

NOVARTIS AG  
Form 6-K  
November 04, 2002

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**SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**FORM 6-K**

**REPORT OF FOREIGN PRIVATE ISSUER**

**PURSUANT TO RULE 13a-16 or 15d-16 OF  
THE SECURITIES EXCHANGE ACT OF 1934**

**Report on Form 6-K for the month of October 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 acquires rights to AGE-breaker compound from Torrent
2. Novartis Oncology sharpens focus on key growth drivers
3. Novartis' bid for Lek clears important hurdle
4. New study confirms, Novartis drug Zelmac® is safe and effective for women with irritable bowel syndrome
5. New study shows Zelmac® effective and safe for people with non-Diarrhea Irritable Bowel Syndrome
- 6.

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Long-term benefit of Visudyne® therapy for wet age related macular degeneration published in Archives of Ophthalmology

7. Novartis close to successfully concluding its tender offer for Lek
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  10. Novartis looks ahead to continued dynamic launch program of innovative new medicines
  11. Diovan® (valsartan) improved survival and reduced hospitalizations in heart failure patients who did not take ACE inhibitors
  12. Novartis Ophthalmics and QLT launch phase III program to treat skin cancer
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13. Data suggest Novartis' Sandostatin® LAR® may treat newly-diagnosed acromegaly patients, avoiding need for invasive surgery
  14. Study shows benefits for patients with generalized tonic-clonic seizures with Trileptal®
  15. Studies show pharmacoeconomic benefits with Trileptal®
  16. First EU launch in France of Atopica®, a new medication for atopic dermatitis in dogs
  17. European health officials recognize unique dual inhibition properties of Alzheimer's disease drug Exelon®
  18. CIBA Vision and CooperVision Reach, Settlement in Color Contact Lens Patent Suit
  19. Study of aromatase inhibitor Femara® in adjuvant breast cancer setting reaches enrollment milestone
  20. Novartis' Zometa® a major advance in the treatment of serious bone-related complications of advanced prostate cancer featured in *National Cancer Institute* publication
  21. New long-term study shows Zelmac® safe and well tolerated by patients with irritable bowel syndrome
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**MEDIA RELEASE    COMMUNIQUE AUX MEDIAS    MEDIENMITTEILUNG**

**Novartis acquires rights to AGE-breaker compound from Torrent**

Basel, 31 October, 2002 Novartis Pharma AG announced today that it has reached an agreement with Torrent Pharmaceuticals Ltd., Ahmedabad, India, regarding global rights to an early-stage development compound known as an "AGE-breaker" and under investigation for potential use in the treatment of heart disease.

Torrent will be responsible for early stage research and development activities up to pre-defined endpoints, when Novartis has an option to acquire exclusive global rights. In addition to upfront and milestone payments, Torrent would also receive royalties on global sales and lead the co-promotion of the compound in India.

Thomas Ebeling, CEO of Novartis Pharma, said: "AGE is a potentially interesting target for our scientists. Joining forces with Torrent underscores our widening search for innovative compounds and partners throughout the world".

Samir Mehta, Managing Director of Torrent, said: "This association with Novartis will reinforce confidence in Torrent's research team".

AGE-breakers are so named because they break "crosslinks" between Advanced Glycosylation End products ("AGE"), which result from chemical interactions between sugars and proteins. Potentially harmful AGE molecules build up gradually in the body during the normal aging process. Scientists suspect that crosslinks, or chemical chains between AGE molecules, can cause stiffening of blood vessels and other soft tissues in the body. The development of AGE-breaker compounds able to break up these crosslinks could reduce age-associated vascular stiffness, providing benefits for patients by reducing hypertension.

The outstanding Novartis cardiovascular franchise includes Diovan® and Lotrel®, two of the fastest-growing anti-hypertensives in the US, as well as development projects such as the orally active renin inhibitor Aliskiren (SPP100).

The foregoing press release contains certain forward-looking statements related to the business of Novartis, that can be identified by terminology such as "potential use", "will be responsible", "an option", "would also", "potentially interesting", "could reduce", or similar expressions, or by discussions regarding potential future products. 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 potential product discussed here will ever be commercialized in any market. In particular, management's expectation regarding the commercial potential of Torrent's compound and Aliskiren in any market could be affected by, among other things, 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

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general, as well as factors discussed in the Company's Form 20-F filed with the Securities and Exchange Commission. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those described herein as anticipated, believed, estimated or expected.

Novartis AG (NYSE: NVS) is a world leader in pharmaceuticals and consumer 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 74 000 people and operate in over 140 countries around the world. For further information please consult <http://www.novartis.com>.

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**- Investor Relations Release -**

**Novartis Oncology sharpens focus on key growth drivers**

*Leucomax® rights sold to co-development and co-marketing partner Schering-Plough*

Basel, 30 October 2002 Novartis has signed an agreement to sell its international marketing and distribution rights for Leucomax® (molgramostim) to Schering-Plough Corporation (NYSE: SGP). Leucomax, which is used to reduce the severity of neutropenia (loss of white blood cells) in patients undergoing cancer chemotherapy, was co-developed by Novartis and Schering-Plough and has been co-marketed by the two companies in various countries since 1991. Financial details were not disclosed.

"This transaction enables us to further focus our portfolio on fast-growing treatments such as Glivec®, Femara® Sandostatin® LAR®, and Zometa® the successor compound to Aredia®\* which has just been very successfully launched for treating bone complications of advanced cancers", said David Epstein, President of Novartis Oncology.

The foregoing press release contains forward-looking statements that can be identified by terminology such as "to further focus" or similar expressions, or by implicit or explicit statements regarding future sales of our 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 regarding the sales levels for any product mentioned in any market. Any such sales can be affected by, among other things, uncertainties associated with the development and manufacturing of the treatment, the conduct and results of clinical trials, regulatory actions or delays or government regulations generally, the ability to obtain or maintain patent and other proprietary intellectual property protection, and competition in general, as well as factors discussed in Novartis AG's Form 20-F on file, and other filings with the US Securities and Exchange Commission. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those described herein as anticipated, believed, estimated or expected.

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**- Investor Relations Release -**

**Novartis' bid for Lek clears important hurdle**

*More than 51% of all Lek shares already tendered in public offer*

Basel, 29 October 2002 Novartis announced today that its public offer for Slovenia's leading drugmaker, which was due to expire on 4 November 2002, has already been accepted by shareholders holding the majority of Lek's shares - more than a week before the offer was due to end. The number of shares tendered in the offer now exceeds 985 920, or 51% of the total number of Lek's shares, which is the threshold needed for the bid to be declared "successful" when the offer expires.

As a result, and in accordance with Slovenian regulations, the offer now has to remain open for an additional 14 days until 12.00 noon on 18 November 2002, which will give all remaining Lek shareholders the opportunity to accept by tendering their shares. However, shareholders who wish to accept the offer are advised to tender their shares three or four days prior to this date, especially if they still have to set up a securities account. Novartis will publish the total number of shares tendered when the offer finally closes.

"The response we have received from Lek's shareholders since we raised the price has been very good. It underlines the attractiveness of the offer and reflects the fact that the main shareholders support the transaction", commented Christian Seiwald, Head of Novartis Generics.

The announced friendly intention of Novartis to acquire Lek would create a leading player in generics in the US, Western Europe, Central Eastern Europe (CEE), South Eastern Europe (SEE) and the Commonwealth of Independent States (CIS). With their unique complementarity and potential for stronger growth, both companies believe that they are partners of choice.

**About Lek**

Based in Ljubljana, Slovenia, Lek is an international group of generics companies and ranks among the leading pharmaceutical businesses in the CEE, SEE and CIS region, while having a broader international presence in several specific product lines. Lek is active in pharmaceuticals and veterinary products. In pharmaceuticals, it has a wide-ranging product portfolio, with substantial expertise in anti-infectives, cardiovascular and gastrointestinal tract products. The Lek Group employs about 3600 people in various regions and achieved total sales of SIT 78.5 billion (CHF 544 million), operating

income of SIT 9.6 billion (CHF 67 million) and net income of SIT 8.2 billion (CHF 57 million) in 2001. The company's market capitalization on 22 August 2002 was approximately SIT 129 billion (CHF 834 million). For further information please consult <http://www.Lek.si>.

**About Novartis**

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Novartis' Generics Business Unit comprises a number of companies that produce high-quality generics and active ingredients for the pharmaceutical and biotechnology industry. Because of its expertise in production and formulation, Novartis Generics can offer a broad range of high-quality pharmaceuticals at competitive prices. The Business Unit employs more than 7000 people worldwide and achieved sales of CHF 2.6 billion in 2001. In the first nine months of 2002, Novartis Generics' sales jumped 24% to CHF 2.02 billion.

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**MEDIA RELEASE    COMMUNIQUE AUX MEDIAS    MEDIENMITTEILUNG**

### **New study confirms, Novartis drug Zelmac® is safe and effective for women with irritable bowel syndrome**

*American College of Gastroenterology gives Zelmac "Grade A" recommendation*

Basel, 22 October 2002 New data published in *Alimentary Pharmacology & Therapeutics* (vol. 16, no 11) show the novel Novartis drug, Zelmac®\* (tegaserod) provides rapid relief from the multiple symptoms of abdominal pain, discomfort, bloating and constipation associated with Irritable Bowel Syndrome (IBS) with constipation in women. This study, one of the largest ever conducted in IBS, was one of three pivotal Phase III trials that were the basis for regulatory marketing applications for Zelmac.

In addition, today at the 67<sup>th</sup> Annual Meeting of the American College of Gastroenterology (ACG), the ACG Functional Gastrointestinal Disorders Task Force released a position statement on the management of IBS to assist physicians with diagnosing and treating patients. In this consensus statement, Zelmac received a "Grade A" recommendation, after a comprehensive review of Zelmac clinical trial data which demonstrated effective relief from the multiple symptoms of abdominal discomfort and pain, bloating, and constipation associated with IBS with constipation.

A "Grade A" recommendation is the highest of three (A, B, C) designations given by the American College of Gastroenterology Functional Gastrointestinal Disorders Task Force cited in the "Evidence-Based Position Statement on the Management of Irritable Bowel Syndrome in North America"<sup>1</sup>. These recommendations are supported by evidence of randomized controlled trials with p values < 0.05, adequate sample sizes and appropriate methodology.

"These study results and the treatment recommendations announced today reinforce our faith in Zelmac and highlight the benefit of Zelmac for treating patients suffering from the multiple symptoms of abdominal pain, discomfort and bloating associated with IBS with constipation", said Joerg Reinhardt, Head of Development, Novartis Pharma AG.

Zelmac significantly improved the multiple symptoms of IBS with constipation compared to placebo (P<0.05%), as measured by the Subject's Global Assessment of Relief (SGA), and other efficacy endpoints. The SGA is a tool for assessing overall relief by taking into consideration disease symptoms as well as general well-being. Symptom improvements were seen within the first week of Zelmac treatment, and were maintained throughout the treatment period. The twelve-week study results also showed Zelmac was safe and well tolerated.

"These data show tegaserod provided rapid and sustained symptom relief for women with IBS with constipation", said James S. Novick, MD, Principal Investigator, Charm City Research, Towson, Maryland, USA, the lead author of the study. "Importantly, the patients in this study are reflective of the general IBS patient population, and these data should be very heartening for the millions of women whose lives are

repeatedly disrupted because of their disorder".

### Study Details

In this prospective, randomized, double-blind, placebo-controlled study, 1,519 women at 131 centers in the United States received either Zelmec 6 mg b.i.d. (n=767), or placebo (n=752) for 12 weeks. The treatment period was preceded by a four-week baseline period without treatment, and followed by a four-week open withdrawal period. The primary efficacy endpoint was the patients' response, based on the SGA, and other efficacy variables included relief of abdominal pain/discomfort, bowel habits and bloating.

Patients in the Zelmec treatment arm experienced significant improvement in daily gastrointestinal symptoms from baseline versus patients in the placebo group, specifically less bloating, more bowel movements with a softer consistency and less need to strain. There was also an immediate improvement in stool consistency for patients treated with Zelmec during the first week of the double-blind treatment portion of the study, which was maintained throughout the treatment period and was significantly greater than with placebo (P<0.05).

IBS symptoms returned rapidly after the cessation of therapy, but did not return to baseline within the four-week study withdrawal period, suggesting that the efficacy of Zelmec in IBS with constipation persists for at least 12 weeks of treatment. The most common adverse event reported with Zelmec treatment was mild and transient diarrhea, at rates comparable to those seen in previous studies.

### About Irritable Bowel Syndrome

IBS is characterized by abdominal pain and discomfort, bloating and altered bowel function (constipation and/or diarrhea). The prevalence of IBS differs by country, however recent studies suggest that the disorder affects approximately 10-20% of the Western population. Until recently, the cause of IBS has been poorly understood and the disorder under-appreciated. However, in recent years, research has yielded a better understanding of IBS and its causes. People who have abdominal pain and discomfort, bloating and constipation associated with IBS may have altered sensitivity and altered motility of their lower GI tract. This may be due to the way their lower GI tract reacts to changes in serotonin (5HT), a naturally occurring chemical in their body that regulates motility and perception of pain and discomfort in the intestinal system.

### About Zelmec

Zelmec is the first in a new class of medicines, known as serotonin-4 receptor agonists (5HT<sub>4</sub> agonists) developed especially for the treatment of the multiple symptoms associated with IBS with constipation. By activating 5HT<sub>4</sub> receptors in the gastrointestinal tract, Zelmec normalizes impaired motility and reduces sensitivity of the intestinal tract. In clinical studies, significantly more patients experienced a general relief of symptoms when treated with Zelmec, such as a decrease in abdominal pain, bloating and constipation. In most patients, the onset of relief occurred within just one week. The medicine was well tolerated and showed a profile of side effects similar to that of placebo.

Zelmec was discovered and developed by Novartis. Zelmec known in the United States, Canada and South Africa as Zelnorm, is approved in more than 30 countries including Australia, Switzerland, Canada, the United States and Brazil.

The foregoing press release contains certain forward-looking statements related to the business of Novartis, which can be identified by implicit or explicit discussions regarding potential future sales of Zelmec/Zelnorm. 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 future sales of Zelmec/Zelnorm will reach any particular level. Management's expectation regarding the commercial potential of Zelmec/Zelnorm in any market could be affected by, among other things,

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 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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### Reference:

1. American Journal of Gastroenterology, Vol. 97, No. 11, 2002.

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**MEDIA RELEASE    COMMUNIQUE AUX MEDIAS    MEDIENMITTEILUNG**

### **New study shows Zelmac® effective and safe for people with non-Diarrhea Irritable Bowel Syndrome**

#### *Large study in Asian-Pacific population demonstrates Zelmac significantly improved symptoms*

Basel, 21 October 2002 New data presented today showed Zelmac®\* (tegaserod) is effective, safe and well tolerated for the treatment of non-Diarrhea Irritable Bowel Syndrome (non-D-IBS). The data were presented at the 10<sup>th</sup> Annual United European Gastroenterology Week (UEGW) congress in Geneva.

"These results showed tegaserod was effective in providing satisfactory relief of abdominal pain, discomfort and bloating for patients with non-Diarrhea Irritable Bowel Syndrome", said Professor John Kellow, of the Royal North Shore Hospital, University of Sydney, Australia and primary study investigator.

Zelmac-treated patients experienced significantly greater relief from their IBS symptoms, with approximately a 20% improvement versus placebo during the first four weeks of a twelve-week clinical trial. A consistent pattern of improvement for other efficacy variables, including response profiles and individual symptom relief, were observed in Zelmac-treated patients, with a significant effect on the number of days without abdominal discomfort/pain and bloating in the last four weeks of treatment.

"These results are very encouraging and demonstrate the efficacy and safety of Zelmac for the many patients with non-Diarrhea Irritable Bowel Syndrome", said Joerg Reinhardt, Head of Development, Novartis Pharma AG.

The study objective was to assess the efficacy and safety of 12 mg/d treatment of Zelmac in 520 Asian-Pacific patients with non-D-IBS. After a two-week placebo-free baseline period, patients fulfilling the Rome II criteria for non-D-IBS were randomized to receive Zelmac (n=259) or placebo (n=261) over a 12-week double-blind treatment period, followed by a four-week placebo-free withdrawal period. Efficacy was assessed weekly by the overall relief of IBS symptoms. The primary and secondary efficacy variables were the response profiles over weeks 1-4 and weeks 1-12 respectively. Additional efficacy variables included intensity of abdominal discomfort/pain and bloating.

The overall frequency of adverse events was comparable between the two study groups, with diarrhea as the most common adverse event (10.4% Zelmac group vs. 4.2% placebo group). The overall discontinuation rate was 16% in the Zelmac group and 12% for the placebo group.

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



IBS is characterized by abdominal pain and discomfort, bloating, and altered bowel function (constipation and/or diarrhea). 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 and discomfort, bloating and constipation associated with IBS may have altered sensitivity and altered motility of their lower GI tract. This may be due to the way

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their lower GI tract reacts to changes in serotonin (5HT), a naturally occurring chemical in their body that regulates motility and perception of pain and discomfort in the intestinal system.

#### **About Zelmac**

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**- Investor Relations Release -**

**Long-term benefit of Visudyne® therapy for wet age related macular degeneration published in Archives of Ophthalmology**

*Positive 36 and 48 month trial extension results show vision benefit over time in predominantly classic subfoveal wet AMD*

Basel, 21 October 2002 Data published in the current issue of Archives of Ophthalmology shows that visual outcomes remain stable during the third year of Visudyne® (verteporfin) therapy in patients treated for choroidal neovascularization (CNV) due to age-related macular degeneration (AMD), the leading cause of blindness in people over the age of 50. The research was sponsored by Novartis Ophthalmics, the eye health unit of Novartis AG and QLT Inc. and is based on an open-label extension of the two pivotal Phase III clinical trials, the Treatment of AMD in Photodynamic Therapy (TAP) Investigation.

The average visual acuity of patients originally assigned to Visudyne with predominantly classic subfoveal CNV caused by AMD remained stable between the 24 and 36 month follow-up as reported in the publication. Analysis of 48 month results recently presented at the Joint Meeting of the Retina Society and Vitreous Society in San Francisco, confirmed the maintenance of vision over this longer period.

"For a chronic, often progressive disease such as the wet form of advanced AMD, evidence of longer term maintenance of vision through three and four years is very good news for both patients and physicians. We now know that by treating with Visudyne therapy today we not only are helping our patients reduce their risk of vision loss, but also that visual loss does not appear to continue indefinitely. The chance of additional vision loss appears unlikely to occur in a patient beyond two years after the onset of therapy", said Dr. Neil Bressler, Chair of the Visudyne Study Advisory Group, and retinal specialist and the James P. Gills Professor of Ophthalmology at the Wilmer Eye Institute of the Johns Hopkins University School of Medicine in Baltimore, Maryland, USA.

In the 48 month follow-up, the number of Visudyne treatments required in the ongoing trial was just over 7 with approximately half the patients needing a treatment in the 4th year to maintain their vision. Furthermore, the favorable safety profile previously demonstrated with Visudyne continued throughout the 36 and 48 month analyses.

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Visudyne therapy is a relatively painless two-step procedure. Following intravenous administration, Visudyne is activated by a non-thermal laser light. This process is known as photodynamic therapy. Visudyne selectively targets abnormal blood vessels on the retina, resulting in a reduction in their growth, without affecting normal/healthy retina tissue. This in turn stops the leakage associated with wet AMD.

Following the conclusion of the TAP Investigation, consisting of 2 two-year randomized, double-masked, placebo-controlled trials, 78% of the 609 patients originally included were offered Visudyne therapy in an ongoing 3-year, open-label extension trial regardless of whether they previously received Visudyne or a placebo in the original study.

**About AMD**

AMD and its associated vision loss have been shown to decrease patient quality of life significantly. Every day tasks such as driving and walking can be severely affected. Awareness of the condition and treatment in the early stages of the disease are essential in order to help patients take the necessary steps to visit their physician and begin therapy to halt progression of AMD. Through its unique mode of action, Visudyne provides the chance to preserve vision long-term.

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 months to years. "Occult" and "classic" are terms used to describe the different patterns of CNV leakage as seen on fluorescein angiography. Classic CNV appears as a well-demarcated area of hyperfluorescence in the early-phase frames of the angiogram. The boundaries of occult CNV are often poorly defined or difficult to demarcate and hyperfluorescence appears in the late-phase frames of the angiogram.

## About Visudyne

Visudyne therapy, the only drug approved for the treatment of some forms of wet AMD, has treated over 200,000 patients worldwide. Visudyne is commercially available in more than 65 countries for the treatment of predominantly classic subfoveal CNV and in 24 countries for occult subfoveal CNV caused by AMD. It is also approved in over 45 countries, including the EU, U.S. and Canada, for the treatment of subfoveal CNV due to pathologic myopia (severe near-sightedness). In some countries Visudyne is also approved for presumed ocular histoplasmosis or other macular diseases.

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).

## Note to editors

Funding for the study described was provided by Novartis Ophthalmics and QLT Inc. Dr. Bressler has been paid as a consultant to both companies. The terms of this agreement are being managed by the Johns Hopkins University in accordance with its conflict of interest policies.

The foregoing press release contains forward-looking statements, that can be identified by discussions regarding potential future sales of Visudyne, or regarding the consequences of long-term use of Visudyne therapy. 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

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statements. There can be no guarantee that future sales of Visudyne will reach any particular level. Neither can there be any guarantee of the consequences for any patient or patients of long-term use of Visudyne. Any such future results, performance or achievements may be affected by a number of factors which include, but are not limited to: 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; outcome of litigation claims, product liability claims and insurance; government regulation; anti-takeover provisions; dependence on corporate relationships; volatility of share prices; QLT Inc.'s rapid growth, its history of operating losses and uncertainty of future profitability, its access to capital; and additional information and other 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.

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).

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 most successfully launched ophthalmology product ever. For more information, visit our web site at [www.qltinc.com](http://www.qltinc.com).

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**- Investor Relations Release -**

**Novartis close to successfully concluding its tender offer for Lek**

*Major shareholders of Lek commit to support Novartis' takeover bid for Slovenia's leading drugmaker, at a price of SIT 105 000 per share*

Basel, 18 October 2002 In recognition of additional business potential identified in the generics market where Lek is active Novartis has indicated its readiness to increase its offer to SIT 105 000 per share (A and B shares) to all Lek shareholders. This implies a market capitalization for Lek of approximately SIT 203 billion (CHF 1.3 billion). Lek's main shareholders have agreed to tender all of their Lek shares at the now increased offer price and to fully support the combination of Lek and Novartis Generics. In accordance with Slovenian regulations the price increase will automatically lead to an extension of the offer by one week to 4 November 2002.

Christian Seiwald, Head of Novartis Generics explained the rationale for Novartis' decision: "Our decision to increase our offer is following the reassessment of the business opportunities created by the combination with Lek and the irrevocable commitment of Lek's main shareholders to tender their shares and to support the transaction".

The announced friendly intention of Novartis to acquire Lek would create a leading player in generics in the US, Western Europe, Central Eastern Europe (CEE), South Eastern Europe (SEE) and the Commonwealth of Independent States (CIS). With their unique complementarity and potential for stronger growth, both companies believe that they are partners of choice.

**About Lek**

Based in Ljubljana, Slovenia, Lek is an international group of generics companies and ranks among the leading pharmaceutical businesses in the CEE, SEE and CIS region, while having a broader international presence in several specific product lines. Lek is active in pharmaceuticals and veterinary products. In pharmaceuticals, it has a wide-ranging product portfolio, with substantial expertise in anti-infectives, cardiovascular and gastrointestinal tract products. The Lek Group employs about 3600 people in various regions and achieved total sales of SIT 78.5 billion (CHF 544 million), operating income of SIT 9.6 billion (CHF 67 million) and net income of SIT 8.2 billion (CHF 57 million) in

2001. The company's market capitalization on 22 August 2002 was approximately SIT 129 billion (CHF 834 million). For further information please consult <http://www.Lek.si>.

**About Novartis**

Novartis' Generics Business Unit comprises a number of companies that produce high-quality generics and active ingredients for the pharmaceutical and biotechnology industry. Because of its expertise in production and formulation, Novartis Generics can offer a broad range of high-quality pharmaceuticals at competitive prices. The Business Unit employs more than 7000 people worldwide and achieved sales of CHF 2.6 billion in 2001. In the first nine months of 2002, Novartis Generics' sales jumped 24% to CHF 2.02 billion.

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

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### - Investor Relations Release -

#### Novartis signs an agreement with Tanabe Seiyaku to develop LFA-1 antagonists

Basel, 18 October 2002 Novartis Pharma AG announces that it has signed an agreement with Tanabe Seiyaku Co., Ltd. to collaborate on the research, development and potential commercialization of Tanabe's Leukocyte Function-Associated Antigen-1 (LFA-1) antagonists. These early stage compounds have potential in inflammatory autoimmune diseases, as well as immunosuppression for transplantation.

Under the agreement, Novartis gains the exclusive license to develop, market and sell any of Tanabe's LFA-1 antagonists for all indications in a territory that includes the United States and Europe and many other countries. Tanabe retains these rights in Japan and selected Asian countries. It is intended to start with clinical development of these early stage compounds within two years.

Thomas Ebeling, CEO of Novartis Pharma, said, "LFA-1 antagonists are a novel approach that have potential for the treatment of diseases such as rheumatoid arthritis, psoriasis, transplantation and multiple sclerosis. We are excited about exploring the opportunities that this agreement with Tanabe Seiyaku presents".

#### About Leukocyte Function-Associated Antigen-1

LFA-1 is an integrin-type cell adhesion molecule expressed on the surface of white blood cells (leukocytes) responsible for leukocyte trafficking and T-cell co-activation. Leukocyte trafficking and T-cell co-activation are important processes in the pathogenesis of inflammatory disease states. The importance of the LFA-1 target in inflammatory and autoimmune diseases has been validated in animal disease models. The LFA-1 antagonists identified by Tanabe inhibit leukocyte trafficking and T-cell co-activation, suggesting a therapeutic potential in the treatment of autoimmune disorders such as rheumatoid arthritis and psoriasis, and for the prevention of the rejection of organ transplantations.

This press release contains forward-looking statements that can be identified by terminology such as "to collaborate", "potential" "intended to start", "exploring the opportunities", or similar expressions, or by discussions or by discussions regarding the potential development and commercialization of new products. 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. There can be no

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guarantee that any new product will be developed or commercialized in any market as a result of the collaboration described above. In particular, management's expectations regarding future research development results, in particular in connection with early stage compounds such as those described here, could be affected by, among other things, uncertainties relating to clinical trials and product development; unexpected regulatory delays or restrictions or government regulation generally; the company's ability to obtain or maintain patent and other proprietary intellectual property protection; and competition in general, as well as factors discussed in the Company's Form 20F filed with the US Securities and Exchange Commission. Should one or more of these risks or uncertainties materialise, or should underlying assumptions prove incorrect, actual results may vary materially from those described herein as anticipated, believed, estimated or expected.

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**- Investor Relations Release -**

**Novartis looks ahead to continued dynamic launch program of innovative new medicines**

*Steady flow of compounds in development: ten new molecular entities (NMEs) launched in the US since 2000; broad innovative platform of 67 projects in clinical development*

*Comprehensive clinical development programs for recently launched, innovative products including Glivec/Gleevec, Zometa, Zelmac/Zelnorm, Diovan, Lotrel, and Elidel offer significant additional growth opportunities*

New York/Basel, 17 October 2002 At its Pharmaceuticals "R&D day" in New York today, Novartis is unveiling details of its pipeline, a strong R&D engine to sustain the launch of innovative medicines. This event is being webcast on <http://www.novartis.com>.

**Broad innovative portfolio of 67 pipeline projects in attractive markets**

In the past two years, Novartis has achieved the highest number of key-market approvals in the pharmaceutical industry, with 20 registrations and 22 major submissions in the US, EU and Japan. Novartis has successfully launched a number of high profile new products in the key US market, including *Glivec/Gleevec* and *Zometa* for cancer patients, *Elidel* for eczema and *Zelmac/Zelnorm* for irritable bowel

syndrome, further rejuvenating the product portfolio. For all of these major brands, development projects are underway to support further indications and fully develop their therapeutic and commercial potential.

With a steady flow of development compounds, the pipeline is under constant review and currently comprises a total of 67 projects in clinical development. Overall, there are 30 projects in late-stage development (Phase III/regulatory), to sustain mid-term growth, and a substantial number (25) of projects in Phase II. To increase R&D capacity and strengthen the skill base, more than 1000 research scientists and associates have been added over the past two years.

## Highlights

### Projects supporting innovative product launches and new indications

**Diovan** (hypertension): To realize the full therapeutic potential of its leading blockbuster antihypertensive, Novartis is undertaking the most comprehensive clinical trial program among the angiotensin II receptor blocker class of antihypertensives. It includes some 37 500 patients and is investigating areas of high medical need beyond the currently approved formulations, strengths and indications. In addition to broadening the extensive base of safety data, this program has already led to the launch of new dosage strengths and to *Diovan* becoming the only ARB to gain approval for treatment in heart failure for patients intolerant of ACE inhibitors. The major ongoing trials are evaluating long-term use (VALUE), post myocardial infarction (VALIANT), and blood pressure control in diabetes and impaired glucose tolerance outcomes (NAVIGATOR).

**Lotrel** (hypertension): Novartis' second flagship antihypertensive is being expanded into the moderate-to-severe disease segment. Data show that nearly 50% of patients who start on an ACE inhibitor as monotherapy will not achieve their blood pressure goal. In contrast, approximately 90% of *Lotrel* patients do, without compromising on the added benefits of an ACE inhibitor.

**Elidel** (eczema): This effective and well-tolerated steroid-free treatment has become the number-one branded topical treatment for eczema in the US within just six months of launch, and is also the subject of an intense clinical program. Studies are in progress to expand the treatment population in order to explore further applications.

**Zelnorm/Zelmac** (constipation prone irritable bowel syndrome): Because irritable bowel syndrome is an under-diagnosed and under-treated disease, a science-based approach is being adopted to inform physicians and patients about diagnosis and treatment benefits. Based on scientific advice from the EMEA, a clinical trial is in progress to support approval in the EU. An advanced program is underway to explore new indications, including chronic constipation, functional dyspepsia and gastro-esophageal reflux disease.

**Visudyne** (treatment in age-related macular degeneration): Novartis and QLT Inc. have initiated Phase III trials to expand photodynamic therapy with verteporfin into the treatment of skin cancer and other dermatological conditions.

### NMEs in late-stage development (Phase III)

**Certican** (transplantation) was recently submitted in Europe for approval in kidney and heart transplantation and will be filed in the US by December 2002, strengthened by additional long-term data in renal and heart transplantation.

**Myfortic**, a compound in development for transplantation is an advanced enteric-coated formulation of mycophenolate sodium and has been developed to protect the upper gastrointestinal tract. European and US launches are slated for 2003 and 2004 respectively.

**Prexige** (osteoarthritis, rheumatoid arthritis and pain): Novartis' COX-2 inhibitor is on track for filing in the US and Europe in December 2002, with launches forecast in 2004. The product has demonstrated fast, powerful and sustained pain relief with good overall tolerability and a favorable gastrointestinal safety profile. Initial filings are anticipated for the 400 mg dose in acute pain and dysmenorrhea and the 200 mg dose in chronic arthritis indications. TARGET, the world's largest clinical trial to date in arthritis involving more than 18 000 patients, will complete recruiting in December and will deliver long-term tolerability data.

**Zoledronic acid** (postmenopausal osteoporosis and Paget's disease) progressed to Phase III clinical trials in January 2002. New data were published in the February edition of the *New England Journal of Medicine* demonstrating the drug's efficacy in increasing bone mineral density in post-menopausal

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women with osteoporosis after a once-yearly dose. A study in 7400 postmenopausal osteoporosis patients is under way. With Phase III progressing well, promising results suggest a possible launch in 2006 in Paget's disease.

**Xolair** (asthma), a novel treatment for allergic asthma, gained its first marketing approval in Australia. With its partner Genentech, Novartis has doubled the number of patients in clinical trials to more than 6000 and expects to resubmit its file with additional data in the US at the end of the current year and in the EU at the end of 2003. *Xolair* is a monoclonal antibody to IgE in development by Novartis, Genentech Inc., and Tanox Inc.

#### **Rich early to mid-term pipeline: compounds in Phase II / I**

To complement the post-launch and Phase III pipeline, Novartis has an attractive portfolio of novel compounds in early and mid development, balanced over a range of therapeutic areas.

#### **Primary Care**

**SPP100** (hypertension), the first oral renin inhibitor, may offer a new alternative for mono- and combination therapy for hypertension and several cardiovascular conditions. Novartis exercised its call-back option from Speedel for this compound, and Phase III is scheduled to begin in the second half of 2003.

**LAF237** (type 2 diabetes) represents a novel therapeutic concept: DPP IV inhibition leading to increased levels of GLP-1. Initial findings confirm safety, tolerability and the drug's ability to lower glucose levels without increasing overall insulin exposure. An extensive clinical program is in progress.

**AMP397** (epilepsy) is the first competitive AMPA receptor antagonist in development as an oral anticonvulsant. Phase II studies are expected to commence in 2003.

**TCH346** (Parkinson's disease) is currently undergoing Phase II clinical trials for Parkinson's disease and amyotrophic lateral sclerosis. Preclinical trials suggest that TCH346 has a unique pharmacological action that may offer neuroprotection, bringing much benefit to the rapidly growing population of Parkinson's disease sufferers.

**AAG561** (anxiety, depression) could be the first in class among the corticotropin releasing factor 1 antagonists, a novel concept in the treatment of depression and anxiety, which encompasses huge patient populations. Phase II clinical trials are expected to start early next year.

**QAB149** (asthma and COPD) is a new once-a-day bronchodilator with a fast onset action and a long duration. Phase II clinical trials have been initiated.

**AAE581** (osteoporosis) is an innovative cathepsin K (an enzyme that degrades bone matrix) inhibitor in development. This new drug inhibits cathepsin K activity in osteoclasts which leads to reduced collagen breakdown and decreased bone resorption. Phase II is scheduled to begin in January 2003.

**SAB378** (chronic pain), a cannabinoid (CB<sub>1</sub>) agonist, is a novel concept in treating chronic pain, which, on the basis of preclinical results, could be more potent than major current treatments. The clinical program is under way, with the proof of efficacy study results expected in 2003.

#### **Transplantation**

**FTY720**, a novel concept in selective immunosuppression, is being evaluated for prevention of acute rejection and graft loss in kidney transplant patients. It has been shown to protect the transplanted organ against T-cells without changing the host's ability to respond to antigens. Currently in Phase II, FTY720 has shown very low acute rejection rates in combination with low-dose Neoral.



## Oncology

**ICL670**, an oral iron chelating compound for the treatment of iron overload in transfusion-dependent anemias. With a once daily administration, it is expected to eventually replace the current treatment, *Desferal*, which is administered via a daily subcutaneous infusion over 8-12 hours. Phase III clinical trials of ICL670 will be initiated in early 2003.

**PTK787**, an angiogenesis inhibitor working through the VEGF pathway, blocks blood vessels that supply tumors. The compound is a co-development, co-marketing project with Schering AG. Phase III trials are expected to commence soon. PTK787 could be the first oral drug of its kind to reach the market.

**EPO906** exerts its anti-tumor activity by inhibiting microtubule depolymerization in cancer cells. Early results in several solid tumor types have been promising and Phase II trials are underway.

## Development times and costs streamlined

In a conservative regulatory climate, Novartis Development has continued to achieve productivity improvements, cutting the average time to commercialize its new products from eight and a half years in 1996-8 to the current seven, just over a year faster than the industry average. This has been achieved by continuously improving skills and processes and exploiting innovative approaches, such as e-clinical management, where Novartis is among the leaders. Electronic data capture is now used in more than 90% of new trials, leading to a marked reduction in outsourced clinical trials, improved data quality and speed of clinical trial reporting. Another important advantage of e-clinical is the deployment of E-portals for patients, offering for example greater information to patients during trials and improvement of patient recruitment.

This press 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 "looks ahead", "launches planned", "on track for filing", "in progress", "intended", "forecast", "expected" or similar

expressions or by discussions of strategy, plans, intentions or potential outcomes. Such statements include descriptions of the Company's investment and research and development programs and anticipated expenditures in connection therewith, descriptions of new products expected to be introduced by the Company and anticipated customer demand for such products as well as products in the Company's existing portfolio. Such statements reflect the current views of the Company with respect to future events and are subject to certain risks, uncertainties and assumptions. There can be no guarantee that any product or potential new indications for existing products 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. These factors include, among other things, unexpected regulatory delays, uncertainties relating to clinical trials and product development, the introduction of competing products, increased government pricing pressures, and the Company's ability to obtain or maintain patent and other proprietary intellectual property protection as well as other 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.

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**MEDIA RELEASE    COMMUNIQUE AUX MEDIAS    MEDIENMITTEILUNG**

### **Novartis looks ahead to continued dynamic launch program of innovative new medicines**

*Data demonstrate long-term benefit and safety of the 15-minute Zometa infusion; breast-cancer patients had lower risk of developing bone complications on Zometa than on pamidronate*

Basel, Switzerland, 16 October 2002 Novartis announced today it is submitting a supplemental new drug application (sNDA) with the US Food and Drug Administration (FDA) to include data demonstrating the longer-term benefit of Zometa® (zoledronic acid) for patients with bone metastases from advanced cancers.

Zometa is indicated for the treatment of patients with multiple myeloma and patients with documented bone metastases from solid tumors, in conjunction with standard antineoplastic therapy. In prostate cancer, patients should have progressed after treatment with at least one hormonal therapy. The solid tumors studied included prostate, breast, lung, renal and colorectal cancer. This indication is based on data from three large pivotal trials that evaluated the drug for a treatment period of approximately one year. The sNDA reports on approximately two years of treatment and safety data.

The final analyses not only confirm the long-term efficacy and safety profile of Zometa in all tumor types studied but also demonstrate in a multiple event analysis that breast cancer patients with metastasis to bone who have been treated with Zometa 4 mg in a 15 minute infusion had a lower risk of developing skeletal complications than women treated with pamidronate 90 mg infused over two hours. The multiple event analysis measures the occurrence of Skeletal Related Events (SREs) over the entire course of treatment. These complications include among others pathologic fractures, a need for radiation or surgery to bone, spinal cord compression and hypercalcemia.

"Tens of thousands of patients have benefited from Zometa, an effective and convenient therapy to treat the debilitating bone complications associated with advanced cancer", said David Epstein, President, Novartis Oncology. "The new data demonstrate that the benefits of Zometa are sustained over a longer-time period, and that Zometa should be the treatment of choice for this patient population".

## Clinical Data

The data were analyzed from three large multicentre, randomized pivotal trials of more than 3,000 patients. Combined, they represented the largest clinical program ever conducted to evaluate the efficacy and safety of bisphosphonates in patients with bone metastases. The final analysis of these three trials demonstrate that the benefits of Zometa were maintained over the approximately two years of treatment follow-up. In addition, breast cancer patients treated with Zometa 4 mg had a lower risk of developing skeletal complications ( $p=0.025$ ) after two years of treatment, compared with those treated with pamidronate 90 mg.

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The final analyses of the three pivotal trials of Zometa in patients with multiple myeloma and metastasis to bone from solid tumors, such as prostate, breast, lung and renal, confirm the significant clinical benefit seen and submitted as part of the original FDA filing. (Prostate cancer 15-month data updated to show a total of 24 months of follow-up; lung cancer and other solid tumors nine-month data updated to show a total of 21 months of follow-up; breast cancer and multiple myeloma 13-month data updated to show a total of 24 months of follow-up).

Zometa was initially studied at both a 4 mg and an 8 mg dose in these trials. However, the 8 mg dose offered no efficacy advantage when compared with the recommended dose of 4 mg infused in 15 minutes, but was associated with a higher incidence of adverse events, including increased serum creatinine levels, and renal function deterioration, as well as renal failure. Therefore, dosing in these arms was changed from 8 mg to 4 mg and this group was not included in these efficacy analyses.

Zometa also is indicated for the treatment of hypercalcemia of malignancy (HCM), the most common life-threatening metabolic complication of cancer.

## About Zometa

Novartis has received marketing authorization for Zometa in more than 50 countries, including the United States and the European Union Member States, for the prevention of skeletal related events in patients with advanced malignancies involving bone. These malignancies include multiple myeloma, prostate cancer, breast cancer, lung cancer, renal cancer and other solid tumors. Previously, Novartis received marketing clearance for Zometa in the treatment of hypercalcaemia of malignancy (HCM), also known as tumor-induced hypercalcaemia (TIH), in more than 70 countries throughout the world.

## Contraindications and adverse events

In clinical trials in patients with bone metastases and hypercalcemia of malignancy, Zometa had a safety profile similar to other intravenous bisphosphonates. The most commonly reported adverse events included flu-like syndrome (fever, arthralgias, myalgias, skeletal pain), fatigue, gastrointestinal reactions, anemia, weakness, cough, dyspnea and edema. 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. 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.

The foregoing release contains forward-looking statements that can be identified by discussions regarding potential new indications for Zometa, or regarding potential future sales of Zometa. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results with Zometa to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Zometa will be approved for any additional indications in any market. Neither can there be any guarantee regarding potential future sales of Zometa. In particular, management's ability to ensure satisfaction of the health authorities' further requirements is not guaranteed and management's expectations regarding commercialization of Zometa could be affected by, among other things, additional analysis of Zometa clinical data; new clinical data; unexpected clinical trial results; unexpected regulatory actions or delays or government regulation generally; the company's ability to obtain or maintain patent or other proprietary intellectual property protection; competition in general; and other risks and factors referred to in the Company's current Form 20-F on file with the US Securities and Exchange Commission of the United States. Should one or more of these risks or uncertainties materialize, or should underlying

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assumptions prove incorrect, actual results may vary materially from those anticipated, believed, estimated or expected.

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Additional information on Novartis Oncology and Zometa can be found at [www.novartisoncology.com](http://www.novartisoncology.com) or [www.zometa.com](http://www.zometa.com). Additional media information can be found at [www.novartisoncologyvpo.com](http://www.novartisoncologyvpo.com).

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**MEDIA RELEASE    COMMUNIQUE AUX MEDIAS    MEDIENMITTEILUNG**

**Diovan® (valsartan) improved survival and reduced hospitalizations in heart failure patients who did not take ACE inhibitors**

*New findings from Val-HeFT published in the Journal of the American College of Cardiology*

Basel, 16 October 2002 Data published today in the *Journal of the American College of Cardiology* demonstrates that valsartan, an angiotensin II receptor blocker (ARB), significantly reduced heart failure mortality by 33 per cent ( $p=0.017$ ), morbidity by 44 per cent ( $p<0.001$ ) and hospitalizations by 56.4 per cent ( $p=0.010$ )<sup>1</sup> compared with placebo in patients from the Valsartan Heart Failure Trial (Val-HeFT) who also took standard heart failure therapies,<sup>1</sup> but not ACE inhibitors. The lead author of the article was Professor Aldo Maggioni, one of the Val-HeFT investigators, from the GISSI Group (Gruppo Italiano per lo Studio della Sopravvivenza nell'Infarto), Italy.\*

Based on these findings of Val-HeFT, findings, Diovan recently became the only ARB approved in the United States for the treatment of heart failure in patients who cannot tolerate ACE inhibitors. Despite their known benefits, studies have shown that 20 to 54 per cent of heart failure patients are not prescribed ACE inhibitors because of side effects or other factors.<sup>1,2</sup> Treatment guidelines by the European Society of Cardiology (ESC) and other similar prestigious organizations already recommend the use of ARBs such as Diovan for patients who cannot tolerate ACE inhibitors.

"While ACE inhibitors are known to reduce mortality and morbidity from heart failure, many patients are not prescribed these drugs because of concerns about side effects", Professor Maggioni said. "Our analysis suggests that valsartan can serve as a safe, effective substitute for ACE inhibitors for the management of heart failure".

In addition to these findings an economic analysis recently presented at the 2002 ESC Congress showed that Diovan is a highly cost-effective treatment for heart failure patients who are not already taking ACE inhibitors.<sup>3</sup> This analysis, based on data from Val-HeFT, showed that on average direct treatment costs were USD \$929 lower in heart failure patients who took Diovan along with other heart failure treatments prescribed by their physicians, but not ACE inhibitors.

In Val-HeFT, 366 study patients were not treated with ACE inhibitors by their physicians. In addition to the significant reductions in heart failure mortality, morbidity and hospitalizations, findings on other endpoints in this group were also consistently positive, indicating favorable

effects on disease progression.<sup>1</sup> These findings included important measures of cardiac function including significant improvements in ejection fraction, and significantly smaller mean left ventricular internal diastolic diameter/body surface area at last observation. In addition, quality of life, as measured by the Minnesota Living with Heart Failure Questionnaire (MLHFQ), a standard assessment tool, was significantly improved in the valsartan group at one year with a trend for sustained improvement at two years and at study conclusion.<sup>1</sup>

"This new Val-HeFT analysis published today is consistent with was the basis for the recent FDA approval and reinforces the critical role Diovan plays in the management of heart failure," said Joerg Reinhardt, Global Head of Pharma Development, Novartis Pharma AG. "Novartis is committed to exploring the benefits of Diovan beyond hypertension spanning the entire continuum of cardiovascular disease."

A landmark study of 5,010 patients in 302 centers in 16 countries, Val-HeFT studied the effects of valsartan in heart failure patients also taking standard heart failure therapies, which included beta blockers, diuretics, digoxin, and ACE inhibitors.<sup>1</sup>

Val-HeFT was the largest study ever conducted in heart failure. Overall findings of Val-HeFT, published in the *New England Journal of Medicine* demonstrated valsartan significantly reduced morbidity by 13.2 per cent ( $p=0.009$ ) and hospitalization for heart failure by 27.5 per cent ( $p<0.001$ ) in patients already receiving prescribed therapy.<sup>4</sup> Previously released findings also showed valsartan significantly improved ejection fraction ( $p=0.001$ ), NYHA functional class ( $p<0.001$ ) and clinical signs and symptoms of heart failure. Patients taking valsartan also experienced a significantly better quality of life ( $p=0.005$ ), as measured by the MLHFQ. The rate of all-cause mortality was similarly low in the two groups during the course of the study.<sup>4</sup> The benefits demonstrated in Val-HeFT did not appear to extend to the subgroup of patients taking Diovan in combination with both an ACE inhibitor and a beta blocker.<sup>4</sup>

Heart failure is currently the fastest growing cardiovascular disease in the world and the most common reason why the elderly are hospitalized. An estimated 20 million people worldwide suffer from this devastating condition.<sup>5</sup>

Diovan is already approved for first-line treatment of high blood pressure in more than 80 countries, including the US, where it is also indicated for treatment of heart failure patients who are intolerant of ACE inhibitors. One of the fastest growing agents among the top 10 branded prescription medications for this condition, an estimated three million patients worldwide take Diovan for high blood pressure.

Diovan is supported by the world's largest clinical trial programme with an ARB involving more than 40,000 patients including more than 8,000 with diabetes in major ongoing trials. These studies are examining the effects of Diovan in patients across the cardiovascular continuum, from those with impaired glucose tolerance (IGT commonly referred to as pre-diabetes), to those with hypertension at high-risk of cardiovascular events, and post-MI patients. Besides Val-HeFT, other trials examining the effect of Diovan beyond its existing indications for hypertension and heart failure include, VALUE (patients with hypertension at high-risk of cardiovascular events), VALIANT (post-myocardial infarction patients), and NAVIGATOR (patients with IGT at high risk for cardiovascular events).

This release contains certain "forward-looking statements", relating to the business of Novartis, which can be identified by the use of forward-looking terminology such as "committed to exploring", "are examining", or similar expressions, or by express or implied statements regarding the potential for additional sales of Diovan in the US as a result of this new information, or by discussions of potential additional indications for Diovan. 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 of any additional sales of Diovan in the US or elsewhere as a result of this new information, or that the aforementioned clinical trials will result in the commercialization of any additional indications for Diovan in any market. Any such commercial success or commercialization of additional indications, or other results, can be affected by, amongst other things, 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 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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Novartis AG (NYSE: NVS) is a world leader in pharmaceuticals and consumer 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 74 000 people and operate in over 140 countries around the world. For further information please consult <http://www.novartis.com>.

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The GISSI Group is jointly sponsored by the Italian Association of Hospital Cardiologists (ANMCO) and the Istituto di Ricerche Farmacologiche, Mario Negri, Italy.

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**MEDIA RELEASE    COMMUNIQUE AUX MEDIAS    MEDIENMITTEILUNG**

### **Novartis Ophthalmics and QLT launch phase III program to treat skin cancer**

*Trials will investigate the ability of using Photodynamic therapy with verteporfin to eliminate multiple basal cell carcinoma*

Basel, 11 October 2002 Novartis Ophthalmics, the eye health unit of Novartis, and QLT Inc. announced today the start of patient enrollment in two phase III clinical trials using photodynamic therapy (PDT) with verteporfin for the treatment of multiple basal cell carcinoma.

The trials are designed to determine the safety and efficacy of using verteporfin with PDT to eliminate multiple basal cell carcinoma. Approximately 180 patients will be enrolled in two randomized, multi-centered, placebo-controlled trials at 19 centers in North America.

The design of the phase III program is based on the results of a randomized phase II clinical study conducted at four centers with 421 tumors treated in 54 patients. The phase II trial demonstrated the preliminary safety and efficacy of verteporfin at three different light doses in patients with non-melanoma skin cancer with multiple lesions. The group of patients exposed to the highest light dose had the best response rate with 98% of the assessed tumors showing a complete clinical response six months after initial treatment.

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"We are very excited that verteporfin, in addition to ocular indications, also showed promising results for patients suffering from multiple basal cell carcinoma. This may further extend usage of verteporfin for the benefit of patients", said Luzi von Bidder, head of Novartis Ophthalmics.

"Photodynamic therapy using verteporfin has a high probability of success and offers clear advantages over existing treatments because it is a non-invasive procedure that can treat multiple tumors simultaneously", said Mohammad Azab, M.D., QLT Inc.'s senior vice president, clinical and medical affairs. "Randomized phase II results showed a 98% clinical response rate with a good cosmetic outcome".

Marketed by Novartis Ophthalmics as Visudyne®, verteporfin is the standard of care for some forms of wet age-related macular degeneration (AMD), the leading cause of legal blindness in people over the age of 50. Visudyne has been developed by QLT and Novartis Ophthalmics and is available in more than 65 countries.

### About the treatment

Photodynamic therapy treatment is designed to treat tumors on or just under the surface of the skin and on the lining of the internal organs. As opposed to other standard non-melanoma therapies, the therapy may have the added advantage of being able to treat multiple tumors at once with little or no scarring.

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As a treatment for skin cancer, verteporfin is injected into the patient intravenously and within two hours selectively concentrates in the tumor. Activation of verteporfin by a non-thermal light emitting diode (LED) at a wavelength of 689 nm at the tumor site produces a cytotoxic form of oxygen that destroys the cancer cells. Local pain and discomfort at the treatment sites are among the most common adverse effects but can be well controlled with oral pain relief medication.

### Disease overview

The two most common forms of non-melanoma skin cancer are basal cell carcinoma and squamous cell carcinoma. Basal cell carcinoma accounts for an estimated 75 percent of all skin cancers. The disease typically develops on sun-exposed areas such as the head and neck and is slow-growing.

The most common warning sign of skin cancer is a change in the skin's appearance, especially a new growth or sore that doesn't heal. Basal cell carcinomas typically look like small red or pearl-colored lumps that may crust over, ulcerate or bleed.

Certain statements in this press release, which can be identified by language such as "will be" or "may have" or similar expressions, constitute "forward-looking" statements of QLT and Novartis AG within the meaning of the Private Securities Litigation Reform Act of 1995, which 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. Such statements include, but are not limited to, those with respect to the expected advantages which this treatment will offer, those setting out the anticipated number of patients to be enrolled in the study and the expected number of centres at which the study will be conducted, and those with respect to the expectation that adverse affects can be well controlled with oral pain relief medication. These statements are only predictions and actual events or results may differ materially. Factors that could cause such actual events or results expressed or implied by such forward-looking statements to differ materially from any future results expressed or implied by such statements include, but are not limited to: levels of patient enrollment, actual results from the trials, timing of the trials and additional information and other 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, Novartis AG's Form 20-F, and other filings with the US Securities and Exchange Commission and Canadian Securities Regulatory authorities. Forward-looking statements are based on our current expectations and QLT and Novartis AG are not obligated to update such information to reflect later events or developments.

**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).

**Novartis Ophthalmics:** With world-wide 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).

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**- Investor Relations Release -**

**Data suggest Novartis' Sandostatin® LAR® may treat newly-diagnosed acromegaly patients, avoiding need for invasive surgery**

*Primary octreotide therapy study offers prospect of normalizing growth hormone and insulin-like growth factor-1 levels in a subset of patients*

Basel, 10 October 2002 A new study published in the Journal of Clinical Endocrinology and Metabolism (October 2002, Volume 87, Issue 10) suggests that primary medical therapy with Sandostatin® LAR® depot (octreotide acetate for injectable suspension), a somatostatin analogue, may offer newly diagnosed acromegaly patients an alternative to invasive surgery. The Primary Octreotide Therapy Study (POTS) showed normalized growth hormone (GH) and insulin-like growth factor-1 (IGF-1) levels and tumor shrinkage in a significant subset of acromegalic patients.

Results from the study conducted by researchers in the UK were positive, with 100% of patients enrolled in the study showing tumor shrinkage; median tumor volume reduction was 49% for microadenomas and 43% for macroadenomas. Although a small study, these outcomes suggest the need for further investigation.

"We were excited to observe that a significant subset of newly-diagnosed patients can achieve decreased GH levels, normalization of IGF-1, and tumor shrinkage, with Sandostatin therapy alone", said J.S. Bevan, MD, FRCP, principal investigator of POTS and consultant endocrinologist at Aberdeen Royal Infirmary, Scotland, UK. "For patients who are not fit for, or refuse, surgery, or for those concerned about post-surgery gonadotrophin deficiency or who have no adenoma demonstrable on MRI. Many microadenomas and most macroadenomas could be successfully treated with Sandostatin LAR".

The study was undertaken by researchers in several UK endocrine centers to investigate the effect of Sandostatin LAR in the treatment of newly diagnosed acromegalic patients.



For 30 years, newly diagnosed acromegaly patients have faced invasive surgery to remove the pituitary tumors responsible for excess secretion of GH and IGF-1 levels, which in turn cause acromegaly. Following removal of the tumor via the transsphenoidal route, most patients were then subjected to external pituitary radiotherapy, and interim medical treatment with somatostatin analogues or dopamine agonists to decrease serum GH and IGH-1 levels.

### **100% of patients experienced tumor volume reduction**

The open label prospective study was conducted at nine UK endocrine centers and included 27 newly diagnosed, treatment naïve, acromegalic patients. Twenty patients had macroadenomas and seven had microadenomas. To ensure tolerability of somatostatin analogue therapy, all patients received Sandostatin® (octreotide) initially dosed 100 mg tds for the first 24 weeks (phase 1). In 13 patients, whose mean serum GH remained >5 mU/l (2 mg/l), the dose was increased to 200 mg tds after 4 weeks. Five point GH profiles were measured, high resolution pituitary imaging was conducted, and tumor dimensions and volumes were calculated. After 24 weeks, 15 patients proceeded to Phase 2 and switched to Sandostatin LAR. Further GH profiles and pituitary imaging were performed.

At the end of the study, all patients (27 patients) showed tumor shrinkage, while 79% of patients (<sup>11</sup>/<sub>14</sub> patients) had mean serum GH <5 mU/l, and 53% (<sup>8</sup>/<sub>15</sub> patients) had normal IGF-1. For microadenomas (7 patients) median tumor volume reduction was 49% after 24 weeks (range 12-73) and for macroadenomas (20 patients) 43% (range 6-92). After 48 weeks, the 15 patients who received Sandostatin LAR showed further overall median tumor volume reduction of 25%. Both Sandostatin and Sandostatin LAR were well tolerated and several patients continued primary medical therapy with Sandostatin LAR after the trial was completed.

While the study results suggest macroadenomas with pre-treatment GH level above 50mU/l should still be surgically debulked prior to Sandostatin LAR therapy, many acromegaly patients with GH-secreting microadenomas may be treated primarily with Sandostatin LAR to shrink tumors and normalize GH/IGF-1 levels.

### **About Sandostatin LAR**

Sandostatin LAR (octreotide acetate for injectable suspension), launched in most major countries in 1998 and in the US in 1999 is a convenient, once-monthly injection that reduces and normalizes levels of IGF-1 and growth hormone in the treatment of acromegaly. Sandostatin LAR is indicated for long-term maintenance therapy in acromegalic patients for whom medical therapy is appropriate and who have been shown to respond to and can tolerate Sandostatin (octreotide acetate) injection. In most countries in which it is approved, Sandostatin LAR is also indicated to control symptoms, such as severe diarrhea and flushing, of functional GEP tumors (e.g. metastatic carcinoid tumors and vasoactive intestinal peptide-secreting tumors (VIPomas)) in patients who have responded to and tolerated subcutaneous injections of Sandostatin.

### **Contraindications and adverse events**

In clinical studies of acromegaly, some patients experienced diarrhea, abdominal pain, gas, constipation, nausea, vomiting, pain at injection site, gallstone formation, and high or low blood sugar levels.

The foregoing release contains forward-looking statements that can be identified by terminology such as "suggests", "may offer", "can achieve", "could be successfully treated" or similar expressions, or by discussions regarding potential new indications for Sandostatin LAR, or regarding the long-term impact of a patient's use of Sandostatin LAR. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results with Sandostatin LAR to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Sandostatin LAR will be approved for any additional indications in any market. Neither can there be any guarantee regarding the long-term impact of a patient's use of Sandostatin LAR. In particular, management's ability to ensure satisfaction of the health authorities' further requirements is not guaranteed and management's expectations regarding commercialization of Sandostatin LAR could be affected by, among other things, additional analysis of Sandostatin LAR clinical data; new clinical data; unexpected clinical trial results; unexpected regulatory

actions or delays or government regulation generally; the company's ability to obtain or maintain patent or other proprietary intellectual property protection; competition in general; and other risks and factors referred to in the Company's current Form 20-F on file with the US Securities and Exchange Commission. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those anticipated, believed, estimated, or expected.

Novartis Oncology is a business unit within Novartis AG (NYSE: NVS), a world leader in pharmaceuticals and consumer 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 74 000 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 also at [www.sandostatin.com](http://www.sandostatin.com) and media materials at [www.novartisoncologyvpo.com](http://www.novartisoncologyvpo.com).

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**MEDIA RELEASE    COMMUNIQUE AUX MEDIAS    MEDIENMITTEILUNG**

### **Study shows benefits for patients with generalized tonic-clonic seizures with Trileptal®**

*Meta-analysis in adults and children demonstrate that Trileptal as monotherapy is effective in the treatment of generalized tonic-clonic seizures*

Basel, 9 October 2002 The anti-epileptic drug Trileptal® (oxcarbazepine) when used as monotherapy demonstrated a reduction in generalized tonic-clonic seizures (GTCS), according to data presented today by Gunter Kramer, MD, Medical Director, Swiss Epilepsy Center in Zurich, Switzerland and author of the study at the 5<sup>th</sup> European Congress on Epileptology held at Madrid, Spain. The study examined data from five multi-center, double-blind, active-control trials involving 266 patients (149 Trileptal, 117 active control) over an 11-14 month period. The research found that 62% of patients receiving Trileptal monotherapy had no generalized tonic-clonic seizures for the duration of therapy.

"Trileptal, given as a monotherapy, helped control seizures over the long term in patients with GTCS", said Dr. Kramer. "Additionally, seizure control with monotherapy or a single drug is important because it helps avoid the issues associated with polypharmacy, such as drug-drug interactions or cumulative side effects".

The findings, presented by Dr. Kramer, examined data from four trials in adults and one trial in children, aged 5 to 18, with untreated or refractory epilepsy. All trials evaluated Trileptal as monotherapy in patients with partial seizures or GTCS. Adult patients in the active control cohort received phenytoin, valproate, carbamazepine or phenobarbital. Children in the active control cohort received phenytoin. During double-blind treatment, 62% of Trileptal patients had no generalized tonic-clonic seizures during treatment. Nearly 60% of Trileptal patients completed the treatment phase. The most common adverse events experienced by Trileptal patients were headache (32.9%), somnolence (26.7%) and dizziness (16.8%).

### **Generalized tonic-clonic seizures**

Generalized seizures occur in about 40% of patients with seizure disorders. Unlike partial seizures, which affect only one hemisphere of the brain, generalized seizures affect both sides of the brain and therefore tend to affect the entire body. Generalized tonic-clonic (or grand mal) seizures occur in two phases. In the tonic phase, the person loses consciousness and falls, as the body grows rigid. In the clonic phase, the body convulses. After the seizure, consciousness returns slowly.

### **About Trileptal®**

Trileptal is an antiepileptic drug with proven efficacy either as a monotherapy or in combination therapy in the treatment of partial seizures (including seizure subtypes of simple, complex, and partial seizures evolving to secondarily generalized seizures) in adults and children with epilepsy.

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Trileptal has a favorable safety profile. There is no black box warning and it is not associated with aplastic anemia, agranulocytosis, hepatotoxicity or pancreatitis. In addition, no monitoring of liver functions and blood counts is required. Trileptal has limited interactions with other anti-epileptic drugs ("AEDs"). However, when Trileptal at doses greater than 1200 mg per day is added to phenytoin, a decrease in the dose of phenytoin may be required. As monotherapy in adults, Trileptal is well tolerated, with discontinuation rates comparable to placebo.

Trileptal is not generally associated with weight gain or cosmetic side effects. As monotherapy or adjunctive therapy in adults previously treated with other AEDs, the most common (>5%) adverse events occurring substantially more frequently than in placebo patients were dizziness, somnolence, diplopia, fatigue, nausea, vomiting, ataxia, abnormal vision, abdominal pain, tremor, dyspepsia, and abnormal gait these were typically mild to moderate in severity. As add-on therapy in pediatric patients, adverse events with Trileptal were similar to adults.

Clinically significant hyponatremia (sodium <125 mmol/L) has been observed in 2.5% of Trileptal-treated patients in controlled clinical trials. Measurement of serum sodium levels should be considered for patients at risk of hyponatremia.

Of patients who have demonstrated hypersensitivity to carbamazepine, 25% to 30% will experience a reaction to Trileptal. Caution should be exercised when prescribing Trileptal for patients with a history of hypersensitivity to carbamazepine. (Please see Warnings section of the complete prescribing information.)

The foregoing press release contains forward-looking statements that can be identified by forward-looking terminology such as "suggest(s)," "avoid the issues associated with polypharmacy", "has been shown to control", "may be clinically useful", or similar expressions. Such 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, management's expectation regarding the commercial success of Trileptal 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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**MEDIA RELEASE    COMMUNIQUE AUX MEDIAS    MEDIENMITTEILUNG**

**Studies show pharmacoeconomic benefits with Trileptal®**

*Treatment found to reduce adverse events and lower healthcare-related costs compared to carbamazepine*

Basel, 9 October 2002 According to two studies presented at the 5<sup>th</sup> European Congress on Epileptology, the anti-epileptic drug Trileptal® (oxcarbazepine) was associated with fewer treatment-related adverse events and lower healthcare-related costs than carbamazepine. The studies directly compared the costs associated with the incidence of adverse events and healthcare utilization. Results from one study showed that by reducing adverse events, costs of hospitalizations were expected to be reduced by an average of 11%. In the other study, when additional medication costs were factored in, Trileptal treatment saved an average of USD 222 per patient per year.

"The results of these studies suggest that treatment with Trileptal is a good option, in terms of both tolerability and cost effectiveness", said Michael T. Halpern, MD, PhD, MPH, principal scientist at Exponent, Inc. and author of one of the studies.

**Study design and results**

The first study, presented by Dr. Halpern, evaluated the incidence and impact of adverse events (AEs) with Trileptal and carbamazepine over a three-month review period. Data was derived from the United States Food and Drug Administration's Adverse Event Reporting System (AERS), and all events in which Trileptal or carbamazepine were specified as the primary or concomitant treatment were included in the study. During the review period, researchers identified 43 events associated with Trileptal and 307 with carbamazepine. The hospitalization rate for adverse events associated with Trileptal was 74.4% compared to 76.2% for the carbamazepine group. In addition, associated hospital stays were projected to be 0.6 days shorter for Trileptal patients, on average. The mean cost of hospitalization for patients in the Trileptal group was expected to be 11% lower than the carbamazepine group, resulting in cost savings per adverse event of USD 600.

The second study, presented by Luke Boulanger, MA, Boston Health Economics, Inc., compared healthcare utilization and costs for patients in a managed care setting treated with Trileptal or carbamazepine. Researchers reviewed administrative claims data to determine costs associated with patients using seizure-related healthcare. Costs were assessed on a descriptive basis in terms of net change over a 12-month period. It was found that compared to the carbamazepine-treated group the Trileptal group had a smaller increase in physician visits (2.5% vs. 6.7%). While emergency department visits and hospitalizations were reduced in both groups, the decreases were greater in the Trileptal group than the carbamazepine group (15.4% vs. 7.3% and 7.7% vs. 0.2% respectively). In addition, over the 12 month study period mean medical costs were USD 484 lower in the Trileptal group. When costs of medication were factored in, the Trileptal group realized an average savings per person of USD 222.

**About Trileptal**

Trileptal is an antiepileptic drug with proven efficacy either as a monotherapy or in combination therapy in the treatment of partial seizures (including seizure subtypes of simple, complex, and partial seizures evolving to secondarily generalized seizures) in adults and children with epilepsy.

Trileptal has a favorable safety profile. There is no black box warning and it is not associated with aplastic anemia, agranulocytosis, hepatotoxicity or pancreatitis. In addition, no monitoring of liver functions and blood counts is required. Trileptal has limited interactions with other AEDs. However, when Trileptal at doses greater than 1200 mg per day is added to phenytoin, a decrease in the dose of phenytoin may be required. As monotherapy in adults, Trileptal is well tolerated, with discontinuation rates comparable to placebo.

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The foregoing press release contains forward-looking statements that can be identified by forward-looking terminology, such as "suggest(s)", "reduce adverse events and lower healthcare-related costs", "may be a good option" 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, management's expectation regarding the commercialization of Trileptal could be affected by amongst other things, 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.

Novartis AG (NYSE: NVS) is a world leader in pharmaceuticals and consumer 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 74 000 people and operate in over 140 countries around the world. For further information please consult <http://www.novartis.com>.

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**MEDIA RELEASE    COMMUNIQUE AUX MEDIAS    MEDIENMITTEILUNG**

### **First EU launch in France of Atopica®, a new medication for atopic dermatitis in dogs**

Basel, 4 October 2002 A new medication from Novartis Animal Health offers unprecedented relief for dogs suffering from atopic dermatitis. In a large, multi-centered clinical trial, the new medication, Atopica® (cyclosporine A), was shown to provide superior response rates, better skin lesion improvement and higher remission rates as compared to methylprednisolone, with fewer side effects. It is the only medication developed specifically for the treatment of canine atopic dermatitis.

The new product was launched in France at the annual congress of the European Society of Veterinary Dermatology in Nice between September 26<sup>th</sup> and 28<sup>th</sup> 2002, where Novartis Animal Health also introduced a comprehensive training for vets regarding diagnosis and use of Atopica. Atopica was the subject of extensive laboratory and clinical trials, and has demonstrated a wide safety margin. Under both experimental and field conditions, there was no evidence of kidney impairment or liver toxicity, even at those high doses tested. Furthermore, there was no increased susceptibility to bacterial, viral or fungal infections.

Atopic dermatitis is a recurrent, chronic, inflammatory and pruritic allergic skin disease. It is estimated that one in ten dogs suffer from the condition, usually requiring life long treatment. It is the second most common form of canine skin allergy.

"Atopica represents a breakthrough in the pharmacological treatment of canine atopic dermatitis", said Roberta D'Amore, international brand manager of Novartis Animal Health. "As a selective immuno-modulator, Atopica has multiple yet targeted inhibition effects on cell functions initiating and producing the allergic response. The new drug offers a unique combination of efficacy and paucity of side effects".

France is the reference member state under the European mutual recognition procedure. Atopica is already available in Switzerland, Australia and New Zealand. European registration and US FDA approval is expected in 2003. The new drug is approved for use in dogs more than six months old and weighing more than two kilograms. It is available in gel capsules that are administered according to the dog's weight. Atopica is not intended for use in breeding, pregnant or lactating animals. Adverse reactions include vomiting, diarrhea or soft stools. In clinical studies, all adverse reactions resolved upon discontinuation of administration.

The forgoing press release contains forward-looking statements that involve known and unknown risks, uncertainties and other factors that may cause actual results to be materially different from any result, performance or achievements expressed or implied by such statements. These statements can be identified by terminology such as "offers", "expected", or similar expressions, or by express or implied statements regarding

the potential commercialization of Atopica in future markets. There are no guarantees that the aforementioned clinical trials or applications for registration will result in the commercialization of the product in any future markets. Any such commercialization can be affected by, among other things, uncertainties relating to product development, regulatory action or delays or

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government regulation generally, the ability to obtain or maintain patent or other proprietary intellectual property protection and competition in general. Any of these and other factors can cause the actual results to differ materially from the expected or predicted results.

Novartis Animal Health researches, develops and commercializes leading animal treatments that meet the needs of pet owners, farmers and veterinarians. Headquartered in Basel, Switzerland and present in 40 countries, Novartis Animal Health employs approximately 2300 associates worldwide and achieved sales of CHF 962 million in 2001. For more information, please consult [www.ah.novartis.com](http://www.ah.novartis.com).

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**- Investor Relations Release -**

**European health officials recognize unique dual inhibition properties of Alzheimer's disease drug Exelon®**

*Additional inhibition of butyrylcholinesterase added to product label*

Basel, 4 October 2002 The inhibition of not just one but two enzymes involved in Alzheimer's Disease by the drug Exelon® (rivastigmine) has been recognized by European health officials. The Committee for Proprietary Medicinal Products (CPMP) announced it has approved the addition of the fact that Exelon is an inhibitor of both acetylcholinesterase (AChE) and butyrylcholinesterase (BuChE) to Exelon's product label.

This makes Exelon unique in its class, as the other cholinesterase inhibitors commonly used to treat Alzheimer's disease, such as donepezil and galantamine, inhibit only AChE.

Alzheimer's Disease is a progressive, degenerative disease that alters the functioning of the brain and is associated with a decrease in signal transmission between nerve cells in the brain, as a result of decreased amounts of the neurotransmitter acetylcholine. In the brain, acetylcholine is broken down by AChE and BuChE, and by blocking the action of both enzymes Exelon may maintain brain function for longer by increasing

the amount of acetylcholine available for nerve signal transmission.<sup>1</sup>

Recent research suggests that BuChE may play an increasingly important role in regulating brain acetylcholine levels as Alzheimer's disease progresses, and that the dual inhibitory action of Exelon may provide additional treatment benefits for patients with the disorder.<sup>2,3</sup> A study by Ezio Giacobini et al. (*Journal of Neural Transmission*, July 2002) showed a strong association between the additional inhibition of BuChE by Exelon and improved cognitive function (memory, thinking and learning).<sup>1</sup> In the August issue of *Neurology*, T. Darreh-Shori presented a study, which found that Exelon provided sustained reductions in AChE and BuChE activity.<sup>3</sup> Patients with greater BuChE inhibition scored higher in neuropsychological tests.<sup>3</sup>

Further studies are planned on the role of BuChE in Alzheimer's disease and the effect of Exelon.

This press release contains forward looking statements which can be identified by the use of forward-looking terminology such as "suggests", "may play an increasingly important role", "may provide", "are planned", or similar expressions, or by express or implied discussions regarding potential additional sales or expanded indications for Exelon. Such forward looking statements involve known

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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 guarantees of any additional sales or expanded indications for Exelon in any market. Any such additional sales or expanded indications, or other results, performance or achievements expressed or implied in such statements, could be affected by, amongst other things, 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 Novartis AG's Form 20-F filed with the Securities and Exchange Commission. Any of these and other factors can cause the actual results to differ materially from the expected or predicted results.

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

1. Ballard CG. Advances in the treatment of Alzheimer's disease: benefits of dual cholinesterase inhibition. *Eur Neurol* 2002; 47(1):64-70.
2. Giacobini E, Spiegel R, Enz A, Veroff A, Cutler NR. Inhibition of acetyl- and butyryl-cholinesterase in the cerebrospinal fluid of patients with Alzheimer's disease by rivastigmine: correlation with cognitive benefit. *J Neural Transm* 2002; 109:1053-1065.
3. Darreh-Shori, et al. Sustained cholinesterase inhibition in AD patients receiving rivstigmine for 12 months. *Neurology* 2002; 59:563-572.

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**CIBA Vision and CooperVision Reach  
Settlement in Color Contact Lens Patent Suit**

**ATLANTA, 3 October 2002** CIBA Vision Corporation, the eye care unit of Novartis AG (NYSE: NVS), announced today that it has reached a settlement agreement terminating its patent infringement lawsuits pending against CooperVision (NYSE: COO) worldwide.

CIBA Vision filed the U.S. suit April 20, 2001, on behalf of its wholly owned subsidiary, Wesley Jessen, in the U.S. District Court for the Central District of California. The suit claimed that Frequency® Colors infringe the innovative color technology protected by U.S. Patent No. 5,414,477 ("Jahnke" patent) and U.S. Patent No. 4,668,240 ("Loshack" patent) owned by Wesley Jessen. In addition, CIBA Vision had litigation pending against CooperVision in the U.K., Germany and France that included additional patent rights (the "Knapp" patents).

On August 22, 2002, the U.S. Court granted CIBA Vision's Motion for Summary Judgment of Infringement and affirmed that CooperVision's Frequency Colors contact lenses infringe the Jahnke patent that protects the FreshLook® ColorBlends® brand of contact lenses. A trial was scheduled for October 15, 2002, to decide the issue of validity of the Jahnke patent, as well as issues of infringement and validity of the Loshack patent.

CIBA Vision has agreed to license these and other color contact lens patents to CooperVision in return for a royalty and a cross-license of some of CooperVision's intellectual property rights. Specific financial details of the agreement are confidential.

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"We were confident in the strength of our patents, however, the agreement with CooperVision is advantageous to both companies as well as to our customers", said Scott Meece, vice president and general counsel for CIBA Vision. "This agreement reinforces the protection of our valuable intellectual property rights while allowing CooperVision to continue serving a segment of the color contact lens market. Throughout any patent litigation process, we are always open to discussing a reasonable settlement".

While the patent terms vary, the Jahnke patent is enforceable until 2012. CooperVision is the first eye care company to license CIBA Vision's color patent technology, since CIBA Vision acquired Wesley Jessen in October 2000.

With worldwide headquarters in Atlanta, CIBA Vision is a global leader in research, development and manufacturing of optical and ophthalmic products and services, including contact lenses, lens care products and ophthalmic surgical products. CIBA Vision products are available in more than 70 countries. For more information, visit the CIBA Vision web site at [www.cibavision.com](http://www.cibavision.com).

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CIBA Vision is the eye care unit 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 19.21 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 74 000 people and operate in more than 140 countries around the world. For further information, please consult [www.novartis.com](http://www.novartis.com).

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**MEDIA RELEASE    COMMUNIQUE AUX MEDIAS    MEDIENMITTEILUNG**

**Study of aromatase inhibitor Femara® in adjuvant breast cancer setting reaches enrollment milestone**

*Enrollment of 4800 postmenopausal women completed for study evaluating long-term role of Femara in reducing breast cancer recurrence*

Basel, 3 October 2002 A study determining overall and disease-free survival of women with early breast cancer taking the aromatase inhibitor Femara® (letrozole) vs. placebo in the adjuvant setting following five years of endocrine therapy (tamoxifen) has completed enrollment of 4800 postmenopausal women. The study will provide important clinical information on the role of Femara in early breast cancer. This is one of two Femara adjuvant clinical trials that together will comprise one of the largest evaluations of an aromatase inhibitor in the adjuvant setting. 30 August marked the closing date for this trial, which is being conducted by the National Cancer Institute of Canada Clinical Trials Group (NCIC CTG MA-17). The second trial is being conducted by the Breast International Group (BIG 1-98). To date, both studies have enrolled more than 10 000 patients.

"In the adjuvant setting, we know that continuing tamoxifen for more than five years does not provide any additional benefit. Although data from this study is not yet available, the hope of this study is that, after five years of tamoxifen, women taking the aromatase inhibitor Femara may experience either no recurrence or a delay in recurrence of their breast cancer", said lead investigator Paul Goss, M.D., Ph.D., Professor of Medicine, University of Toronto and Princess Margaret Hospital, Canada. "Physicians recognize the efficacy of aromatase inhibitors overall compared to tamoxifen. We believe that the growing body of clinical and scientific evidence for Femara may translate into patients living longer without their disease coming back".

Femara is the first and only aromatase inhibitor to show superiority to tamoxifen in median time to progression of disease and objective tumor response rates when used as first line therapy in postmenopausal women with endocrine sensitive advanced breast cancer. In studies evaluating five versus 10 years of treatment with tamoxifen as adjuvant therapy, researchers found that patients receiving 10 years of tamoxifen had an inferior outcome compared to those receiving it for five years due to complications resulting from an increased incidence of endometrial cancers with long term tamoxifen use. Researchers now hypothesize that reinforcing estrogen suppression with Femara may extend survival once a woman has completed five years of tamoxifen therapy.

**Femara MA-17 adjuvant study details**

The primary objective of the clinical trial is to determine the disease-free and overall survival of postmenopausal women (ER+ and/or PgR receptor positive) taking Femara after at least five years of tamoxifen therapy compared to women taking placebo after at least five years of therapy. The women have been randomized to the two arms of the study and will have received five years of daily treatment of either 2.5 mg of Femara or placebo. Secondary objectives include evaluating the incidence of contralateral breast cancer (spreading to the other breast) and the long-term safety of Femara. In

addition, subsets of the study will explore the effect of Femara on lipid metabolism and bone mineral density areas of significant interest to patients and their physicians.

**Additional Femara adjuvant clinical trial underway**

A second Phase III adjuvant study with Femara is being conducted by the Breast International Group (BIG 1-98) in collaboration with Novartis. This study will compare five years of Femara to five years of tamoxifen, and to both two years of Femara and three years of tamoxifen or the reverse (two years of tamoxifen and three years of Femara). Taken together, studies MA-17 and BIG 1-98 will include almost 13 000 women. Results for both studies are expected to be available in 2004.

**About Femara**

Femara, an aromatase inhibitor, is an oral once-a-day first-line treatment for postmenopausal women with hormone receptor positive or hormone receptor unknown locally advanced or metastatic breast cancer. It is also approved for the treatment of advanced breast cancer in postmenopausal women with disease progression following antiestrogen therapy, and as neo-adjuvant (pre-operative) therapy. Femara is currently available in more than 75 countries worldwide. Not all indications are available in every country.

Data from a first-line survival analysis show that Femara offers a statistically significant greater early survival advantage at one and two years compared to tamoxifen. In addition, approximately five years after initiation of the study (November, 1996), more women who had begun therapy with Femara were 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.

Femara is contraindicated in patients with known hypersensitivity to Femara or any of its excipients. Femara is generally well tolerated and adverse reaction rates in the first-line study in which Femara was compared 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 = 2%.

This release contains certain forward-looking statements that can be identified by terminology such as "will provide", "hope", "believe", "may translate", "hypothesize", "objective... is to determine", "objectives include evaluating", "will explore", "is being conducted", "will compare", "expected", or similar expressions, or by express or implied discussions regarding potential new indications for Femara, or regarding potential future sales of Femara. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results with Femara to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Femara will be approved for any additional indications in any market. Neither can there be any guarantee regarding any future sales of Femara. In particular, management's expectations regarding commercialization of Femara could be affected by, among other things, additional analysis of Femara clinical data; new clinical data; unexpected clinical trial results; unexpected regulatory actions or delays or government regulation generally; the company's ability to obtain or maintain patent or other proprietary intellectual property protection; competition in general; 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

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should underlying assumptions prove incorrect, actual results may vary materially from those anticipated, believed, estimated or expected.

#### **About Novartis**

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**MEDIA RELEASE COMMUNIQUE AUX MEDIAS MEDIENMITTEILUNG**

**Novartis' Zometa® a major advance in the treatment of serious bone-related complications of advanced prostate cancer featured in National Cancer Institute publication**

*Zometa data published in the Journal of the National Cancer Institute; represents the first and only large scale, randomized trial to demonstrate significant efficacy in the treatment of painful and debilitating cancer-related bone complications*

Basel, 3 October 2002 Zometa® (zoledronic acid) significantly reduces the number of bone-related complications by 25% relative to placebo in patients with bone metastases from advanced prostate cancer, according to a study in the October edition of the Journal of the National Cancer Institute. In the study, Zometa was infused at a dose of 4 mg given over 15 minutes.

Prostate cancer is one of the most common cancers in men. The disease frequently metastasizes to the skeleton or bone, and Zometa represents a major advance in treating these debilitating complications.

As a result of this metastases, advanced prostate cancer patients are at high risk for bone complications or skeletal related events (SREs) such as pathologic fractures, need for radiation or surgery to bone, spinal cord compression and changes in anticancer therapy to treat bone pain. A recently published analysis indicates that skeletal fractures in patients with prostate cancer can correlate with decreased survival. Prior to Zometa, therapeutic options included hormonal therapy, surgery, radiotherapy, chemotherapy and analgesics for pain management.

"Bone metastases and their complications can be catastrophic for patients with advanced cancer. This study shows that Zometa significantly reduces and delays these complications including pathological fractures, spinal cord compression and the need for radiation to treat bone pain. This represents a major advance in the treatment of advanced prostate cancer", said Fred Saad, MD, Director of Urologic Oncology, Associate Professor, Montreal, Canada.

#### **Clinical Results**

The results were from a randomized, Phase III double-blind, placebo-controlled study of 643 prostate cancer patients who progressed through hormonal therapy with at least one bone metastasis. The 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.

The data demonstrated that patients taking Zometa 4 mg experienced 25% fewer SREs compared to those patients taking placebo (Zometa 33% vs. placebo 44%, p=0.021). The 15-month data also demonstrated that patients taking Zometa 4 mg had 41% fewer pathologic fractures 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 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. 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.

#### **About Zometa**

Novartis has received marketing authorization for Zometa in more than 50 countries, including the United States and the European Member States, for the prevention of skeletal related events in patients with advanced malignancies involving bone. These malignancies include multiple myeloma, prostate cancer, breast cancer, lung cancer, renal cancer and other solid tumours. Previously, Novartis received marketing clearance for Zometa in the treatment of hypercalcaemia of malignancy (HCM), also known as tumour-induced hypercalcaemia (TIH), in more than 70 countries throughout the world.

**Contraindications and adverse events**

In clinical trials in patients with bone metastases, Zometa had a safety profile similar to other intravenous bisphosphonates. The most commonly reported adverse events in bone metastases clinical trials, regardless of causality with Zometa, included flu-like syndrome (fever, arthralgias, myalgias, skeletal pain), fatigue, gastrointestinal reactions, anaemia, weakness, cough, dyspnoea and oedema.

Zometa is contraindicated during pregnancy, in breast-feeding women and 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. 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. Since safety and pharmacokinetic data are limited in patients with severe renal impairment, Zometa is not recommended in patients with bone metastases with severe renal impairment. In the clinical studies, patients with serum creatinine >3.0 mg/dL were excluded.

The foregoing release contains forward-looking statements including express or implied statements regarding potential new indications for Zometa, or regarding potential future sales of Zometa. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results with Zometa to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Zometa will be approved for any additional indications in any market. Neither can there be any guarantee regarding potential future sales of Zometa. In particular, management's ability to ensure satisfaction of the health authorities' further requirements is not guaranteed and management's expectations regarding commercialization of Zometa could be affected by, among other things, additional analysis of Zometa clinical data; new clinical data; unexpected clinical trial results; unexpected regulatory actions or delays or government regulation generally; the company's ability to obtain or maintain patent or other proprietary intellectual property protection; competition in general; and other risks and factors referred to in the Company's current Form 20-F on file with the US Securities and Exchange Commission of the United States. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those anticipated, believed, estimated or expected.

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Additional information on Novartis Oncology and Zometa can be found at [www.novartisoncology.com](http://www.novartisoncology.com) or [www.zometa.com](http://www.zometa.com). Additional media information can be found at [www.novartisoncologyvpo.com](http://www.novartisoncologyvpo.com).

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**MEDIA RELEASE    COMMUNIQUE AUX MEDIAS    MEDIENMITTEILUNG**

**New long-term study shows Zelmac® safe and well tolerated by patients with irritable bowel syndrome**

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

Basel, 2 October 2002 New clinical study results published in *Alimentary Pharmacology & Therapeutics* (vol. 16, issue 10) show that the novel Novartis drug Zelmac®\* (tegaserod) is safe and well tolerated in the long-term treatment of patients with Irritable Bowel Syndrome (IBS) with constipation. These data, from one of the longest and largest clinical trials ever conducted for IBS, reinforce Zelmac's safety and tolerability profile with 12-month results in nearly 600 patients.

"IBS is a chronic condition, which can have a profound effect on patients' quality of life", said Gervais Tougas, MD, Associate Professor, Department of Medicine, McMaster University, lead author of the study. "These tegaserod data represent an important advance for the long-term management of patients with IBS with constipation, showing that the drug is safe over the long term".

IBS is characterised by abdominal pain and discomfort, bloating, and altered bowel function (constipation and/or diarrhoea). The prevalence of IBS differs by country, however recent studies suggest that the disorder affects approximately 10-20% of the Western population.

"Novartis is very encouraged by the results of this study, which reinforce Zelmac's safety and tolerability profile and demonstrates the potential for long-term use of Zelmac", said Joerg Reinhardt, Head of Development, Novartis Pharma AG.

### Study Design

A total of 601 patients with IBS with constipation were enrolled in this open label study, 579 of which entered the treatment phase of the study, from 35 centres world-wide, including Canada, Finland, France, Germany, Italy, Netherlands, Norway, UK and the USA. 567 patients were included in the 12-month safety analysis (97.9% of those entered into the treatment phase). Twelve patients were excluded due to lack of post-baseline assessment.

During the first month of study patients received Zelmac 2 mg b.i.d., and then either 2 mg b.i.d. or 6 mg b.i.d. for the remaining active treatment period. For the majority of patients receiving 2 mg b.i.d. the Zelmac dose was increased to 6 mg b.i.d. within the first 3 months of therapy. At the end of the 12-month study period 82% of patients were receiving Zelmac 6 mg b.i.d.

The safety of Zelmac was assessed during office visits at months 1, 2, 4, 6, 8, and 10, and telephone monitoring was conducted between the office visits on months 3, 5, 7, 9 and 11. Safety assessments consisted of recording all adverse events with their severity and relationship to study drug and influence on the course of the study, the regular monitoring of haematology, blood chemistry and urinalysis, repeated pregnancy testing, regular recordings of vital signs and ECGs and the performance of physical examinations. ECGs from all the sites were interpreted centrally by an independent expert.

The most common treatment-related adverse event reported was diarrhoea (10.1%), which was generally mild, transient and typically resolved with continued treatment. Other treatment-related

adverse events reported include headache (8.3%), abdominal pain (7.4%) and flatulence (5.5%). A total of 65 patients (11.2%) discontinued study participation due to adverse events, with diarrhoea (3.5%) being the most common reason for discontinuation.

Overall, 52.5% of patients who received Zelmac treatment completed the 12-month treatment period. The discontinuation rate after three months of study was 15%, which is consistent with other short-term clinical trials in IBS patients of 16-24%. According to the report the lack of longer-term trials in this category makes it impossible to compare discontinuation rates at later stages of the study. However, the authors note that dropout rate could be due to such factors as the cyclic nature of chronic IBS with constipation, the difficulty in getting active, non-retired patients to keep medical appointments during a full year, and the known tendency for study participants to drop out in the case of either improved or worsened condition.

### About Irritable Bowel Syndrome

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 and discomfort, bloating and constipation associated with IBS may have altered sensitivity and altered motility of their lower GI tract. This may be due to the way their lower GI tract reacts to changes in serotonin (5HT), a naturally occurring chemical in their body that regulates motility and perception of pain and discomfort in the intestinal system.

### About Zelmac

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Zelmac is the first in a new class of medicines, known as serotonin-4 receptor agonists (5HT<sub>4</sub> agonists) developed especially for the treatment of the multiple symptoms associated with IBS with constipation. By activating 5HT<sub>4</sub> receptors in the gastrointestinal tract, Zelmac normalises impaired motility and reduces sensitivity of the intestinal tract. In clinical studies, significantly more patients experienced a general relief of symptoms when treated with Zelmac, such as a decrease in abdominal pain, bloating and constipation. In most patients, the onset of relief occurred within just one week. The medicine was well tolerated and showed a profile of side effects similar to that of placebo.

Zelmac was discovered and developed by Novartis. Zelmac, known in the United States and Canada as Zelnorm, is approved in more than 30 countries including Australia, Switzerland, Canada, the United States and Brazil.

The foregoing press release contains certain forward-looking statements related to the business of Novartis, which can be identified by the use of forward-looking terminology such as "potential", or similar expressions, or by express or implied discussions regarding potential additional sales or expanded indications for Zelmac. 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 guarantees that clinical study results described above will result in the any additional sales or expanded indications for Zelnorm in any market. Any such additional sales or expanded indications, or other results, performance or achievements expressed or implied in such statements, could be affected by, amongst other things, 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 20-F filed with the Securities and Exchange Commission. Should one or more of these risks or uncertainties materialise, or should underlying assumptions prove incorrect, actual results may vary materially from those described herein as anticipated, believed, estimated or expected.

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

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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 74 000 people and operate in over 140 countries around the world. For further information please consult <http://www.novartis.com>.

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### SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

#### Novartis AG

Date: November 1, 2002

By: /s/ MALCOLM B. CHEETHAM

Name: Malcolm B. Cheetham  
Title: Head Group Financial Reporting and Accounting

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QuickLinks

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Novartis acquires rights to AGE-breaker compound from Torrent

Novartis Oncology sharpens focus on key growth drivers

Novartis' bid for Lek clears important hurdle

New study confirms, Novartis drug Zelmac® is safe and effective for women with irritable bowel syndrome

New study shows Zelmac® effective and safe for people with non-Diarrhea Irritable Bowel Syndrome

Long-term benefit of Visudyne® therapy for wet age related macular degeneration published in Archives of Ophthalmology

Novartis close to successfully concluding its tender offer for Lek

Novartis signs an agreement with Tanabe Seiyaku to develop LFA-1 antagonists

Novartis looks ahead to continued dynamic launch program of innovative new medicines

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Diovan® (valsartan) improved survival and reduced hospitalizations in heart failure patients who did not take ACE inhibitors

Novartis Ophthalmics and OLT launch phase III program to treat skin cancer

Data suggest Novartis' Sandostatin® LAR® may treat newly-diagnosed acromegaly patients, avoiding need for invasive surgery

Study shows benefits for patients with generalized tonic-clonic seizures with Trileptal®

Studies show pharmacoeconomic benefits with Trileptal®

First EU launch in France of Atopica®, a new medication for atopic dermatitis in dogs

European health officials recognize unique dual inhibition properties of Alzheimer's disease drug Exelon®

CIBA Vision and CooperVision Reach Settlement in Color Contact Lens Patent Suit

Study of aromatase inhibitor Femara® in adjuvant breast cancer setting reaches enrollment milestone

Novartis' Zometa® a major advance in the treatment of serious bone-related complications of advanced prostate cancer featured in National Cancer Institute publication

New long-term study shows Zelmac® safe and well tolerated by patients with irritable bowel syndrome

SIGNATURES