

NOVARTIS AG  
Form 6-K  
March 03, 2004

[QuickLinks](#) -- Click here to rapidly navigate through this document

---

---

# 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 February 2004  
(Commission File No. 1-15024)

---

## Novartis AG

(Name of Registrant)

Lichtstrasse 35  
4056 Basel  
Switzerland

(Address of Principal Executive Offices)

---

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

Form 20-F:  Form 40-F:

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

Yes:  No:

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

Yes:  No:

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

Yes:  No:

Enclosures:

1. Novartis, Genentech and Tanox settle disputes surrounding Xolair and TNX-901 (Basel, 26 February 2003)
2. Novartis' shareholders approve new share repurchase program and dividend increase (Basel, 24 February 2004)

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

3. Novartis completes strategic acquisition to strengthen number two position in global medical nutrition business (Basel, 17 February 2004)
  4. New European study shows Zelmac\* significantly improves IBS symptoms (Basel, 13 February 2004)
  5. Novartis launches Spanish version of its global website (Basel, 11 February 2004)
  6. Novartis successfully completes European Mutual Recognition Procedure for Myfortic® its new immunosuppressant (Basel, 10 February 2004)
  7. Susan Gasser to head Friedrich Miescher Institute (Basel, 5 February 2004)
  8. Sandoz powers up new cell-culture production units to manufacture biopharmaceuticals (Kundl (Austria), 4 February 2004)
- 
- 
- 

**Novartis International AG**  
Novartis Communications  
CH-4002 Basel  
Switzerland  
Tel +41 61 324 2200  
Fax+ 41 61 324 3300  
Internet Address:  
<http://www.novartis.com>

### **MEDIA RELEASE    COMMUNIQUE AUX MEDIAS    MEDIENMITTEILUNG**

#### **Novartis, Genentech and Tanox settle disputes surrounding Xolair and TNX-901**

Basel, 26 February 2003 Novartis Pharma AG, Genentech, Inc. (NYSE: DNA) and Tanox, Inc. (Nasdaq: TNOX) announced today that they have settled all litigation among them and finalized the detailed terms of their three-party collaboration, begun in 1996, to develop and commercialize certain anti-IgE antibodies including Xolair® (omalizumab) and TNX-901.

The following details of the settlement were disclosed: Genentech and Novartis will each reimburse Tanox US\$3.3 million for a portion of its TNX-901 development costs. Tanox will relinquish any rights to manufacture Xolair and, in exchange, will receive payments tied to the quantity of Xolair produced. In addition, Tanox will benefit from an accelerated forgiveness of a loan to finance the construction of its biologics manufacturing plant in the mid-1990s.

As in the original agreement, Genentech and Novartis share U.S. marketing rights for all collaboration products, while Novartis has marketing rights outside the U.S. The existing royalty- and profit-sharing percentage will remain unchanged. Committees with representatives from all three companies have been established to co-operatively oversee further development and commercialization of Xolair, and possibly other collaboration products.

#### **Peanut allergy**

The partners are committed to developing Xolair as the lead molecule for the treatment of peanut allergy. An Investigational New Drug (IND) application for Xolair in this indication was filed with the U.S. Food and Drug Administration (FDA) in November 2003. Patient enrollment in a Phase II proof of concept clinical trial is expected to begin early this year.

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", "are committed to developing", "is expected", or similar expressions, or 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 Group with respect to future events and are subject to certain risks, uncertainties and assumptions. 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, new clinical data; unexpected clinical trial results; unexpected regulatory actions or delays or government regulation generally; the company's ability to obtain or maintain patent or other proprietary intellectual property protection; competition in general; and other risks and factors referred to in the Company's current Form 20-F on file with the US Securities and Exchange Commission. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those 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>.

# # #

3

**Novartis International AG**  
Novartis Communications  
CH-4002 Basel  
Switzerland  
Tel +41 61 324 2200  
Fax+ 41 61 324 3300  
Internet Address:  
<http://www.novartis.com>

**MEDIA RELEASE    COMMUNIQUE AUX MEDIAS    MEDIENMITTEILUNG****Novartis' shareholders approve new share repurchase program and dividend increase**

*Driven by record results in 2003, annual dividend reaches CHF 1.00 per share(+5%), increasing for the 7<sup>th</sup> year in a row*

*New share buyback program for up to 3 billion CHF approved*

*Continued dynamic business growth and new record income level expected for 2004*

Basel, 24 February 2004 At the Annual General Meeting held in Basel today, 2,714 shareholders, representing 933,365,449 votes or 33.32% of the 2,801,470,000 shares issued, approved all proposals of the Board of Directors, including a 5% rise in the dividend to CHF 1.00 per share. The increase marked the seventh year, since the merger, that the dividend has climbed. The company's consistent strategic focus drove record results in 2003, with performance outpacing the market, and all business units gaining market share.

**Chairman's address**

In his address, Dr. Vasella attributed the company's strong 2003 performance to the success of its core pharmaceuticals business, which showed particularly dynamic growth in the key oncology and cardiovascular franchises, with cancer medicines Glivec, Femara, Zometa, and the blood pressure medication Diovan delivering especially impressive results. The company's commitment to innovation is evident in the full pipeline of 79 projects, of which 64 are in Phase II or III. Dr. Vasella highlighted the company's unique position of providing both innovative

medicines and high quality generics in an environment where costs are spiraling due to an aging population.

"Novartis seeks to offer patients, physicians and health insurers the best possible range of medicines a combination of innovative medicines and high-quality, cost effective generics," Dr. Vasella said. "Our commitment to continuously innovate will improve medical therapies, as novel drugs meet patients needs. By providing doctors with a range of treatment options, we make a unique contribution to improving patients' health and controlling costs."

Dr. Vasella thanked Novartis associates for their commitment, which is the foundation for the company's good results. The positive culture and working environment was recognized by *Fortune* magazine as Novartis was just named one of "10 Great Companies to Work for in Europe."

Dr. Vasella emphasized the priority placed on transparency and good corporate governance. In 2003, the company implemented the new regulations of Sarbanes-Oxley Section 302, and this year will implement Section 404.

In terms of outlook, Dr. Vasella concluded. "Overall, we expect to see further dynamic growth in the high single-digit region, additional gains in market share, and a new record level of income, barring any unforeseen events."

4

---

#### **Further share repurchase program approved**

The new CHF 3 billion share buyback program continues a strategy of returning surplus liquidity to shareholders by using up to half of free cash flow to repurchase company stock and reduce share capital. Novartis completed buyback programs of CHF 4 billion each in 1999 and 2001.

#### **Board elections and terms of office**

Shareholders also amended the Articles of Incorporation to allow a director who has reached the statutory age of retirement or completed twelve years in office to be re-elected for more than one further three-year term.

Directors Hans-Jörg Rudloff, Professor Dr. Helmut Sihler and Dr. Daniel Vasella were re-elected for three-year terms. Professor Sihler, who stood for re-election at the board's request, has announced his intention to retire from the board after two years.

Two new directors were added in 2003, Professor Srikant Datar and Dr. Wendelin Wiedeking. With the retirement of directors Walter G. Frehner and Heini Lippuner, the board now comprises twelve members.

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 "expected", "will", "intention", "expect" or similar expressions, or by 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, 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. 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; 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.

#### **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>.

5

**Investor Relations**

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

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

**Investor Relations Release**

**Novartis completes strategic acquisition to strengthen number two position in global medical nutrition business**

*New presence in US retail medical nutrition channel, access to Japanese market and strong brand portfolio benefit Novartis Medical Nutrition*

Basel, Switzerland, February 17, 2004 Novartis has completed the acquisition of Mead Johnson & Company's global adult medical nutrition business in a USD 385 million cash transaction. No divestments were required to obtain regulatory approval of the deal, which officially closed February 13, 2004.

The acquisition adds strong brands like Boost®, Isocal® and Ultracal® to Novartis Medical Nutrition's portfolio and expands its ability to meet the medical nutritional needs of a growing outpatient and ageing population.

Novartis Medical Nutrition now enjoys a strong presence in the fast-growing US retail channel for medical nutrition products, a platform in the Japanese market and increased opportunities to build its existing institutional medical nutrition business.

Announced on December 16, 2003, the acquisition includes the brands, trademarks, patents and intellectual property assets of Mead Johnson & Company's adult medical nutrition business.

Novartis Medical Nutrition, with global sales of USD 815 million in 2003 (including Nutrition & Santé), offers a complete range of enteral (tube feeding) and oral nutrition products and devices tailored to the varying needs of patients and healthcare professionals. The product range encompasses supplements, which are taken orally, as well as other products administered through tube feeds and specific medical devices. Its key brands include Isosource®, Novasource®, Resource®, Impact® and Compat®.

**Disclaimer**

This release contains certain "forward-looking statements," relating to the Company's business, which can be identified by the use of forward-looking terminology such as "increased opportunities," or similar expressions, or by express or implied discussions regarding the potential development and commercialization of new products or regarding potential future sales from any such products. 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 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 can 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, increased government pricing pressures, and competition in general, as well as factors discussed in the Company's Form 20-F filed with the US Securities and Exchange Commission. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those described herein as anticipated, believed, estimated or expected. Novartis is providing the information in this press release as of this date and does not undertake any obligation to update any forward-looking statements contained in this press release as a result of new information, future events or otherwise.

**About Novartis**

Novartis AG (NYSE: NVS) is a world leader in pharmaceuticals and consumer health. In 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>.

###

**Novartis Global Investor Relations**

**Karen J. Huebscher, Ph.D.** +41 61 324 84 33  
[karen.huebscher@group.novartis.com](mailto:karen.huebscher@group.novartis.com)

**International office**

Nafida Bendali +41 61 324 35 14  
[nafida.bendali@group.novartis.com](mailto:nafida.bendali@group.novartis.com)

Katharina Furrer +41 61 324 53 16  
[katharina.furrer@group.novartis.com](mailto:katharina.furrer@group.novartis.com)

Silke Zentner +41 61 324 86 12  
[silke.zentner@group.novartis.com](mailto:silke.zentner@group.novartis.com)

e-mail: [investor.relations@group.novartis.com](mailto:investor.relations@group.novartis.com)

Fax: +41 61 324 84 44  
[www.novartis.com](http://www.novartis.com)

**North American office**

John Menditto +1 212 830 24 44  
[john.menditto@group.novartis.com](mailto:john.menditto@group.novartis.com)

Sabine Moravi +1 212 830 24 56  
[sabine.moravi@group.novartis.com](mailto:sabine.moravi@group.novartis.com)

Jill Pozarek +1 212 830 24 45  
[jill.pozarek@group.novartis.com](mailto:jill.pozarek@group.novartis.com)

e-mail: [investor.relations@gruoup.novartis.com](mailto:investor.relations@gruoup.novartis.com)

Fax: +1 212 830 24 05  
[www.novartis.com](http://www.novartis.com)

7

---

**Investor Relations**

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

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

**Investor Relations Release**

**New European study shows Zelmac\* significantly improves IBS symptoms**

*Results from first, large, multinational study in Nordic countries published*

Basel, 13 February 2004 Zelmac® (tegaserod), a new treatment for irritable bowel syndrome (IBS) provides patients satisfying overall relief of symptoms, including abdominal pain and discomfort, bloating and constipation, according to a new study just published in the *Scandinavian Journal of Gastroenterology*.

More than 600 IBS patients in five Nordic countries (Denmark, Finland, Iceland, Norway and Sweden) participated in TENOR (Tegaserod Nordic Trial), comparing Zelmac to placebo.<sup>1</sup> The results highlight Zelmac's ability to significantly improve patients' overall symptoms and to provide reliable overall relief of specific IBS symptoms throughout the entire study period.<sup>1</sup> The study findings show that patients using Zelmac were 78% more likely to experience satisfactory relief of their symptoms over a period of 12 weeks than patients taking placebo (P<0.0001).<sup>1</sup>

"Sustained relief and even improvement of symptoms over time is very important to our IBS patients," said associate professor Henry Nyhlin, head of the Centre of Gastrointestinal Disease at Ersta Hospital in Stockholm, Sweden and the study's primary investigator. "IBS is a chronic disease with symptoms that are impacting patients' lives more than has been appreciated. Tegaserod is the first pharmacological treatment that is effective, safe and well-tolerated."

Treatment with Zelmac provided statistically significant, and to the patient, satisfying overall relief of IBS symptoms during the first month of treatment as well as over the full three-month treatment period compared with placebo (p=0.0049, p<0.0001, respectively).<sup>1</sup> The study authors also note that the Zelmac response rates in TENOR fall within the guidelines recommended by the European Committee for Proprietary Medicinal Products (CPMP) for IBS studies. According to the guidelines, a positive response to IBS treatment is achieved when a pre-specified improvement of a patient's symptoms is noted at least 50% of the time of the study period.<sup>2</sup> In TENOR, significantly more Zelmac-treated patients reported overall satisfactory-relief 50% of the time during the first month of the study than placebo, as well as the full study treatment period (12 weeks). For the full three month treatment period there were more Zelmac patients reporting satisfactory relief 75% of the time during the study than those taking placebo (weeks 1-12, p=0.0216).<sup>1,2</sup>

TENOR was a double-blind, placebo-controlled, randomized study of 18 weeks with 647 male and female IBS patients, without diarrhea, at 86 centres across the Nordic region receiving Zelmac 6 mg b.i.d (n=327) or placebo (n=320).<sup>1</sup> The trial featured a two-week baseline period without treatment, followed by a 12-week treatment period, and then a 4-week withdrawal period with no active treatment.<sup>1</sup> The primary efficacy endpoint was the patients' response (Yes/No) over the first four weeks of the double-blind treatment period to the following question: "Over the past week, do you consider that you have had satisfactory relief from your symptoms of IBS?" A secondary efficacy variable was the patients' weekly overall assessment of relief from IBS symptoms over the entire 12-week period.<sup>1</sup>

8

---

The safety and tolerability data also collected during the study shows the adverse event (AE) profile of Zelmac/Zelnorm-treated patients was similar to that of the placebo-treated patients and raised no issues of clinical concern. The most frequently reported AEs in the study were headache (8% tegaserod, 4.7% placebo) and diarrhea (9.2% tegaserod, 1.2% placebo).<sup>1</sup>

### **About Irritable Bowel Syndrome (IBS)**

IBS is characterized by abdominal pain/discomfort, bloating, and altered bowel function (constipation and/or diarrhea).<sup>3,4,5</sup> Until recently, the cause of IBS has been poorly understood and under-appreciated. However, in recent years, new research has yielded a better understanding of IBS and its causes. People who have abdominal pain/discomfort, bloating and constipation associated with IBS may have impaired gut motility, increased colonic water absorption, and altered sensitivity of their GI tract.<sup>6,7</sup> This may be due to the way their lower GI tract reacts to changes in 5HT (serotonin), a naturally occurring substance in their body that regulates motility and perception of pain and discomfort in the intestinal system.<sup>8,9,10</sup>

### **About Zelmac/Zelnorm**

Zelmac/Zelnorm was discovered and developed by Novartis. Zelmac, known in the United States, Canada, Philippines and South Africa as Zelnorm, is approved for the treatment of IBS in more than 55 countries including Australia, Switzerland, Canada, the United States, Mexico, China and Brazil.

Zelmac/Zelnorm is a breakthrough therapy in a new class of medicines, known as 5HT<sub>4</sub> agonists. By activating 5HT<sub>4</sub> receptors in the gastrointestinal tract, Zelmac/Zelnorm normalizes impaired intestinal motility, enhances mucosal secretion, and reduces sensitivity of the intestinal tract.<sup>12,13,14</sup> Clinical studies showed that significantly more patients experienced a general relief of symptoms when treated with Zelmac/Zelnorm such as a decrease in abdominal pain, bloating and constipation.<sup>15,16,17,18,19</sup> In most patients who responded to Zelmac/Zelnorm, the onset of relief occurred within just one week.<sup>15,16,18</sup> The medicine was well tolerated and showed a side effect profile similar to that of placebo.<sup>15,18,20</sup> Zelmac/Zelnorm is being studied as a potential treatment for other important gastrointestinal disorders, such as gastroesophageal reflux disease (GERD) and dyspepsia. For more information about IBS please visit <http://www.IBSMediacentre.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 "significantly improves", "satisfying overall relief", "reliable", "effective, safe, and well-tolerated", "potential treatment", or similar expressions, or express or implied discussions regarding potential future approvals or revenue from Zelmac. 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 Zelmac will be approved for sale in any new markets or 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; increased government pricing pressures and competition in general; and other risks and factors referred to in the Company's current Form 20-F on file with the US Securities and Exchange Commission. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those 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.

---

## 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>.<sup>21</sup>

###

## References

- 1 Nyhlin H, Bang C, Elsborg L, Silvennoinen J, Holme I, Ruegg P, Jones J, Wagner A. A double-blind, placebo-controlled, randomized study to evaluate the efficacy, safety and tolerability of tegaserod in patients with irritable bowel syndrome. *Scand J Gastroenterol* 2004;39:(2)
- 2 CPMP/EWP/785/97. Points to consider on the evaluation of medicinal products for the treatment of irritable bowel syndrome. Final version-March 19, 2003
- 3 Hungin AP, Whorwell PJ, Tack J, Mearin F. The prevalence, patterns and impact of irritable bowel syndrome: an international survey of 40 000 subjects. *Aliment Pharmacol Ther* 2003;17(5):643-650
- 4 Mearin F, Balboa A, Badia X, Baro E, Caldwell E, Cucala M, Diaz-Rubio M, Fueyo A, Ponce J, Roset M, Talley NJ. Irritable bowel syndrome subtypes according to bowel habit: revisiting the alternating subtype. *Eur J Gastroenterol Hepatol* 2003;15(2):165-172
- 5 Thompson WG, Longstreth GF, Drossman DA, Heaton KW, Irvine EJ, Müller-Lissner SA. Functional bowel disorders and functional abdominal pain. *Gut* 1999;45(Suppl II):43-47
- 6 Camilleri M, Heading RC, Thompson WG. Consensus report: clinical perspectives, mechanisms, diagnosis and management of irritable bowel syndrome. *Aliment Pharmacol Ther* 2002;16:1407-1430
- 7 Drossman D et al. Irritable bowel syndrome: a technical review for practice guideline development. *Gastroenterology* 1997;112:2120-2137
- 8 Crowell MD. The role of serotonin in the pathophysiology of irritable bowel syndrome. *Am J Manag Care* 2001;7(8 Suppl):S252-260
- 9 Hunt RH, Tougas G. Evolving concepts in functional gastrointestinal disorders: promising directions for novel pharmaceutical treatments. *Best Pract Res Clin Gastroenterol* 2002;16(6):869-883



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

Jin JG, Foxx-Orenstein AE, Grider JR. Propulsion in guinea pig colon induced by 5-hydroxytryptamine (HT) via 5-HT<sub>4</sub> and 5-HT<sub>3</sub> receptors. *J Pharmacol Exp Ther* 1999;288(1):93-97

11

Novartis Data on File

12

Chey WD. Tegaserod and other serotonergic agents: what is the evidence? *Rev Gastroenterol Disord* 2003;3Suppl2:S35-40

13

Kellum JM, Albuquerque FC, Stoner MC, Harris RP. Stroking human jejunal mucosa induces 5-HT release and CI secretion via afferent neurons and 5-HT<sub>4</sub> receptors. *Am J Physiol*. 1999;277(3Pt1):G515-520

14

Camilleri M. Serotonergic modulation of visceral sensation: lower gut. *Gut* 2002;51(Suppl)1:i81-86

15

Novick J, Miner P, Krause R, Glebas K, Bliesath H, Ligozio G, et al. A randomized, double-blind, placebo-controlled trial of tegaserod in female patients suffering from irritable bowel syndrome with constipation. *Aliment Pharmacol Ther* 2002;16(11):1877-1888

10

---

16

Müller-Lissner SA, Fumagalli I, Bardhan KD, Pace F, Pecher E, Nault B, et al. Tegaserod, a 5-HT<sub>4</sub> receptor partial agonist, relieves symptoms of irritable bowel syndrome in patients with abdominal pain, bloating and constipation. *Aliment Pharmacol Ther* 2001;15:1655-1666

17

Lefkowitz M, Shi Y, Schmitt C, Krumholz S, Tanghe J. The 5-HT<sub>4</sub> partial agonist, tegaserod, improves abdominal discomfort/pain and normalizes altered bowel function in irritable bowel syndrome (IBS) *Am J Gastroenterol* 1999;94(9):266

18

Kellow J, Lee OY, Chang FY, Thongsawat S, Mazlam MZ, Yuen H, Gwee KA, Bak YT, Jones J, Wagner A. An Asia-Pacific, double blind, placebo controlled, randomised study to evaluate the efficacy, safety and tolerability of tegaserod in patients with irritable bowel syndrome. *Gut* 2003;52(5):671-676

19

Camilleri M. Review article: tegaserod. *Aliment Pharmacol Ther*. 2001;15(3):277-289

20

Tougas G, Snape WJ Jr, Otten MH, Earnest DL, Langaker KE, Pruitt RE, Pecher E, Nault B, Rojavin MA. Long-term safety of tegaserod in patients with constipation-predominant irritable bowel syndrome. *Aliment Pharmacol Ther* 2002;16(10):1701-1708

21

Novartis Pharmaceuticals Corporation. Caring and Curing. Novartis Annual Report 2002. Available at: [http://www.novartis.com/investors/en/financial\\_reports.shtml](http://www.novartis.com/investors/en/financial_reports.shtml)

### Novartis Global Investor Relations

**Karen J. Huebscher, Ph.D.** +41 61 324 84 33  
[karen.huebscher@group.novartis.com](mailto:karen.huebscher@group.novartis.com)

**International office**

**North American office**

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

Nafida Bendali +41 61 324 35 14  
[nafida.bendali@group.novartis.com](mailto:nafida.bendali@group.novartis.com)

John Menditto +1 212 830 24 44  
[john.menditto@group.novartis.com](mailto:john.menditto@group.novartis.com)

Katharina Furrer +41 61 324 53 16  
[katharina.furrer@group.novartis.com](mailto:katharina.furrer@group.novartis.com)

Sabine Moravi +1 212 830 24 56  
[sabine.moravi@group.novartis.com](mailto:sabine.moravi@group.novartis.com)

Silke Zentner +41 61 324 86 12  
[silke.zentner@group.novartis.com](mailto:silke.zentner@group.novartis.com)

Jill Pozarek +1 212 830 24 45  
[jill.pozarek@group.novartis.com](mailto:jill.pozarek@group.novartis.com)

e-mail: [investor.relations@group.novartis.com](mailto:investor.relations@group.novartis.com)

e-mail: [investor.relations@gruoup.novartis.com](mailto:investor.relations@gruoup.novartis.com)

Fax: +41 61 324 84 44  
[www.novartis.com](http://www.novartis.com)

Fax: +1 212 830 24 05  
[www.novartis.com](http://www.novartis.com)

11

---

**Novartis International AG**  
Novartis Communications  
CH-4002 Basel  
Switzerland  
Tel +41 61 324 2200  
Fax+ 41 61 324 3300  
Internet Address:  
<http://www.novartis.com>

### **MEDIA RELEASE    COMMUNIQUE AUX MEDIAS    MEDIENMITTEILUNG**

#### **Novartis launches Spanish version of its global website**

Basel, 11 February 2004 Novartis announced today the launch of the Spanish-language version of its global website. Novartis.com in Spanish is designed to serve the nearly half a billion Spanish-speakers worldwide. In addition to the latest company information, investor news, media resources, job openings, and Novartis' commitment to corporate citizenship, the website includes a 22 000 page health encyclopedia on common diseases and conditions, symptoms, and nutrition.

The new Spanish website can be accessed at <http://www.novartis.com/espanol>.

"Novartis recognizes the need for a culturally and linguistically appropriate online channel for Spanish- speakers, and the Spanish version of the Novartis website illustrates our company's commitment to educating our customers and clients in diverse settings," said Dr. Luis Villalba, Latin America Corporate Regional Director of Novartis Pharmaceuticals Corporation.

Spanish-speakers are one of the fastest growing groups of online users. Today, there are approximately 47 million Spanish-speakers online worldwide, and their growth has outpaced other language groups. For example, Internet usage in Latin America soared to 21 million users in 2003 from 6.2 million in 1999, a growth of 240% in this time period<sup>1</sup>. In Spain, there are currently 14 million online users, an increase of 160 percent between 2000 and 2003<sup>2</sup>. In the US, about 12.4 million Hispanics are online, half of which prefer to browse in Spanish<sup>3</sup>. This represents a growth of 20 percent per year<sup>2</sup>. In addition, whilst there is a growing prevalence of conditions such as hypertension, diabetes and obesity among Spanish speakers worldwide, the quality of health information on Spanish-language sites continues to be sparse and less accurate than English-language sites<sup>5</sup>.

Novartis believes it is important that its Spanish-speaking clients and their caregivers have easier access to the latest advances in health information, as well as to up-to-date news about the company, in their native language.

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> and <http://www.novartis.com/espanol>.

###

## References

1. Pegasus Research International. *Latin American web users*. Available at: <http://www.pegasusresearch.net/metrics/growthla.htm>
2. Internet World Stats. *The top 25 countries with the highest number of Internet users*. Available at: <http://www.internetworldstats.com/top25.htm>

12

---

3. comScore Media Metrix. *Hispanic online users in U.S. exceed total online population of many major Spanish-speaking nations*. Available at: <http://www.comscore.com/metrix/hs.asp>
4. Morrissey, B. *Univision online reports ad surge*. Available at: <http://www.internetnews.com/IAR/article.php/1573651>
4. RAND Health. *Proceed With Caution: A Report on the Quality of Health Information on the Internet*. California HealthCare Foundation, 2001:4.

13

---

## Investor Relations

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

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

## Investor Relations Release

### **Novartis successfully completes European Mutual Recognition Procedure for Myfortic® its new immunosuppressant**

Basel, 10. February 2004 Novartis Pharma AG announced today that its application for the new enteric-coated immunosuppressant, Myfortic (mycophenolate sodium) successfully completed the European Mutual Recognition Procedure (MRP) in 17 countries. Myfortic is a life-long adjunctive therapy in combination with ciclosporin, such as Neoral® (ciclosporin microemulsion), and corticosteroids for the prevention of acute rejection of kidney allografts (transplants) in adult patients. All countries involved in the MRP are expected to issue a marketing authorization in the coming months.

"This is extremely good news for transplant patients and healthcare professionals as Myfortic provides a valuable new immunosuppressive treatment option that combines excellent efficacy and good tolerability," said Professor Georges Mourad, Director, Department of Nephrology and Transplantation, Hospital Lapeyronie, France. "Gastrointestinal side effects frequently observed under current mycophenolate mofetil or MPA therapy are a cause of discomfort for patients and may result in dose reduction or treatment discontinuation. This can pose difficult treatment decisions for transplant physicians, as these dose reductions or interruptions are associated with decreased graft survival."

A recent study (retrospective analysis) has demonstrated that more than 70% of patients taking mycophenolic acid (MPA) treatments such as mycophenolate mofetil (MMF) require at least one dose change, with 21% of these dose changes being the result of gastrointestinal side effects. In the majority of cases, dose change involved dose reduction. Patients who undergo an initial reduction in MMF dose are eight times more likely to suffer acute allograft rejection than those who have not had a dose adjustment.<sup>1</sup>

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

Myfortic is designed to avoid these MPA-related gastrointestinal side effects by delaying the release of MPA until it reaches the small intestine, with the goal of minimizing dose reductions. Results of two pivotal global multicentre trials indicate that Myfortic and MMF are therapeutically equivalent in *de novo* renal transplant patients and that the conversion to Myfortic from MMF is safe in maintenance renal transplant patients.<sup>2,3</sup>

"We are pleased that the European health authorities recognize the exceptional benefits that Myfortic can offer transplant patients," said Tony Rosenberg, Head, Transplantation and Immunology Business Unit, Novartis Pharma AG. "Myfortic, the latest Novartis transplant drug, is a much anticipated addition to our transplant product portfolio, setting us apart from other companies in the transplant field."

At the completion of the MRP, the following countries have endorsed the mutually agreed summary of product characteristics: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Iceland, Italy, Luxemburg, Netherlands, Norway, Portugal, Spain, Sweden and the United Kingdom. Myfortic received approval from the French regulatory authorities in October 2003.

14

---

The Novartis Transplantation and Immunology Team is committed to developing a new and innovative range of therapeutic products for the prophylaxis of organ rejection in order to provide the most extensive choice of drugs to the transplant community and to maintain Novartis' role as a global market leader in this field of medicine.

This release contains "forward-looking statements," relating to the Company's business, which can be identified by the use of forward-looking terminology such as "are expected", or similar expressions, or by express or implied discussions regarding the approval, marketing, or potential futures sales of Myfortic. Such statements reflect the current views of the Company with respect to future events and are subject to certain risks, uncertainties and assumptions that may cause actual results with Myfortic to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantees that Myfortic will be commercialized in any market. Any such commercialization can be affected by, among other things, uncertainties relating to 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, increased government price pressures, as well as factors discussed in the Company's Form 20-F filed with the Securities and Exchange Commission. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those described herein as anticipated, believed, estimated or expected. Novartis is providing 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>.

###

### References:

- 1 Pelletier RP, Akin B, Henry ML, et al. The impact of mycophenolate mofetil dosing patterns on clinical outcome after renal transplantation. *Clin Transplant* 2003; 17: 200-205.
- 2 Salvadori M, Holzer H, De Mattos A, et al. Enteric-coated mycophenolate sodium is therapeutically equivalent to mycophenolate mofetil in *de novo* renal transplant patients. *Am J Transplant* 2004; 4(2): 231-236

15

---

- 3 Budde K, Curtis J, Knoll G, et al. Enteric-coated mycophenolate sodium can be safely administered in maintenance renal transplant patients: results of a 1-year study. *Am J Transplant* 2004; 4(2): 237-243.

**Novartis Global Investor Relations**

**Karen J. Huebscher, Ph.D.** +41 61 324 84 33  
*karen.huebscher@group.novartis.com*

**International office**

Nafida Bendali +41 61 324 35 14  
*nafida.bendali@group.novartis.com*

Katharina Furrer +41 61 324 53 16  
*katharina.furrer@group.novartis.com*

Silke Zentner +41 61 324 86 12  
*silke.zentner@group.novartis.com*

e-mail: [investor.relations@group.novartis.com](mailto:investor.relations@group.novartis.com)

Fax: +41 61 324 84 44  
[www.novartis.com](http://www.novartis.com)

**North American office**

John Menditto +1 212 830 24 44  
*john.menditto@group.novartis.com*

Sabine Moravi +1 212 830 24 56  
*sabine.moravi@group.novartis.com*

Jill Pozarek +1 212 830 24 45  
*jill.pozarek@group.novartis.com*

e-mail: [investor.relations@gruoup.novartis.com](mailto:investor.relations@gruoup.novartis.com)

Fax: +1 212 830 24 05  
[www.novartis.com](http://www.novartis.com)

16

**Novartis International AG**

Novartis Communications  
CH-4002 Basel  
Switzerland  
Tel +41 61 324 2200  
Fax+ 41 61 324 3300  
Internet Address:  
<http://www.novartis.com>

**MEDIA RELEASE COMMUNIQUE AUX MEDIAS MEDIENMITTEILUNG**

**Susan Gasser to head Friedrich Miescher Institute**

Basel, 5 February 2004 Susan Gasser, Professor for Molecular Biology at the University of Geneva, has been named the new director of the Friedrich Miescher Institute (FMI) in Basel.

Founded in 1970, the FMI is devoted to fundamental biomedical research and focuses on epigenetics, growth control and neurobiology.

"Professor Gasser's experience and excellence in the field of fundamental research of chromosomal organization and patterning of gene expression will greatly benefit the FMI," said Professor Paul Herrling, Head of Corporate Research at Novartis. "Her scientific expertise, leadership and ability to create a lively educational environment will greatly contribute to the training of highly talented young scientists from around the world."

Professor Gasser previously led a research group at the Swiss Institute for Experimental Cancer Research (ISREC) in Lausanne for 15 years. Her research addresses questions of long-range chromosomal organization and genome stability using the model organism *Saccharomyces cerevisiae*, commonly known as baker's or budding yeast. Professor Gasser received a B.A. in Biophysics with honors from the University of Chicago and completed her Ph.D. at the University of Basel. A dual citizen of the United States and Switzerland since 1979, Professor Gasser grew up in Roseburg, Oregon.

During her distinguished career, Professor Gasser has served as a member of the Swiss National Science Foundation, on the directing board of ISREC, as vice-chair and chair of the European Molecular Biology Organization (EMBO) Council, and on various editorial review

committees and advisory boards.

The FMI seeks to contribute to the understanding of basic biological processes relevant to biomedical research and provides young scientists from all over the world with an opportunity to participate in scientific research. Most group members are young students or postdoctoral fellows who have come to the institute from over 30 different countries, providing a rich environment of varied scientific experience and a unique blend of culture. Presently, the FMI laboratories train 90 Ph.D. students and 75 postdoctoral fellows.

One of the three corporate research institutes at Novartis, the FMI is part of the Novartis Research Foundation. It has extensive collaborations with several institutes and universities around the world as well as with the different research groups within Novartis. The FMI has a total staff of 280 organized in 20 research groups.

The other two Novartis Corporate Research Institutes are the Genomics Institute of the Novartis Foundation (GNF) in La Jolla, and the Novartis Institute for Tropical Diseases (NITD) in Singapore. The mission of Novartis Corporate Research is to leverage the specific expertise of its three member institutes to address unmet medical needs, with a particular focus on the developing world and neglected disease.

17

---

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 media information and pictures can be found at:**

[http://novartis.imagedirector.net/album?album\\_code=6szq95q4ppa3](http://novartis.imagedirector.net/album?album_code=6szq95q4ppa3)

**Additional information about the FMI can be found at:**

<http://www.fmi.ch>

**Additional information on recent research of Susan Gasser can be found at:**

<http://www.molbio.unige.ch/gasser>

18

---

**Sandoz GmbH**

Biochemiestraße 10

A-6250 Kundl

Phone +43 5338-200-2202

Fax +43 5338 8866

[www.sandoz.com](http://www.sandoz.com)

**MEDIA RELEASE    COMMUNIQUE AUX MEDIAS    MEDIENMITTEILUNG**

**Sandoz powers up new cell-culture production units to manufacture biopharmaceuticals**

*Overall investment of EUR 68 million in Austria and Slovenia marks a milestone for Biopharmaceuticals franchise*

Kundl (Austria), 4 February 2004 Sandoz today inaugurated a new manufacturing plant at its Schafteuau site (near Kufstein) in Tyrol, Austria, which has been built to produce innovative biopharmaceuticals. Completed in just two years for an investment of more than EUR 50 million, the new facility further positions Sandoz as a manufacturing partner of choice in this field. Tomorrow, Sandoz' Slovenian affiliate Lek will also open a new biopharmaceutical production facility, the first of its kind in Eastern and Central Europe.

Sandoz CEO Christian Seiwald commented: "The new Schafteuau plant is a milestone for our Biopharmaceuticals franchise. It opens the way for us to expand into cell-culture technology and the development of recombinant proteins and recombinant antibodies for cooperation partners in the pharmaceutical and biotechnology industry."

Biopharmaceuticals are human proteins (e.g. hormones, insulins, antibodies etc) developed for therapeutic use and manufactured using recombinant DNA technologies. Sandoz has a longstanding expertise in biotechnological pharmaceutical production and was one of the world's first manufacturers to produce a recombinant protein (interferon) on an industrial scale, in 1981.

Friedrich Nachtmann, Head of Biotech Cooperations, said: "For more than 20 years we have been building a global reputation as a leader in modern microbial fermentation, and can now also offer our customers state-of-the-art development and production expertise in cell-culture technology. We are scheduled to begin contract manufacture in the second half of this year and are delighted with the broad interest already shown by business partners."

The new facility has a highly flexible, multi-purpose modular design and comprises a 100-liter line for producing initial batches for clinical trials, and two production-scale fermenters with capacities of 3,000 and 13,000 liters. Both fermentation units can be operated in batch mode and provide fully equipped downstream processing lines, with state-of-the-art isolation and purification technologies. Sandoz is thus able to produce to high cGMP standards and to offer top quality to its customers.

19

---

The expansion underscores the strategic importance of Sandoz' new Biopharmaceuticals franchise. Just a year ago, the company opened a new 13,000 liter fermentation plant for biopharmaceutical production using microbial technology at its neighboring Kundl site. The two new facilities have together created more than 100 highly skilled jobs.

In addition to this announcement, Lek Pharmaceuticals will also open a new biopharmaceutical manufacturing plant equipped with two 200 liter perfusion fermenters. Located in Menges (near Ljubljana) the new facility will be opened by Slovenian President Dr. Janez Drnovsek, and is the first of its kind in Slovenia and Central and Eastern Europe. The new cell-culture facility was built in just two years for an investment of more than EUR 18 million.

**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 Pharmaceuticals, Biopharmaceuticals and Industrial Products Franchises. 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 both the Novartis Group's and Sandoz' businesses, which can be identified by the use of forward-looking terminology such as "to manufacture", "positions", "opens the way", "scheduled to begin" or similar expressions or by discussions of strategy, plans or intentions. Such statements reflect the current views of Novartis with respect to future events

