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NOVARTIS AG  
Form 6-K  
June 06, 2002

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 May 2002

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 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 Drug Glivec(R) (imatinib)\* Approved in European Union for Treatment of Life-Threatening GI Cancer (May 31, 2002)
2. Novartis Ophthalmics and QLT announce positive recommendation for Visudyne(R) approval in Europe from European Committee for Proprietary Medicinal Products (May 31, 2002)
3. Data demonstrating Zometa(R) as effective treatment for debilitating bone complications in prostate cancer patients presented at major urology meeting (May 27, 2002)
4. Geneva announces US District Court invalidates Augmentin(R) patents (May 23, 2002)

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5. Data presented at APA meeting suggest Ritalin(R) LA (methylphenidate hydrochloride) extended-release capsules are an effective once-daily

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- treatment for ADHD (May 22, 2002)
6. Two studies show Focalin(TM) (dexamethylphenidate HCl) is an effective treatment for ADHD (May 22, 2002)
  7. Data demonstrating Zometa(R) as important advance in treating lung cancer-related bone complications presented at major oncology meeting (May 22, 2002)
  8. Aromatase inhibitors in breast cancer assessed by ASCO Committee (May 21, 2002)
  9. New head-to-head data show Glivec(R) is nearly three times more effective as first-line treatment for chronic myeloid leukemia patients than interferon combination therapy (May 21, 2002)
  10. Glivec(R) maintains responses in patients with life-threatening gastrointestinal tumors after one year of treatment (May 21, 2002)
  11. Head-to-head worldwide study of the two leading aromatase inhibitors shows more women respond to Femara(R) than Arimidex(R) in advanced breast cancer (May 21, 2002)
  12. Novartis launches TARGET, largest world-wide arthritis clinical trial (May 21, 2002)
  13. Gastrointestinal safety studies highlight benefits of investigational COX-2 inhibitor (May 21, 2002)
  14. Elidel(R) cream offers new non-steroid approach to treating atopic eczema in babies and sensitive skin areas (May 16, 2002)
  15. LOGIC, new 9,000-patient study, demonstrates patients switched to Lotrel (R) from Norvasc(R) experience better blood pressure control with less edema (May 14, 2002)
  16. Starlix(R) enhances glucose control in people with impaired glucose tolerance (May 8, 2002)
  17. Glivec(R) (imatinib)\* may be effective in rare blood disease according to new report in The Lancet (May 3, 2002)
  18. Interim data from MO2ART study using Neoral(R) C2 monitoring demonstrates impressive, low rates of kidney rejection (May 2, 2002)
  19. Novartis broadens horizons in post-transplant immunosuppression: FTY720 plus Certican(TM) shows efficacy and safety in a calcineurin inhibitor (CNI) - free regimen (May 2, 2002)

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- Investor Relations Release -

Novartis Drug Glivec(R) (imatinib)\* Approved in European Union for Treatment of Life-Threatening GI Cancer

Glivec is approved to treat gastrointestinal stromal tumours (GISTs), the second indication in a record seven months

Basel, Switzerland, 31 May 2002 - Novartis announced today that, in record time, the European Commission (EC) has issued approval for the breakthrough drug Glivec(R) (imatinib)\* for the treatment of patients with Kit (CD 117)-positive unresectable (inoperable) and/or metastatic malignant gastrointestinal stromal tumours (GISTs). The approval follows a positive recommendation by the EU's Committee for Proprietary Medicine (CPMP) in February 2002. It is the second EC approval for Glivec in seven months: the first, on 7 November 2001, was as an oral therapy for the treatment of adult patients with Philadelphia (Bcr-Abl) chromosome-positive chronic myeloid leukemia (CML) in chronic phase after failure of interferon-alpha therapy, or in accelerated phase or blast crisis.

"Patients with GISTs have traditionally had very limited treatment options, so we are especially pleased that authorities are recognising the value of Glivec in treating this life-threatening cancer," said Daniel Vasella, MD, Chairman and CEO of Novartis. "Glivec has already had a significant impact on the lives of people with CML and GISTs, and we are continuing to study it in other cancers to determine if it has the potential to help patients, either alone or in combination with other therapies."

GISTs are the most common malignant form of sarcoma that arise in the gastrointestinal tract. Worldwide, there are approximately 12,000 new cases each year. The incidence is highest in people 30-60 years of age. Historically, GISTs have been very difficult to treat due to their resistance to treatment with available chemotherapy and radiation therapy.

For patients with metastatic or unresectable disease, GISTs were an incurable malignancy with a median survival of 20 months and, with local recurrence, a median survival of 9-12 months. Until now, surgery has been the only treatment option, resulting essentially in palliation of the disease.

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\*In the US: Gleevec(TM) (imatinib mesylate); outside the US: Glivec(R) (imatinib)

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About Glivec and GISTs

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The EC approval for the GIST indication is supported by data from an open-label, multinational study conducted in 147 patients with Kit (CD117) positive unresectable and/or metastatic malignant GISTs. Patients were randomised to receive either 400 mg or 600 mg of Glivec daily until remission. The overall response rate was 40%, based on confirmed partial responses and stable disease at the time of the data cut-off for the submission.

Data which have emerged since the submission for approval were presented in May 2002 at the 38th annual meeting of the American Society of Clinical Oncology (ASCO) in Orlando, Florida, USA. The data showed that in this study, more than 60% of patients with GIST achieved confirmed partial response to Glivec, and an additional 20% attained some degree of tumour shrinkage or stabilisation of their disease. The data also revealed that at a median follow-up of 15 months, 73% of patients remained on the study.

Glivec, a signal transduction inhibitor, is one of the first cancer drugs to be developed using rational drug design, based on an understanding of how some cancer cells are generated and exhibit unrestrained growth. Glivec targets the activity of specific enzymes called tyrosine kinases that play an important role within certain cancer cells. The activity of a tyrosine kinase known as Kit, a receptor that is the product of a gene called c-kit, is very often mutated and is known to drive the growth and division of most GISTs.

### Glivec To Date

The U.S. Food and Drug Administration (FDA) was the first to approve Glivec for the GIST indication, for which it was designated as an Orphan Drug, on 1 February 2002. Glivec also is approved for the GIST indication in Switzerland, where it was approved on 15 April 2002. To date, Novartis has received marketing clearance for Glivec for the CML indication worldwide.

### Contraindications and Adverse Events

Although the majority of patients had adverse events reported at least once during this trial, most events were mild to moderate in severity and included nausea, diarrhoea, periorbital oedema, muscle cramps, fatigue, headache and skin rash. About 23% of the patients had severe drug-related side effects that included low white blood cell counts, tumor haemorrhage and abdominal pain. In the GIST trial submitted for registration, drug was discontinued for adverse events in 13 patients (9% of patients). In this clinical trial, the most common adverse events were oedema, nausea, diarrhoea, abdominal pain, muscle cramps, fatigue and rash. In this trial, seven patients (5%) were reported to have gastrointestinal bleeds and/or intratumoral bleeds. Gastrointestinal tumor sites may have been the source of GI bleeds. Glivec is contraindicated in patients with known hypersensitivity to imatinib or any of its excipients. Women of childbearing potential should be advised to avoid becoming pregnant while taking Glivec.

In most countries where Glivec is approved, it is indicated for the treatment of patients with Philadelphia chromosome-positive CML in blast crisis, accelerated phase, or in chronic phase after failure of interferon-alpha therapy.

The foregoing release contains forward-looking statements that can be identified by terminology such as "shown the potential to help," "until now," "authorities are recognizing the value," or similar expressions. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results with Glivec to be materially different from any future results, performance or achievements expressed or implied by such statements. In particular, management's ability to ensure satisfaction of the FDA's further requirements is not

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guaranteed and management's expectations regarding further commercialisation of Glivec could be affected by, among other things, additional analysis of data; new data; unexpected clinical trial results for Glivec; 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 Securities and Exchange Commission of the United States. 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.

### About Novartis

Novartis AG (NYSE: NVS) is a world leader in healthcare with core businesses in pharmaceuticals, consumer health, generics, eye-care, and animal health. In 2001, the Group's businesses achieved sales of CHF 32.0 billion (USD 19.1 billion) and a net income of CHF 7.0 billion (USD 4.2 billion). The Group invested approximately CHF 4.2 billion (USD 2.5 billion) in R&D. Headquartered in Basel, Switzerland, Novartis Group companies employ about 72,600 people and operate in over 140 countries around the world. For further information please consult <http://www.novartis.com>.

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

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Novartis Ophthalmics and QLT announce positive recommendation for Visudyne(R) approval in Europe from European Committee for Proprietary Medicinal Products

This represents a major step in the marketing approval process in Europe for expanded use in patients with occult CNV secondary to age-related macular degeneration

Basel, 31 May 2002 - Novartis Ophthalmics, the eye health unit of Novartis AG, and QLT Inc. today announced that the Committee for Proprietary Medicinal Products (CPMP) of the European Medicines Evaluation Agency (EMEA), has adopted a positive opinion on Visudyne(R) (verteporfin) therapy to also include the treatment of patients with evidence of recent or ongoing disease progression in occult subfoveal choroidal neovascularization (CNV) secondary to age-related macular degeneration (AMD), a leading cause of blindness among people over the age of 50. The CPMP opinion will now be considered by the European Commission, which should make a final decision within three months regarding marketing authorization in the European Union.

Visudyne therapy is the only drug approved for the treatment of certain forms of wet AMD. AMD consists of two forms: wet and dry. Although only 15% of AMD patients suffer from the wet form of the disease this type is more aggressive and accounts for approximately 90% of severe vision loss. Approximately 500,000 new cases of the wet form of AMD occur each year worldwide, and this estimate is expected to grow dramatically as the population ages.

"We look forward to the European Commission's final decision and to being able to provide Visudyne to the many patients for whom there is no approved drug treatment currently available," said Paul Hastings, president and CEO of QLT.

This application was based on favorable two-year results from the Verteporfin in Photodynamic Study trial (VIP), a phase IIIb clinical trial, which included 258 patients with subfoveal occult without classic CNV, who had recent disease progression. The study showed that patients who received Visudyne therapy for 24 months had a significantly reduced risk of moderate and severe vision loss compared to the placebo group. The results were published in the May 2001 issue of the peer-reviewed American Journal of Ophthalmology.

"We are very pleased with the committee's recommendation for approval of Visudyne for occult wet AMD, " said Luzi von Bidder, head of Novartis Ophthalmics. "This positive recommendation is a very important milestone as occult CNV represents a considerable portion of the total wet

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AMD population and if approved this indication could expand the current market for Visudyne to two-thirds of the total patient population in Europe."

### About AMD

AMD is caused by a growth of abnormal blood vessels (CNV) under the central part of the retina or macula and occurs in two forms, dry and wet AMD. In the wet form, the vessels leak fluid and blood that lead to the development of scar tissue that destroys the central retina. This results in a deterioration of sight over a period of two months to three years. "Occult" and "classic" are terms used to describe the different patterns of CNV leakage as seen on fluorescein angiography.

### About Visudyne

Visudyne therapy, the only drug approved for the treatment of some forms of wet

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AMD, has treated approximately 150,000 patients worldwide. Visudyne is commercially available in 62 countries for the treatment of predominantly classic subfoveal CNV caused by AMD. It is also approved in 40 countries, including the EU, U.S. and Canada, for the treatment of subfoveal CNV due to pathologic myopia (severe near-sightedness). In the U.S., Visudyne has received an additional approval for CNV due to presumed ocular histoplasmosis.

Visudyne therapy, developed by Novartis Ophthalmics and QLT Inc., is a relatively painless two-step procedure performed in a doctor's office. Visudyne is injected intravenously into the patient's arm, and then a non-thermal laser light is shone into the patient's eye to activate the treatment. Visudyne targets the abnormal blood vessels and does not affect normal/healthy blood vessels.

Visudyne is generally well tolerated and has an excellent safety profile. Potential side effects include injection site reactions, headaches, back pain, blurring, decreased sharpness and gaps in vision, and in 1-5% of patients a substantial decrease in vision with partial recovery in some patients. People should avoid direct sunlight for five days to avoid sunburn. People with porphyria should not be treated. For more information, visit [www.visudyne.com](http://www.visudyne.com).

Visudyne(R) is a trademark of Novartis AG.

The foregoing press release contains forward-looking statements, that can be identified by terminology such as "should make" or "could expand", or by discussions regarding potential new indications for existing products. Such forward-looking statements involve known and unknown risks, uncertainties and other factors, which may cause the actual results and assumptions to be materially different from any future results, performance or achievements expressed or implied by such statements. There are no guarantees that any of the potential potential new indications will be commercialized in any market. Any such commercialization can be affected by, among other things, the risk that the CPMP opinion may be rejected by the European Commission, uncertainty regarding the market size of the occult wet AMD population in Europe and the effect of the CPMP opinion and pending decision of the European Commission on Visudyne sales, other risks associated with the development and commercialization of the treatment, including uncertainties relating to manufacturing, clinical trials, registration, pricing and reimbursement; patient and physician demand for the treatment; competition; any uncertainty regarding patents and proprietary rights; and additional factors as described in detail in QLT Inc.'s Annual Information Form on Form 10-K and recent and forthcoming quarterly reports on Form 10Q, and Novartis AG's Form 20-F, and other filings with the US Securities and Exchange Commission and Canadian Securities Regulatory authorities.

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### Background on Novartis Ophthalmics and QLT

Novartis Ophthalmics: With worldwide headquarters in Bulach, Switzerland, Novartis Ophthalmics is a global leader in research, development and manufacturing of leading ophthalmic pharmaceuticals that assist in the treatment of glaucoma, age-related macular degeneration, eye inflammation, ocular allergies and other diseases and disorders of the eye. Novartis Ophthalmics products are available in more than 110 different countries. The North American headquarters is based in Atlanta, Georgia. Novartis Ophthalmics has production sites in Switzerland, France and Canada. For more information, visit [www.novartisophthalmics.com](http://www.novartisophthalmics.com) or [www.novartisophthalmics.com/us](http://www.novartisophthalmics.com/us).

Novartis AG (NYSE: NVS) is a world leader in healthcare with core businesses in

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QLT Inc. (NASDAQ: QLTI; TSE:QLT) is a global biopharmaceutical company dedicated to the discovery, development, and commercialization of innovative therapies to treat cancer, eye diseases and immune disorders. Combining expertise in ophthalmology, oncology and photodynamic therapy, QLT has commercialized two products to date, including Visudyne therapy which is the largest selling ophthalmology product ever launched. For more information, visit our web site at [www.qltinc.com](http://www.qltinc.com).

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MEDIA RELEASE o COMMUNIQUE AUX MEDIAS o MEDIENMITTEILUNG

Data demonstrating Zometa(R) as effective treatment for debilitating bone complications in prostate cancer patients presented at major urology meeting

Basel, Switzerland, 27 May 2002 - The Novartis drug Zometa(R) (zoledronic acid) is effective for the treatment of potentially debilitating skeletal related events from bone metastases in prostate cancer patients according to the data presented at the 97th annual meeting of the American Urological Association (AUA) in Orlando, Florida, USA. Patients with advanced prostate cancer are at high risk for developing bone complications-or skeletal related events (SREs)-which include bone pain, pathologic fractures, need for radiation or surgery to bone, spinal cord compression and hypercalcaemia. This study marks the first time a bisphosphonate has demonstrated efficacy in treating bone metastases in this patient population. Further, Zometa offers patients, nurses and clinicians a convenient 4 mg (in 100 ml of solution), 15-minute infusion time.

"Bone metastases can result in debilitating pain, fractures and compression of the spine and are a significant problem for patients with advanced prostate cancer. Until now, there were few effective therapies available for these patients," said Fred Saad, MD, Associate Professor of Urology and Director of Urologic Oncology at the Montreal Cancer Institute, University of Montreal.



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"Zometa represents a significant advance in the overall treatment of advanced prostate cancer patients and should be a welcome addition for urologists and oncologists in the care of their patients."

### Study Design

The study was designed to investigate the efficacy of Zometa in patients with bone complications resulting from prostate cancer, particularly with respect to reducing the proportion of patients with SREs and delaying the time to first SRE. A total of 643 patients with at least one bone metastasis participated in the multicentre, randomized, placebo-controlled trial. The final analysis was based on evaluating Zometa 4 mg (in 100 ml of solution) compared to placebo at an infusion rate of 15 minutes, given every three weeks for 15 months. Initially, a third arm of the study evaluated an 8 mg dose of Zometa; however, that dose offered no efficacy advantage compared to the recommended dose (4 mg/15 minute infusion), but was associated with a higher incidence of adverse events, including increased serum creatinine levels. Therefore, dosing on this arm was changed to 4 mg and was not included in this efficacy analysis.

### Clinical Data

The data demonstrated that 25% fewer patients taking Zometa 4 mg experienced any SRE compared to those patients taking placebo (Zometa 33% vs. placebo 44%,  $p=0.021$ ). The 15-month data also demonstrated that fewer patients taking Zometa 4 mg had a pathologic fracture compared to those patients taking placebo (Zometa 13% versus placebo 22%,  $p=0.015$ ). Patients taking Zometa 4 mg also showed a slower rate of progression of pain compared with placebo. All

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patients experienced a mean increase from baseline in composite Brief Pain Inventory (BPI) pain scores over time; however, the increases were lower at every time point for patients treated with Zometa 4 mg compared with placebo (statistically significant at months three and nine).

### About Prostate Cancer and Bone Metastases

Bone metastases are the spread of cancerous cells from the original tumor to bones. Bone metastases/lesions are common in prostate cancer and research indicates bone metastases occur in 65-75% of all advanced prostate cancer patients and often bone is the only site of metastases. Some studies have shown that complications of metastases are the primary cause of death among patients with prostate cancer; therefore, treating the bone metastases may successfully improve clinical outcome. Prior to Zometa, current therapeutic options for complications of bone metastases included hormonal therapy, surgery, radiotherapy, chemotherapy and analgesics for pain management.

### About Zometa

Zometa received U.S. FDA approval on 22 February 2002 for the treatment of patients with multiple myeloma and patients with documented bone metastases from solid tumors, in conjunction with standard antineoplastic therapy. These solid tumors studied include prostate cancer, breast cancer and other solid tumor types including renal, colorectal and lung. In prostate cancer, patients should have progressed after treatment with at least one hormonal therapy. Zometa also received a positive opinion for this indication from the Committee for Proprietary Medicinal Products (CPMP) in the European Union (EU). The EU Commission usually grants approval of products four months after a CPMP positive opinion.

### Contraindications and Adverse Events

In clinical trials in patients with bone metastases, Zometa was generally well tolerated, with a safety profile similar to other intravenous bisphosphonates.

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The most commonly reported adverse events included flu-like syndrome (fever, arthralgias, myalgias, skeletal pain), fatigue, gastrointestinal reactions, anaemia, weakness, cough, dyspnoea and oedema. Zometa should not be used during pregnancy. Zometa is contraindicated in patients with clinically significant hypersensitivity to zoledronic acid or other bisphosphonates, or any of the excipients in the formulation of Zometa.

Zometa and other bisphosphonates have been associated with reports of renal insufficiency. Patients should have serum creatinine assessed prior to receiving each dose of Zometa. Caution is advised when Zometa is administered with other potentially nephrotoxic drugs. Due to the risk of clinically significant deterioration in renal function, single doses of Zometa should not exceed 4 mg and the duration of infusion should be no less than 15 minutes.

This release may contain forward-looking statements regarding the potential launch of Zometa in markets in which it currently is not approved, or regarding potential new indications for Zometa in existing markets. Such forward looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results to be materially different from any future results, performance or achievements expressed or implied by such statements. There are no guarantees that Zometa or any potential new indications for Zometa will be commercialized in any market. Any such commercialization 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 and competition in general, as well as factors discussed in Novartis AG's Form 20-F filed 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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[Geneva Pharmaceuticals Logo]

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MEDIA RELEASE o COMMUNIQUE AUX MEDIAS o MEDIENMITTEILUNG

Geneva announces US District Court invalidates Augmentin(R)patents

Plainsboro, New Jersey, 23 May 2002 - Geneva Pharmaceuticals, Inc. ("Geneva") announced today that the US District Court for the Eastern District of Virginia rendered a decision in Geneva Pharmaceuticals, Inc., et al. v. GlaxoSmithKline PLC, et al. (Civ. Act. Nos. 2:01-CV-391; 2:01-CV-677; and 2:01-CV-925) invalidating the three remaining patents claiming GlaxoSmithKline PLC's ("Glaxo's") antibiotic Augmentin(R) (amoxicillin/clavulanate potassium).

The Court ruled that US Patent Nos. 4,525,352; 4,529,720; and 4,560,552, which are otherwise due to expire on June 25, July 16 and December 24, 2002, respectively, are invalid for double-patenting. The Court had previously granted motions for summary judgment invalidating a number of other patents claiming Augmentin which were due to expire in 2017 and 2018. Geneva has received final approval from the US Food and Drug Administration for its generic version of Augmentin, in several strengths and dosage forms.

Geneva Pharmaceuticals, Inc. is one of the largest prescription generic drug companies in the US Geneva produces more than 200 products each year, with an annual manufacturing capability exceeding 10 billion tablets and capsules. Geneva products range across many therapeutic drug categories including anti-infectives, anti-arthritics, cardiovasculars, gastrointestinal agents and psychotherapeutics. Geneva is an affiliate of the Novartis AG (NYSE: NVS) is a world leader in healthcare with core businesses in pharmaceuticals, consumer health, generics, eye-care, and animal health. In 2001, the Group's businesses achieved sales of CHF 32.0 billion (USD 19.1 billion) and a net income of CHF 7.0 billion (USD 4.2 billion). The Group invested approximately CHF 4.2 billion (USD 2.5 billion) in R&D. Headquartered in Basel, Switzerland, Novartis Group companies employ about 72,600 people and operate in over 140 countries around the world. For more information about Geneva, please see our website at [www.genevarx.com](http://www.genevarx.com). For more information on Novartis, [www.pharma.us.novartis.com](http://www.pharma.us.novartis.com) or [www.novartis.com](http://www.novartis.com).

The foregoing press release contains forward-looking statements that can be identified by terminology such as "will evaluate," "will examine," "will assess," "will be assessed" or similar expressions. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results to be materially different from any future results, performance or achievements expressed or implied by such statements. There are no guarantees that the aforementioned clinical trials will result in the commercialization of any product in any

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protection and competition in general, as well as factors discussed in Novartis' 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.

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MEDIA RELEASE o COMMUNIQUE AUX MEDIAS o MEDIENMITTEILUNG

Data presented at APA meeting suggest Ritalin(R) LA (methylphenidate hydrochloride) extended-release capsules are an effective once-daily treatment for ADHD

Philadelphia, PA, 22 May 2002 - Data presented at the 155th Annual Meeting of the American Psychiatric Association (APA), suggest that Ritalin(R) LA (methylphenidate HCl) extended-release capsules, are an effective and well-tolerated, once-daily formulation of Ritalin(R) (methylphenidate HCl), designed to last the school day and eliminate the need for the midday dose of Ritalin. Results from a double-blind, randomized, placebo-controlled study found that a once-daily morning dose of Ritalin LA was effective in reducing Attention-Deficit/Hyperactivity Disorder (ADHD) symptoms in both home and school settings. Ritalin LA uses SODASTM technology\*, a proprietary drug delivery technology of Elan Corporation, plc.

"The data presented suggest Ritalin LA is an effective and safe once-daily formulation of Ritalin," said Joseph Biederman, MD, Chief, Joint Program in Pediatric Psychopharmacology, Massachusetts General Hospital, Professor of Psychiatry, Harvard Medical School, and lead author of the study. "This formulation would have the significant benefit of eliminating the need to take

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medication during school hours."

One hundred and sixty ADHD patients, aged 6 - 12, were enrolled in a multi-center study to compare the safety and efficacy of Ritalin LA to placebo. After an initial single-blind screening and titration period, the patients were randomized to receive either a once-daily, morning dose of Ritalin LA or placebo. Efficacy was evaluated by examining the presence of ADHD symptoms in the school and home environment. In this analysis, the primary outcome was measured by the change from baseline in the Conners ADHD/DSM-IV total subscale for teachers (CADS-T), a validated tool for the assessment of ADHD symptoms by teachers. Ritalin LA was found to be clinically and statistically superior to placebo in managing ADHD symptoms in all primary and secondary efficacy variables.

Ritalin LA was also shown to be safe and well tolerated. The incidence of adverse events was similar for Ritalin LA and placebo (24.6% vs. 23.9%). In this study, Ritalin LA exhibited a low rate of discontinuation due to adverse events versus placebo, (1.5% vs. 0.0%).

Ritalin LA is designed to deliver an immediate release of Ritalin and a second equal release of approximately 4 hours after administration, mimicking the pharmacokinetic profile of twice-daily Ritalin. The bimodal release formulation of Ritalin LA provides two peak concentrations of medication, mimicking twice-daily Ritalin but with less fluctuation. Ritalin LA provides the same rapid onset as Ritalin and its efficacy lasts throughout the school day. Ritalin LA may be swallowed whole with capsules, or, for children who have difficulty swallowing, it may be administered by sprinkling the beaded contents on applesauce.

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Ritalin LA was developed by Elan's drug delivery division and will be supplied to Novartis under an exclusive worldwide royalty and manufacturing agreement between the companies. Novartis Pharmaceuticals Corporation has commercialization rights to Ritalin LA in the U.S.

ADHD is the most studied childhood psychiatric disorder and is supported by a substantial body of scientific evidence. Its symptoms have been described in the medical literature since 1902. Scientific research indicates that ADHD may be related to disturbances in certain neurotransmitters in the brain. Novartis supports only the proper diagnosis and treatment of ADHD.

The Novartis ADHD product portfolio includes Ritalin, Ritalin SR, and Focalin(TM) (dexamethylphenidate), a refined formulation of Ritalin. Celgene Corporation (Nasdaq: CELG) of Warren, New Jersey granted Novartis Pharma AG an exclusive worldwide (excluding Canada) license covering its intellectual property rights associated with Ritalin LA as well as Focalin. Pursuant to an agreement between Novartis Pharma AG and Novartis Pharmaceuticals Corporation, Novartis Pharmaceuticals Corporation markets Focalin in the U.S.

In addition, Ritalin LA, a once-daily form of Ritalin, is currently under review at the Food and Drug Administration (FDA). Novartis Pharmaceuticals Corporation received an approvable letter from the FDA for Ritalin LA in October 2001.

The foregoing press release contains forward-looking statements that can be identified by forward-looking terminology such as "suggest", "is designed to", "will be" or similar expressions. Such forward looking statements involve known and unknown risks, uncertainties and other factors that may cause the actual results to be materially different from any future results, performance, or achievements expressed or implied by such statements. In particular,

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management's expectation regarding the commercialization of Ritalin LA could be affected by amongst other things, results of future 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 anticipated, believed, estimated or expected.

Novartis Pharmaceuticals Corporation researches, develops, manufacturers and markets leading innovative prescription drugs used to treat a number of diseases and conditions, including central nervous system disorders, organ transplantation, cardiovascular diseases, dermatological diseases, respiratory disorders, cancer and arthritis. The company's mission is to improve people's lives by pioneering novel healthcare solutions.

Located in East Hanover, New Jersey, Novartis Pharmaceuticals Corporation is an affiliate of Novartis AG (NYSE: NVS), a world leader in healthcare with core businesses in pharmaceuticals, consumer health, generics, eye-care, and animal health. In 2001, the Group's businesses achieved sales of CHF 32.0 billion (USD 19.1 billion) and a net income of CHF 7.0 billion (USD 4.2 billion). The Group invested approximately CHF 4.2 billion (USD 2.5 billion) in R&D. Headquartered in Basel, Switzerland, Novartis Group companies employ about 72,600 people and operate in over 140 countries around the world. For further information please consult <http://www.novartis.com>.

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\*SODAS Technology is a trademark of Elan Corporation, plc.

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MEDIA RELEASE o COMMUNIQUE AUX MEDIAS o MEDIENMITTEILUNG

Two studies show Focalin(TM) (dexamethylphenidate HCl) is an effective treatment for ADHD

Philadelphia, PA, 22 May 2002 - Data from two double-blind, randomized, placebo-controlled studies presented today at the 155th Annual Meeting of the American Psychiatric Association (APA) demonstrate that Focalin(TM) (dexamethylphenidate HCl) is effective in the management of the symptoms of Attention-Deficit/Hyperactivity Disorder (ADHD) at half the dose of Ritalin(R) (d,l methylphenidate HCl). Focalin, a refined formulation of Ritalin, contains only the effective, or d-isomer of d,l methylphenidate HCl.

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The first study consisted of 132 ADHD patients, 6 - 17 years of age, randomized to receive Focalin, d,l methylphenidate (Ritalin), or placebo. In this study, the primary rating scale to assess efficacy was the teacher SNAP-ADHD (Swanson, Nolan, and Pelham) rating scale, a standard behavioral assessment tool used in clinical trials. Secondary efficacy measures included change from baseline on the parent-completed SNAP-ADHD Rating Scale (Parent SNAP), Clinical Global Impression-Improvement (CGI-I) scale score, and Math Test performance.

Results of the study showed the treatment effects of Focalin can be obtained at half the milligram dose of d,l methylphenidate. Both Focalin and d,l methylphenidate demonstrated a substantial reduction of ADHD symptoms on primary and secondary efficacy measures across multiple settings including teachers, parents, clinicians and patients. In addition, Focalin, but not d,l methylphenidate showed significant improvements in Parent SNAP (P=.0085) and Math Test (P=.0169) scores at 6 hours post dosing compared with placebo.

The second study was conducted with 89 patients (6 - 17 years of age, all meeting criteria for ADHD) and consisted of three phases: a 6-week, open-label dose-titration (Part A), in which all children received Focalin in doses of 2.5 mg to 10 mg twice daily; a double-blind, placebo-controlled, 2-week withdrawal (Part B), in which half the children previously responding to Focalin received placebo, while half remained on Focalin; and a 44-week open-label extension (Part C) to assess long-term efficacy and safety.

Results from the study showed that patients treated with Focalin demonstrated a substantial reduction of ADHD symptoms on primary and secondary efficacy measures across multiple settings, followed by a significant worsening of symptoms upon withdrawal of the treatment as compared to placebo. The primary efficacy variable was the percentage of Treatment Failures as assessed by the CGI-I scale at the end of the withdrawal phase (Part B). Secondary efficacy variables were included the Teacher SNAP-ADHD, the SNAP-ADHD rated by parents (Parent SNAP-ADHD) at 3 PM and 6 PM, and a Math Test administered at the clinic/office and at home.

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Data reported a duration of action of up to 6 hours for Focalin after the second dose, as supported by significant improvements in both the 6-hour post dose (6 PM) Parent SNAP-ADHD scores.

"The results presented today signify that dexmethylphenidate HCl, which contains only the active d-isomer, is a safe and effective treatment for ADHD at half the dose of Ritalin," said Keith Conners, Ph.D., Professor Emeritus of Psychiatry and Behavioral Sciences, Duke University Medical Center and lead author of the study.

Both studies demonstrated that Focalin was safe and well tolerated with no serious adverse events reported. In addition, no patients needed to discontinue therapy due to adverse events or intolerability in the double blind phase in each of the studies.

Focalin received marketing clearance from the Food and Drug Administration (FDA) in November 2001 for the treatment of ADHD. Focalin is administered twice daily, at least four hours apart. Overall, there was a low incidence of adverse events with the majority being of mild severity. In double-blind, placebo-controlled trials there were no discontinuations due to adverse events. In long-term extension studies, only 7 %, or 50 of 684, of children and adults treated with Focalin experienced an adverse event that resulted in discontinuation. Like most

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drugs approved for the treatment of ADHD, and like Ritalin, Focalin is contraindicated in patients known to be hypersensitive to the drug or to Ritalin, in patients with glaucoma, and in patients with motor tics or with a family history or diagnosis of Tourette's syndrome. It is also contraindicated during treatment with monoamine oxidase inhibitors and also within a minimum of 14 days following discontinuation of a monoamine oxidase inhibitor (hypertensive crises may result). In addition, like most drugs approved for the treatment of ADHD, Focalin is a schedule II drug.

ADHD is the most studied childhood psychiatric disorder and is supported by a substantial body of scientific evidence. Its symptoms have been described in the medical literature since 1902. Scientific research indicates that ADHD may be related to disturbances in certain neurotransmitters in the brain. Novartis supports only the proper diagnosis and treatment of ADHD.

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In addition, Novartis Pharmaceuticals Corporation received an approvable letter from the FDA for Ritalin LA in October 2001. Ritalin LA was developed by Elan Corporation, plc's drug delivery division and will be supplied to Novartis under an exclusive worldwide royalty and manufacturing agreement between the companies. Novartis Pharmaceuticals Corporation has commercialization rights for Ritalin LA in the U.S.

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commercialization of Ritalin LA could be affected by amongst other things, results from future clinical trials, uncertainties relating to product development, 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 20F 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 anticipated, believed, estimated or expected.

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Celgene Corporation, headquartered in Warren, New Jersey, is an independent biopharmaceutical company engaged primarily in the discovery, development and commercialization of orally administered small molecule drugs for the treatment of cancer and inflammatory diseases through gene regulation. Please feel free to visit the Company's Web site at <http://www.celgene.com>.

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- Investor Relations Release -

Data demonstrating Zometa(R) as important advance in treating lung cancer-related bone complications presented at major oncology meeting

Onset of debilitating bone complications delayed for patients; Zometa is first bisphosphonate demonstrating efficacy across a broad range of solid tumors; Data presented at American Society of Clinical Oncology

Basel, 22 May 2002 - Study results demonstrating that Zometa(R) (zoledronic acid) delays the initial onset of bone complications by more than two months in patients with non-small cell lung cancer and other solid tumors were presented at the 38th annual meeting of the American Society of Clinical Oncology (ASCO) in Orlando, Florida, USA. Bone complications - or skeletal related events (SREs) - represent a significant problem for cancer patients in advanced stages of disease; they include bone pain, pathologic fractures, need for radiation or

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surgery to bone, spinal cord compression and hypercalcaemia. For this patient population Zometa represents the first and only bisphosphonate proven effective in delaying the onset of SREs. Further, Zometa at 4 mg offers patients, nurses and clinicians a more convenient 15-minute infusion time.

Zometa received U.S. FDA approval on 22 February 2002 for the treatment of patients with multiple myeloma and patients with documented bone metastases from solid tumors, in conjunction with standard antineoplastic therapy. These solid tumors include prostate cancer, lung cancer, breast cancer and other solid tumor types studied in the clinical trials including renal, bladder and colorectal cancer. Zometa also received a positive opinion for this indication from the Committee for Proprietary Medicinal Products (CPMP) in the European Union (EU). The EU Commission usually grants approval of products four months after a CPMP positive opinion.

"Zometa offers a tremendous benefit for cancer patients," said Lee S. Rosen, MD, Assistant Professor of Medicine, UCLA Jonsson Comprehensive Cancer Center and lead study investigator. "Since bone complications can be devastating, delaying the time when a patient experiences them - by even two months - is a significant advance."

### Study Design

The study was designed to investigate the efficacy of Zometa in the prevention of SREs across a broad range of solid tumors, other than breast cancer or prostate cancer. A total of 773 patients were randomised to the study; 52% of the patients had lung cancer (primarily non-small cell lung cancer) and the remainder had other solid tumors (renal, colorectal and bladder). The final analysis

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was based on evaluating Zometa 4 mg compared to placebo at an infusion rate of 15 minutes, given every three weeks for nine months. Measurements of SREs were the endpoints and included delay in onset of SREs, proportion of patients experiencing any SRE, and the reduction in risk of individual patients experiencing multiple SREs (thus contributing more significantly to morbidity).

### Clinical Data

In regards to multiple SREs, the data in patients with bone metastases from lung cancer and other solid tumors demonstrate that there was a 26% reduction in the rate at which patients experienced skeletal-related events, including multiple SREs ( $p=0.006$ ). Overall, findings demonstrate that patients receiving Zometa 4 mg at an infusion rate of 15 minutes experienced a significant delay in the onset of SREs (230 days for Zometa vs. 155 days for placebo [ $p=0.007$ ]). As the median survival of patients with advanced cancers may be approximately six months, a delay of more than two months provides a significant clinical benefit to physicians and patients. Also, after nine months, patients on Zometa experienced fewer SREs overall (38% of patients receiving Zometa vs. 47% receiving placebo [ $p=0.039$ ]).

### About Zometa

Zometa is a new generation intravenous (IV) bisphosphonate. The approval for Zometa was based on data from three large international clinical trials evaluating more than 3,000 patients with prostate cancer, lung cancer and other solid tumors (renal, bladder and colorectal), breast cancer and multiple myeloma. This is the largest set of clinical trials ever conducted to evaluate the efficacy and tolerability of a bisphosphonate in treating the complications associated with cancerous bone lesions.

Novartis initially received marketing clearance for Zometa in the treatment of

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hypercalcaemia of malignancy (HCM), also known as tumor-induced hypercalcaemia (TIH). It has obtained approval for HCM in countries throughout the world.

### Contraindications and Adverse Events

In clinical trials in patients with bone metastases, Zometa was generally well tolerated, with a safety profile similar to other bisphosphonates. The most commonly reported adverse events included flu-like syndrome (fever, arthralgias, myalgias, skeletal pain), fatigue, gastrointestinal reactions, anaemia, weakness, cough, dyspnoea and oedema. Zometa should not be used during pregnancy. Zometa is contraindicated in patients with clinically significant hypersensitivity to zoledronic acid or other bisphosphonates, or any of the excipients in the formulation of Zometa.

Zometa and other bisphosphonates have been associated with reports of renal insufficiency. Patients should have serum creatinine assessed prior to receiving each dose of Zometa. Caution is advised when Zometa is administered with other potentially nephrotoxic drugs. Due to the risk of clinically significant deterioration in renal function, which may progress to renal failure, single doses of Zometa should not exceed 4 mg and the duration of infusion should be no less than 15 minutes.

This release may contain forward-looking statements regarding the potential launch of Zometa in markets in which it currently is not approved, or regarding potential new indications for Zometa in existing markets. Such forward looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results to be materially different from any future results, performance or achievements expressed or implied by such statements. There are no

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guarantees that Zometa or any potential new indications for Zometa will be commercialized in any market. Any such commercialization 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 and competition in general, as well as factors discussed in Novartis AG's Form 20-F filed 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.

### About Novartis

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MEDIA RELEASE o COMMUNIQUE AUX MEDIAS o MEDIENMITTEILUNG

Aromatase inhibitors in breast cancer assessed by ASCO Committee

Recent studies of aromatase inhibitors - a new generation of hormone therapy - prompt ASCO evaluation

Basel, 21 May 2002 - Data from recent studies on the use of aromatase inhibitors in the treatment of postmenopausal women with breast cancer have generated significant interest from the medical oncology community and have prompted organizations to evaluate current treatment regimens. Following data presented in December at a major breast cancer conference, the American Society of Clinical Oncology (ASCO) convened a blue ribbon panel to review the use of aromatase inhibitors.

#### Adjuvant Setting

Specific to the adjuvant breast cancer setting, the Committee reviewed the ATAC (Arimidex [anastrozole], Tamoxifen Alone or in Combination) data and declined to recommend the use of aromatase inhibitors at this time because of the lack of compelling and mature data. However, Novartis is encouraged that the Committee recognizes the importance of this category; and the Company is looking forward to the results of its ongoing Femara(R) (letrozole) adjuvant studies that should provide data sufficiently robust to enable the Committee to move forward with its recommendations. Currently, the largest set of adjuvant studies evaluating aromatase inhibitors - with more than 10,000 women participating - is evaluating the use of Femara. One study compares Femara to placebo in women who have remained disease free for five years of tamoxifen therapy; the other study compares Femara to tamoxifen in various treatment sequences over a period of five years. Results are expected in 2004.

#### Advanced Setting

Specific to the advanced breast cancer setting, data on aromatase inhibitors have been presented both at this year's ASCO meeting and at the December San Antonio Breast Cancer Symposium (SABCS 2001). At ASCO, data comparing the two leading aromatase inhibitors Femara and Arimidex were presented and demonstrated that 50% more women responded to Femara than Arimidex in the second-line treatment setting. This means that Femara is more likely than is Arimidex to

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shrink breast cancer tumours even in patients who had progressed after prior anti-estrogen therapy. There were no statistically significant differences in time to disease progression (primary endpoint) or other endpoints.

Data presented at the SABCS 2001 meeting showed that in the first-line advanced breast cancer setting, Femara offered a statistically significant greater early survival advantage throughout the first two years of therapy compared to tamoxifen. In addition, approximately five years after initiation of the study (November, 1996), more women who had begun therapy with Femara were

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still alive and free of tumor progression compared to those who started on tamoxifen. No differences were seen in duration of tumor response or overall survival.

Additional data from another study presented at the SABCS 2001 meeting demonstrated that Femara may be more effective than tamoxifen in treating postmenopausal women with ER and HER-2 positive breast cancer. The results are important because HER-2 positive breast cancers in postmenopausal women are especially difficult to treat.

Furthermore, results of the largest neo-adjuvant (pre-operative) trial evaluating endocrine agents demonstrated that Femara is a more effective therapy for postmenopausal women with hormone receptor positive tumours than tamoxifen. In 324 postmenopausal women with hormone-sensitive breast cancer, the number of clinical responses was significantly higher for Femara than for tamoxifen and significantly more women on Femara underwent breast-conserving surgery compared to tamoxifen.

### 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 women with disease progression after prior antiestrogen therapy. Femara is currently available in more than 75 countries worldwide. Not all indications are available in each country.

Femara is contraindicated in patients with known hypersensitivity to Femara or any of its excipients. Femara is generally well tolerated and adverse reactions rates in the first-line study in which Femara was compared to tamoxifen were similar with those seen in second-line studies. The most commonly reported adverse events for Femara vs. tamoxifen were bone pain (20% vs. 18%), hot flushes (18% vs. 15%), back pain (17% vs. 17%), nausea (15% vs. 16%), dyspnea or labored breathing (14% vs. 15%), arthralgia (14% vs. 13%), fatigue (11% vs. 11%), coughing (11% vs. 10%), constipation (9% vs. 9%), chest pain (8% vs. 8%) and headache (8% vs. 7%). 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  $\leq$  2%.

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 "looking forward to," "should provide data," "may be more effective" or similar expressions, or by discussions of potential new treatments or indications for Femara. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that any new

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treatments or indications for Femara will be commercialized in any market. 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. Some of these are uncertainties relating to unexpected regulatory delays; unexpected clinical trial results with Femara; additional analysis of clinical data; new data; government regulation or competition in general; as well as factors discussed in the Company's Form 20-F filed with the Securities and Exchange Commission.

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- Investor Relations Release -

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New head-to-head data show Glivec(R) is nearly three times more effective as first-line treatment for chronic myeloid leukemia patients than interferon combination therapy

Data Comparing Efficacy of Glivec to Interferon/Chemotherapy Combination Presented at American Society of Clinical Oncology Meeting

Basel, 21 May 2002 - Data from the first ever head-to-head study of the Novartis drug Glivec(R) (imatinib)\* demonstrate that Glivec is nearly three times more effective in achieving a cytogenetic response in the first-line treatment of newly diagnosed chronic myeloid leukemia (CML) patients than the combination of interferon-alpha and cytarabine arabinoside, a form of chemotherapy (IFN/Ara-C). In addition, Glivec significantly delayed the time to progression to the more advanced stages of CML compared to IFN/Ara-C. These new data were presented at the 2002 meeting of the American Society of Clinical Oncology (ASCO) in Orlando, Florida, USA. Glivec is a novel therapy that offers new hope to patients suffering from a disease that previously had very limited treatment options, and that has provided researchers with new insights into the biological mechanisms of cancer.

"The results clearly show that the earlier Glivec is used in treating CML, the better the response," said lead investigator Brian Druker, MD, Professor of Medicine, Oregon Health Sciences University. "These data are so supportive of using Glivec in patients newly-diagnosed with CML that physicians need to strongly reconsider the current treatment options for CML patients."

### Clinical Data

The International Randomised Study of Interferon vs. STI571 (IRIS) is an open-label Phase III trial that enrolled 1106 patients in 177 centres across 16 countries. There were two arms to the study: one arm received Glivec at 400 mg/day, the other arm received IFN at a target dose of 5 MIU/M2/day with Ara-C 20 mg/M2/day. The results presented were based on data collected up to 12 months after the last patient was randomised; the median follow-up was 14 months. The results showed that patients had achieved major and complete cytogenetic responses of 84% and 69% (Ph