 and 2003, with a significant increase in the mid- to late-stage clinical pipeline. Novartis led the industry over the past four years with 12 novel compounds that won approval in the US, confirming that Novartis is an industry leader in innovation. In addition, over the past three years, Novartis has succeeded in reducing the average development time by approximately 25%.

Based on the strength of the in-market product portfolio with limited patent exposure and the strong R&D pipeline, Novartis is on track to deliver above-market growth.

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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 "to be submitted," "potential," "may," "will be," or similar expressions, or by express or implied discussions regarding potential future sales of existing products, potential new products or potential new indications for existing products, or by other discussions of strategy, plans or intentions. Such statements reflect the current views of the Company with respect to future events and are subject to certain risks, uncertainties and assumptions. Many factors could cause the actual results to be materially different from any future results, performances or achievements that may be expressed or implied by such forward-looking statements. There can be no guarantee that existing products will reach any particular sales levels, or that any new products will be approved for sale in any market, or that any new indications will be approved for existing products in any market. In particular, management's expectations could be affected by, among other things, uncertainties relating to product development and clinical trials, regulatory actions or delays or government regulation generally, the ability to obtain or maintain patent or other proprietary intellectual property protection and competition in general, as well as factors discussed in the Company's Form 20-F filed with the Securities and Exchange Commission. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those described herein as anticipated, believed, estimated or expected. The Company is providing this information as of this date and does not undertake any obligation to update any forward-looking statements contained in this document as a result of new information, future events or otherwise.

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**Investor Relations Release**

**Femara® Is First Hormonal Therapy To Significantly Reduce Spread Of Early Breast Cancer To Other Parts Of The Body After Standard Tamoxifen Treatment In Postmenopausal Women**

*Landmark MA-17 trial demonstrated significant 40% reduction in the risk of distant breast cancer recurrence post-tamoxifen (extended adjuvant)*

*Femara also reduced mortality by 39% vs. placebo in postmenopausal women with early breast cancer that had spread to the lymph nodes at the time of diagnosis*

Basel, 8 June 2004 - New data from the landmark MA-17 study demonstrated a significant 40% reduction in the rate of distant breast cancer recurrences, or *metastases*, with extended adjuvant (post-tamoxifen) Femara® (letrozole) in postmenopausal women with early breast cancer. These data were presented today during the "Best of Oncology" session at the annual meeting of the American Society of Clinical Oncology (ASCO) in New Orleans. Distant metastases are a well-established risk factor for breast cancer death.

At the median 2.5 year follow-up, a survival advantage has now become apparent in those women whose cancer had already spread to lymph nodes at the time of diagnosis (node-positive). In this group of trial participants, which comprised approximately 50% of all patients in MA-17, deaths were reduced by a significant 39% vs. placebo. Patients with node-positive breast cancer are more likely to develop distant metastases and, therefore, may be at greater risk of dying from the disease. These results from the MA-17 trial indicated that Femara is the first hormonal therapy to demonstrate a survival advantage in any population in the extended adjuvant setting. Across the entire study population, survival differences did not reach statistical significance in this analysis.

The term *extended adjuvant* describes the period following standard adjuvant treatment with tamoxifen. Even years after breast cancer diagnosis and primary treatment the ongoing risk of breast cancer recurrence and mortality remains significant for all patients. Extended adjuvant treatment with Femara is the first therapy to effectively address this ongoing risk.

"Overall, the results of MA-17 may provide a new option for postmenopausal women completing standard adjuvant treatment with tamoxifen," said Paul Goss, MD, PhD, director of Breast Cancer Prevention and Research, Princess Margaret Hospital, Toronto, Canada. "Treatment with Femara resulted in a marked reduction in the risk of recurrent breast cancer and the occurrence of new breast cancer. Most importantly, treatment with Femara also reduced distant metastases, which are very often fatal."

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Coordinated by the National Cancer Institute of Canada Clinical Trials Group at Queens University in Kingston, Ontario and supported by Novartis, the MA-17 study evaluated extended adjuvant treatment with Femara vs. placebo in nearly 5,200 postmenopausal women with early breast cancer. The results showed that Femara significantly lowered the risk of metastases overall by 40%. At the median 2.5 year follow-up, overall survival was unchanged in node-negative patients, but reductions in local recurrences, new primary tumors, and distant recurrences were consistent with those seen in node-positive patients. The data also showed that extended adjuvant treatment with Femara reduced mortality by 39% in women with node-positive disease (P=0.035). Across all patients, 18% fewer deaths occurred with Femara, a difference that, at the median 2.5 year follow-up, had not reached statistical significance.

In addition, an improvement in disease-free survival (reduced risk of disease recurrence in the breast, chest wall, lymph nodes or metastatic sites), the primary endpoint of the study, was achieved across all patients in the Femara group. The data showed that taking Femara after standard adjuvant therapy with tamoxifen cut a woman's risk of recurrence nearly in half as compared with placebo (42% reduced risk of recurrence; including metastases, contralateral breast cancer and recurrence within or near the original site; P=0.00003).

#### **Safety Data**

The MA-17 study also included pre-planned sub-studies that assessed the effect of Femara on bone mineral density and lipid metabolism. There was no significant difference between treatment groups in bone fractures. The authors noted more newly diagnosed cases of osteoporosis in women taking Femara vs. placebo (6.9% vs. 5.5%; P=0.04). The rate of clinical fractures, however, was not statistically higher for Femara than for placebo (5.9% vs. 5.5%).

Neither the core MA-17 protocol nor the lipid sub-study showed significant differences between the Femara and placebo groups in terms of cardiovascular events or lipid profiles. While the HDL:LDL cholesterol ratio decreased after the first six months of therapy, the decrease was similar in both groups.

#### **Study Design**

MA-17 is a Phase III, international, double-blind, randomized, multi-center trial. Last fall, data from an interim checkpoint from the core MA-17 trial prompted an Independent Data Safety Monitoring Committee and the investigators to unblind the study early so patients taking placebo could be offered the opportunity to switch to Femara, regardless of their treatment-free interval since completion of tamoxifen therapy. All patients are still being followed under an amended protocol. The interim results from MA-17 received an expedited review from the *New England Journal of Medicine* and were published in the online edition in October 2003.

#### **About Femara**

Femara, an aromatase inhibitor, is an oral once-a-day first-line treatment for postmenopausal women with hormone receptor positive or hormone receptor unknown locally advanced or metastatic breast cancer. It is also approved for the treatment of advanced breast cancer in postmenopausal women with disease progression following antiestrogen therapy, and as neo-adjuvant (pre-operative) therapy. Femara is currently available in more than 80 countries worldwide. Not all indications are available in every country. Global filings for use of Femara in the extended adjuvant setting were submitted in April 2004.

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### **Femara Contraindications and Adverse Events**

In the interim MA-17 analysis, the most common adverse events were hot flashes, sweating, edema, hypercholesterolemia, headache, arthralgia, myalgia, fatigue, constipation and dizziness, in greater than 10% of patients in either arm of the study. Of these, hot flashes, arthralgia, and myalgia were more common in those receiving Femara than placebo ( $P < 0.05$ ). Vaginal bleeding was more common in those taking placebo ( $P = 0.01$ ).

Femara is contraindicated in patients with known hypersensitivity to Femara or any of its excipients. Femara is generally well tolerated. In a first-line registration trial versus the antiestrogen tamoxifen, the most commonly reported adverse events for Femara were bone pain (22% vs. 21%), hot flashes (19% vs. 16%), back pain (18% vs. 19%), nausea (17% vs. 17%), dyspnea or labored breathing (18% vs. 17%), arthralgia (16% vs. 15%), fatigue (13% vs. 13%), coughing (13% vs. 13%), constipation (10% vs. 11%), chest pain (6% vs. 6%) and headache (8% vs. 6%). Femara may cause fetal harm when administered to pregnant women. There is no clinical experience to date on the use of Femara in combination with other anticancer agents. The incidence of peripheral thromboembolic events, cardiovascular events, and cerebrovascular events was 3-4% in each treatment arm.

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

Additional information regarding Femara or Novartis Oncology can be found at [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).

Pictures as well as specific background information regarding this release can be found at:  
[http://novartis.imagedirector.net/album?album\\_code=tw5sgrgzz0zm](http://novartis.imagedirector.net/album?album_code=tw5sgrgzz0zm).

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**Investor Relations Release**

**Positive results of first phase II study in new class of oral diabetes drugs**

*Long-term improved glycemetic control seen in patients with type II diabetes*

*LAF237 shows promise as mono- and combination therapy*

**Basel, Switzerland, 7 June 2004** Research presented today showed that the investigational drug, LAF237, the first in a new class, improved glycemetic control in patients with type 2 diabetes. In this study LAF237, which is administered as a tablet to be taken orally, was added to the standard diabetes treatment metformin in patients whose diabetes was not adequately controlled by metformin alone. Presented at the annual scientific meeting of the American Diabetes Association, the glucose reduction benefits attributed to the addition of LAF237 in this study were sustained for one year.

"LAF237 works completely differently to all other therapies currently used to treat type 2 diabetes," said Joerg Reinhardt, Head of Development, Novartis Pharma AG. "This research confirms the potential that Novartis has seen in LAF237, and we believe it could offer a whole new strategy for controlling type 2 diabetes at a time when the disease is reaching epidemic proportions worldwide. We are pleased that phase III trials have been initiated for LAF237 to further assess the potential of this novel oral compound."

Exploring new diabetes treatments like LAF237 is critically important, especially given the World Health Organization projections that the number of people with diabetes will double to 366 million by 2030. World Health Organization (WHO). <http://www.who.int/diabetes/en/> Last year alone, more than 3.2 million deaths were attributed to diabetes or diabetes-related causes. WHO. <http://www.who.int/diabetes/actionnow/en/diabetesmessages.pdf> Novartis is leading the way in the development of the new class of oral antidiabetes agents called DPP-4 inhibitors.

Researchers studying LAF237 hope to show that the therapy will help to address the underlying imbalance between insulin and glucose production that is the cause of type 2 diabetes. LAF237 works by increasing levels of a specialised incretin hormone called GLP-1 by blocking the action of DPP-4, an enzyme that normally inactivates GLP-1. GLP-1 is 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.

Based on the strength of these data and other findings from phase II studies, Novartis launched a full phase III clinical trial programme earlier this year. The completed phase II trial presented today was designed to assess the safety and dosing of LAF237 and to make initial efficacy evaluations.

"In this study, HbA1c levels, the primary long-term measure of glycemetic control, decreased significantly when LAF237 was added to a patient's course of therapy, and this benefit was maintained for one year," said Richard Pratley, Professor of Medicine, University of Vermont Medical School. "Bringing patients to an ideal HbA1c level early in the disease process, and maintaining those levels for as long as possible, is critical in type 2 diabetes, making these findings very encouraging."

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Patients who were part of the metformin plus LAF237 treatment arm sustained an HbA1c level that was an average of 1.1 percent lower than the group on metformin plus placebo. 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. The metformin plus LAF237 group maintained lower HbA1c levels for one year. In contrast, researchers saw an increase in HbA1c in the metformin only group during the same period.

LAF was found to be well tolerated with 76.2 and 89.7 percent of patients completing the 52 week investigation in the LAF237 plus metformin arm and metformin plus placebo arms respectively. The metformin plus LAF237 group reported a 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 reported hypoglycemic events in the metformin plus LAF group, none of which was considered serious. No patient discontinued study participation due to hypoglycemia.

Also being presented this week at the ADA meeting are two additional studies from the LAF237 clinical development programme. A 12-week monotherapy trial and a pharmacokinetic/pharmacodynamic interaction study with glyburide.

Diabetes affects about 170 million people worldwide, afflicting increasing numbers of people in both first and developing world countries. WHO. <http://www.who.int/diabetes/en/> According to a recent report issued by the World Health Organization, the number of people with diabetes in Europe is estimated to rise from about 33.3 million in 2000 to more than 48 million in 2030, making new therapies and novel treatment strategies an urgent need. In the year 2000 alone, there were 609,000 deaths in Europe attributable to diabetes. WHO. <http://www.who.int/diabetes/actionnow/en/mapdiabprev.pdf>, WHO. <http://www.who.int/diabetes/actionnow/en/mapdiabdeaths.pdf>

The development of LAF237 is being driven by Novartis' cardiovascular and metabolic drug franchise. A worldwide leader in cardiovascular care and in the treatment of a variety of metabolic disorders, the cardiovascular and metabolic franchise currently markets the diabetes treatment Starlix® (nateglinide) and the hypertensive therapies Diovan® (valsartan) and Co-Diovan® (valsartan and hydrochlorothiazide), the fastest growing hypertensive medication across the globe.

The foregoing release contains forward-looking statements that can be identified by terminology such as "potential," "could offer", "projections", "will double", "hope to show", "will address", "encouraging" or similar expressions, or by express or implied discussions regarding potential approvals to market for LAF237 or potential future sales of 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. Nor can there be any guarantee regarding potential future sales of LAF237. Neither can there be any guarantee regarding the long-term impact of a patient's use of LAF237. In particular, management's expectations regarding commercialization of LAF237 could be affected by, among other things, additional analysis of LAF237 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 materialise, or should underlying assumptions prove incorrect, actual results may vary materially from those anticipated, believed, estimated or expected. Novartis is providing 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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Novartis AG (NYSE: NVS) is a world leader in pharmaceuticals and consumer health. In 2003, the Group's businesses achieved sales of USD 24.9 billion and a net income of USD 5.0 billion. The Group invested approximately USD 3.8 billion in R&D. Headquartered in Basel, Switzerland, Novartis Group companies employ about 78 500 people and operate in over 140 countries around the world.

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

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### Notes for Journalists

Type 2 diabetes is a condition characterised by blood glucose levels that are too high. In people with type 2 diabetes, the body does not produce enough insulin and/or the cells do not respond properly to insulin. In the long term, high blood glucose levels increase the risk of heart disease and stroke and can damage the eyes, kidneys and nerves in particular.

HbA1c (glycated haemoglobin) is a measure of blood glucose control over the previous two or three months. A lower HbA1c indicates better blood glucose control.

Pharmacokinetic changes are changes in the way a drug is absorbed, distributed, metabolised, or eliminated by the body.

Hypoglycaemia (a "hypo") occurs when the level of glucose in the blood falls too low. This may cause shaking, sweating, confusion and irritability.

The prevalence of diabetes in countries in the World Health Organization's European region in 2000 and the predicted prevalence in 2030 can be found on the WHO website at: [http://www.who.int/diabetes/facts/world\\_figures/en/index4.html](http://www.who.int/diabetes/facts/world_figures/en/index4.html)

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**Investor Relations Release**

**Sandoz makes major entry into generic injectables field with acquisition of fast-growing Sabex Holdings Ltd. of Canada**

*Acquisition establishes new Sandoz presence in Canada and attractive global growth platform in injectable generics*

*Transaction continues Sandoz strategy based on strong organic growth and strategic acquisitions to access new geographic markets, therapeutic lines, formulations and production capabilities*

Vienna, June 7, 2004 Sandoz, a Novartis company, today announced plans to acquire Sabex Holdings Ltd. in a USD 565 million cash transaction that will provide strong growth opportunities in injectable generics and new entry into the Canadian generics sector. The deal continues Sandoz strategy of building its global business through strong organic growth and strategic acquisitions that provide access to new geographic markets, therapeutic lines, formulations and production capabilities.

Headquartered in Boucherville, Quebec, Sabex is a privately held generics manufacturer with the leading position in generic injectables in Canada and the number six position in the Canadian generics sector overall. Sustaining recent growth rates in the high teens, the company achieved sales of nearly USD 90 million in fiscal 2003-2004. Sabex offers FDA manufacturing status and a broad range of critical care and ophthalmic medicines as well as suppositories and other products covering more than 80 molecules. Sabex is a portfolio company of RoundTable Healthcare Partners, which holds a majority of shares.

"The acquisition of Sabex provides Sandoz with a leadership position in injectable generics in Canada and a platform to build a generic injectables business globally, particularly in the rapidly growing U.S. market," said Christian Seiwald, CEO of Sandoz. "The deal also gives Sandoz a new operational presence in Canada, the sixth largest market for generics in the world, where we see exciting opportunities to increase sales of our existing portfolio of solid dosage forms."

Between 2003 and 2010, peak sales of US branded injectable medicines losing patent protection is estimated at USD 14 billion compared with 2002 sales of more than USD 7 billion. Sales are highly concentrated in the top 20 brands, which make up 80% of the total branded sales going off patent.

Sabex brings Sandoz a seasoned management team with an average of more than 20 years experience in the pharmaceutical business and a highly successful track record of developing and launching generic products. With eight product approvals in fiscal 2003-2004 and 50 products under development, Sabex has a strong track record for new launches and a complementary pipeline with Sandoz compounds. In addition to the top ranked generic sales force in Canada, the acquisition brings Sandoz new capabilities in the development and production of small volume parenterals and finished dose formulations for injectables.

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

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

This release contains certain "forward-looking statements" relating to the Group's business, which can be identified by the use of forward-looking terminology such as "will provide", "estimated," "see exciting opportunities to...", "brings Sandoz new capabilities" or similar expressions, or by express or implied discussions regarding strategies, plans and expectations. Such statements reflect the current plans or views of the Group with respect to future events and are subject to certain risks, uncertainties and assumptions. Management's expectations could be affected by, among other things, competition in general, and other risks referred to in Novartis AG's Form 20-F on file with the US Securities and Exchange Commission. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those described herein as anticipated, believed, estimated or expected.

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