

NOVARTIS AG  
Form 6-K  
October 03, 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 September 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

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Enclosures:

1. Novartis to pursue bid for Lek shares based on continued support of Lek's management
2. Novartis takes next step to acquire majority of Lek's shares
3. Novartis drug Glivec® receives positive opinion from CPMP for treatment of newly diagnosed adult and paediatric patients with chronic myeloid leukemia; drug moves closer to EU first-line approval
4. Australian Pharmaceutical Benefits Advisory Committee recommends reimbursement of Glivec® for treatment of patients with chronic myeloid leukemia in the chronic phase

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5. Zelmac®, a novel treatment for Irritable Bowel Syndrome from Novartis, is now reimbursable in Switzerland
  6. Novartis and Compugen expand collaboration for identification, prioritization and validation of new drug targets
  7. New data from Val-HeFT shows Diovan (valsartan) is highly cost-effective in treating heart failure patients not taking ACE inhibitors
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### -Investor Relations Release -

#### Novartis to pursue bid for Lek shares based on continued support of Lek's management

Basel, 27 September 2002 In view of the excellent strategic fit of the two companies and based on the continued support of Lek's management, Novartis has decided to publish its offer for Lek's shares tomorrow, 28 September, in order to allow all Lek shareholders to take a decision. The offer, which has been approved by the Slovenian Securities Market Agency (SMA), is for a cash consideration of 95 000 Slovenian Tolars (SIT) per Lek share, with the option of settlement in SIT or Euros.

"We carefully considered the interests of Lek's shareholders, employees and management and believe the offer is full and fair both to the shareholders and the company. It enables us to support Lek's investment program and provides a good platform for our combined growth and expansion", said Christian Seiwald, Head of Novartis Generics. Mr Seiwald emphasized that the bid is conditional on Novartis receiving acceptances for at least 51% of Lek's share capital.

The extraordinary meeting of Lek's shareholders today decided to maintain the restriction on voting more than 15% of the Lek voting stock. However, under Slovenian law, this restriction is due to become invalid in Slovenia on 30 June 2003.

The offer price is based on thorough assessments by Novartis and external experts, taking into account Lek's assets and liabilities, business prospects and reputation as well as prices paid in comparable transactions. It relies on the unique complementarity of Lek and Novartis with their similar cultures and excellent fit. It permits a strategic rationale of accelerating growth and substantial further investment.

#### 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.

Novartis AG (NYSE: NVS) is a world leader in healthcare with core businesses in pharmaceuticals, consumer health, generics, eye-care, and animal health. In 2001, the Group's businesses achieved sales of CHF 32.0 billion and a net income of CHF 7.0 billion. The Group invested approximately CHF 4.2 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>.

## Disclaimer

This document and the content of it does not constitute an offer of securities or an offer to purchase securities, nor a solicitation for an offer of securities or an offer to purchase securities, nor marketing or sales activity for such securities. This document must not be used for such an offer or such marketing activities. This document shall also not be construed to record that an offer of securities or an offer to purchase securities, or a solicitation for an offer of securities or an offer to purchase securities, or marketing or sales activity for such securities have been or will be made. A prospectus has been approved by the Securities Market Agency and will be published in accordance with the Slovenian Takeover Act.

This release contains certain "forward-looking statements", relating to both the Novartis Group's and Lek's businesses, which can be identified by the use of forward-looking terminology or by discussions of strategy, plans or intentions. Such statements include a description of the intention of Novartis to make a tender offer for the shares of Lek. Such statements reflect the current views of Novartis with respect to future events and are subject to certain risks, uncertainties and assumptions. It is possible that the tender offer may be withdrawn if conditions proposed by Novartis are not met in a manner that Novartis deems satisfactory. Other factors that could impact the success of a potential acquisition include uncertainties relating to clinical trials and product development, unexpected regulatory delays or government regulation generally, and obtaining and protecting intellectual property, as well as factors discussed in the Form 20-F filed by Novartis with the US Securities and Exchange Commission. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those described herein as anticipated, believed, estimated or expected.

The information contained herein is not for publication or distribution to persons in the United States of America or any jurisdiction where such sale would be unlawful. The securities referred to herein have not been and will not be registered under the US Securities Act of 1933, as amended, and may not be offered or sold in or from the United States without registration thereunder or pursuant to an available exemption therefrom.

2

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## BACKGROUND

### The proposed transaction

Servipharma AG, a Swiss subsidiary of Novartis AG, has decided to launch the Offer as a public tender offer to acquire all of Lek's 1 792 782 class A shares and 140 394 class B shares. The offer is for a cash consideration of 95 000 Slovenian Tolars (SIT) per Lek share, with the option of settlement in SIT or Euros. The Offer is conditional on Novartis receiving acceptances for at least 51% of Lek's share capital.

The offer document has been approved by the Slovenian Securities Market Agency (SMA) and will be published on 28 September 2002.

The offer will expire at 12.00 noon CET on 28 October 2002

### Indicative Timetable

Publication of the Bid/Prospectus  
Publication of Management Opinion

28 September 2002  
within 10 days of the publication  
of the bid

Expiry of the bid period

12.00 CET 28 October 2002

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3

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**MEDIA RELEASE**

**COMMUNIQUE AUX MEDIAS**

**MEDIENMITTEILUNG**

**Novartis takes next step to acquire majority of Lek's shares**

*Offer price may be increased*

Basel, 26 September 2002 Novartis announced that it has filed the final official document regarding its proposed offer for Lek with the Slovenian Securities Market Agency (SMA). The document is based on an offer price of 95 000 Slovenian Tolars (SIT) per share. Novartis is offering Lek shareholders the option of cash payment for their tendered shares in SIT or Euros.

In recognition of the concerns of the Slovenian funds KAD and SOD, which are the largest shareholders in Lek, Novartis has indicated its readiness to increase its offer to SIT 98 000 per share to all Lek shareholders provided that it receives written assurances from KAD and SOD that they will vote in favor of the motions proposed to the extraordinary shareholders' meeting on 27 September 2002, and will tender their shares in the offer.

The announced friendly intention of Novartis to acquire Lek could create a leading player in generics (off-patent medicines) 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>.

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This release contains certain "forward-looking statements", relating to both the Novartis Group's and Lek's businesses, which can be identified by the use of forward-looking terminology or by discussions of strategy, plans or intentions. Such statements include a description of the intention of Novartis to make a tender offer for the shares of Lek. Such statements reflect the current views of Novartis with respect to future events and are subject to certain risks, uncertainties and assumptions. It is possible that the tender offer may not be made if the conditions proposed by Novartis are not met in a manner that Novartis deems satisfactory. Other factors that could impact the success of a potential acquisition include uncertainties relating to clinical trials and product development, unexpected regulatory delays or government regulation generally, and obtaining and protecting intellectual property, as well as factors discussed in the Form 20-F filed by Novartis 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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#### **BACKGROUND**

##### **The proposed transaction**

Servipharma AG, a Swiss subsidiary of Novartis AG, intends to launch the Offer as a public tender offer to acquire all of Lek's 1 792 782 class A shares and 140 394 class B shares. The Offer is conditional on Novartis receiving acceptances for at least 51% of Lek's share capital.

The offer document has been filed with the Slovenian Securities Market Agency (SMA), subject to the approval of the SMA, and will be published after the General Meeting as described below.

2

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To pave the way for the Offer, Lek's management and Supervisory Board issued a notice to its shareholders on 26 August 2002 to convene a General Meeting to be held on 27 September 2002 at 7.30 a.m. At this meeting, resolutions will be proposed to amend Lek's articles of association (the "Articles") to provide for:

the removal of the restriction on voting more than 15% of the Lek voting stock (a restriction which would become invalid in Slovenia by mid 2003); and

changes in relation to Lek's Supervisory Board in order to allow Novartis to obtain majority representation on that Board immediately after the Offer has been declared successful.

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In addition, the General Meeting will decide on the exclusion of pre-emption rights in relation to Lek's 87 075 treasury shares to enable those shares to be acquired by Novartis pursuant to the Offer.

Such amendments to the Articles and decisions of the General Meeting are material to Novartis' decision as to whether it proceeds with the Offer and, accordingly, Novartis reserves its right not to make the Offer in the event the Lek shareholders do not approve the above-mentioned measures. Novartis may also take such a decision under other circumstances that it considers to be materially adverse to the transaction.

### Indicative Timetable

General Meeting	27 September 2002
Publication of the Bid/Prospectus	28 September 2002
Publication of Management Opinion	within 10 days of the publication of the bid

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3

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### -Investor Relations Release -

#### **Novartis drug Glivec® receives positive opinion from CPMP for treatment of newly diagnosed adult and paediatric patients with chronic myeloid leukemia; drug moves closer to EU first-line approval**

Basel, 20 September 2002 Novartis announced today that it has received a positive opinion from the Committee for Proprietary Medicinal Products (CPMP) in the European Union for the agent Glivec®\* (imatinib) for the first-line treatment of newly diagnosed adults and children with Philadelphia chromosome (Bcr-Abl) positive chronic myeloid leukemia (CML) for whom bone marrow transplantation is not considered as the first line treatment. The European Union Commission usually grants approval of new indications within three to four months of a CPMP positive opinion.

"Novartis is pleased that Glivec is a step closer to becoming available for the treatment of patients in the earliest stage of CML," said David Epstein, President, Novartis Oncology. "The drug has already benefited thousands worldwide. We are excited that the CPMP recognizes the data which show that treatment with Glivec delays progression of CML to its more advanced stages."

#### **About Glivec and CML**

The first-line CML marketing application to the EMEA was based on data from the International Randomized Study of Interferon plus Ara-C vs. GLIVEC (IRIS study), which were presented in May 2002 at the annual meeting of the American Society of Clinical Oncology (ASCO) and in June 2002 at the European Haematology Association (EHA). The data demonstrate that in the first-line treatment of newly diagnosed CML patients, Glivec achieved an 83% major cytogenetic response rate, compared with 20% for the combination of interferon-alpha, a biologic agent, and cytosine arabinoside (IFN/Ara-C), a chemotherapy drug. Also in the IRIS study, Glivec significantly delayed the time to

progression to the more advanced stages of CML compared with IFN/Ara-C. In addition, data presented at EHA also show that Glivec provides newly diagnosed CML patients a significantly better quality of life (QoL) than IFN/Ara-C. The paediatric application was based on a phase I study with children with Ph+ CML who had failed prior IFN therapy or children who had other Ph+ acute leukemias. The results of this study indicated similar efficacy (cytogenetic response, hematologic response) and safety as those seen in studies conducted in adults.

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

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## **About Glivec and GIST**

Glivec received a second EU approval on 31 May 2002, for the treatment of patients with Kit (CD 117)-positive unresectable (inoperable) and/or metastatic malignant gastrointestinal stromal tumors (GISTs). Glivec was designated orphan drug status for GIST in February 2002.

GISTs are the most common malignant form of sarcoma that arise in the gastrointestinal tract. Worldwide, there are approximately 12,000 new cases each year. For patients with metastatic or unresectable disease, GISTs had represented an incurable malignancy with a median survival of approximately 10 to 12 months. Until now, surgery has been the only effective treatment option, resulting essentially in palliation of the disease.

## **Contraindications and Adverse Events**

In the first-line study (IRIS), the safety profile with Glivec was similar to that of previous Phase II studies in other CML patients. Most adverse events were of mild to moderate grade. The most frequently reported drug-related adverse events with Glivec were nausea, vomiting, diarrhoea, oedema and muscle cramps. In the two arms, 2% of Glivec patients compared with 6% of IFN/Ara-C patients discontinued from the study due to adverse events. Additionally, 0.7% of the Glivec patients compared with 23% of the IFN/Ara-C patients crossed over to the control arm due to intolerance to therapy.

The majority of patients treated with Glivec in the Phase II CML clinical trials, upon which the initial approval was based, also experienced adverse events at some time. Most events were of mild to moderate grade, and the drug was discontinued for adverse events in 2% of patients in chronic phase, 3% in accelerated phase and 5% in blast crisis. The most common side effects included nausea, fluid retention, vomiting, diarrhoea, haemorrhage, muscle cramps, skin rash, fatigue, headache, dyspepsia and dyspnoea, as well as neutropaenia and thrombocytopenia.

Glivec is often associated with oedema and occasionally serious fluid retention, GI irritation and severe hepatotoxicity. Because follow-up of most patients treated with Glivec is relatively short, there are no long-term safety data on Glivec treatment.

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

The foregoing release contains forward-looking statements that can be identified by terminology such as "moves closer," "usually grants approval," "a step closer to becoming available," "delays progression of the disease," "significantly delayed the time to progression," or similar expressions, or by discussions regarding potential new indications for Glivec, or regarding the long-term impact of a patient's use of Glivec. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results with Glivec to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Glivec 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 Glivec. In particular, management's ability to ensure satisfaction of the health authorities' further requirements is not guaranteed and management's expectations regarding commercialization of Glivec could be affected by, among other things, additional analysis of Glivec clinical data; new clinical data; unexpected clinical trial results; unexpected regulatory actions or delays or government regulation generally; the company's ability to obtain or maintain patent or other proprietary intellectual property protection; competition in general; 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.

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**MEDIA RELEASE**

**COMMUNIQUE AUX MEDIAS**

**MEDIENMITTEILUNG**

**Australian Pharmaceutical Benefits Advisory Committee recommends reimbursement of Glivec® for treatment of patients with chronic myeloid leukemia in the chronic phase**

Basel, 13 September 2002 Novartis is pleased to announce the recommendation for reimbursement of its oral cancer drug Glivec® (imatinib)\* by the Australian Pharmaceutical Benefits Advisory Committee (PBAC). With this announcement, patients with Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) in the chronic phase who have been unsuccessfully treated with interferon-alpha therapy will now qualify for government reimbursement for Glivec therapy. Previously, only Ph+ CML patients in the accelerated and blast crisis phase were eligible for funding for this treatment. Glivec is a molecularly targeted treatment for CML, one of the four most common types of leukemia.

"Novartis is pleased the PBAC has decided to make Glivec available for Australian CML patients," said David Epstein, President, Novartis Oncology. "This action follows the recent decision by the UK NICE authorities, which also recognized Glivec's value and efficacy."

Worldwide, CML has an incidence of one-to-two cases per 100,000 population per year and is responsible for 15 to 20% of all adult cases of leukemia. In Australia, the incidence of CML is approximately 300 cases per year.

The PBAC is an independent statutory body established on 12 May 1954 under section 101 of the National Health Act 1953 to make recommendations and give advice to the Minister for Health about which drugs and medicinal preparations should be made available as pharmaceutical benefits.

**Glivec An Innovative CML Treatment**

Glivec is one of the first oncology drugs that validate rational drug design based on an understanding of how some cancer cells work. It is a signal transduction inhibitor, which interferes with the pathways that signal the growth of tumour cells. Glivec works by inhibiting an abnormally activated enzyme that is coded for by the Philadelphia chromosome (Ph+), the genetic abnormality that characterizes CML in nearly all patients.

Glivec was originally recommended for reimbursement in Australia for the treatment of patients with Ph+ CML in the accelerated and blast phases in September 2001 and became available on the Pharmaceutical Benefits Scheme (PBS) on 1 December 2001 for the treatment of these patients. In Australia and in most countries where Glivec is approved, it is indicated for the treatment of patients with Philadelphia chromosome-positive CML in blast crisis, accelerated phase, or in chronic phase after failure of interferon-alpha therapy. The effectiveness of Glivec is based on overall haematologic and cytogenetic response rates.



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\* In the US: Gleevec (imatinib mesylate)

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On 28 June 2002, Novartis filed marketing applications in the European Union and the United States for Glivec in the first-line treatment of CML. The data in these applications were from the first-ever head-to-head study of Glivec and demonstrated that it is nearly three times more effective in achieving a cytogenetic response in the first-line treatment of newly diagnosed CML patients than the combination of interferon-alpha and cytosine arabinoside, a form of chemotherapy (IFN/Ara-C). Cytogenetic response, regarded as a major goal of CML treatment, is the disappearance or reduction of the number of cells containing the Philadelphia chromosome.

### **Glivec in GIST a Rare GI Tumour**

In June 2002, the Australian health authorities approved Glivec for the treatment of patients with c-Kit (CD 117) positive unresectable (inoperable) and/or metastatic malignant gastrointestinal stromal tumours (GISTs) a rare GI tumour. Glivec also is approved for the GIST indication in the United States and the EU. Prior to the availability of Glivec, patients with GIST had relatively few treatment options beyond surgery.

### **Contraindications and Adverse Events**

In CML patients, the majority of patients treated with Glivec experience adverse events at some time. Most events are of mild to moderate grade, but in the Phase II clinical trials for the CML submission, the drug was discontinued for adverse events in 2% of patients in late chronic phase, 3% in accelerated phase and 5% in blast crisis. The most common side effects included nausea, fluid retention, vomiting, diarrhoea, haemorrhage, muscle cramps, skin rash, fatigue, headache, dyspepsia and dyspnoea, as well as neutropenia and thrombocytopenia.

Although the majority of patients in the GIST trial had adverse events reported at least once during the trial, most events were mild to moderate in severity. The most common adverse events were oedema, nausea, diarrhoea, abdominal pain, muscle cramps, fatigue and rash. Serious (Grades 3-4) adverse events occurred in 21.1% of patients overall. They included low white blood cell counts, tumour haemorrhage and abdominal pain. In this trial, seven patients (5%) were reported to have gastrointestinal bleeds and/or intratumoural bleeds. Gastrointestinal tumour sites may have been the source of GI bleeds.

Glivec is contraindicated in patients with known hypersensitivity to imatinib or any of its excipients. Women of childbearing potential should be advised to avoid becoming pregnant while taking Glivec. Glivec is often associated with oedema and occasionally serious fluid retention, GI irritation and severe hepatotoxicity. Because follow-up of most patients treated with Glivec is relatively short, there are no long-term safety data on Glivec treatment.

The foregoing release contains forward-looking statements that can be identified by terminology such as "will now," "first ever," or similar expressions, or by discussions regarding potential new indications for Glivec, or regarding the long-term impact of a patient's use of Glivec. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results with Glivec to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Glivec 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 Glivec. In particular, management's ability to ensure satisfaction of the health authorities' further requirements is not guaranteed and management's expectations regarding commercialization of Glivec could be affected by, among other things, additional analysis of Glivec clinical data; new clinical data; unexpected clinical trial results; unexpected regulatory actions or delays or government regulation generally; the company's ability to obtain or maintain patent or other proprietary intellectual property protection; competition in general; 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.

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

3

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**MEDIA RELEASE**

**COMMUNIQUE AUX MEDIAS**

**MEDIENMITTEILUNG**

**Zelmac®, a novel treatment for Irritable Bowel Syndrome from Novartis, is now reimbursable in Switzerland**

Basel, 9 September 2002 Novartis announced today that the Swiss Federal Department for Social Security (BSV) has granted reimbursable status to Zelmac® (tegaserod), its novel treatment of Irritable Bowel Syndrome (IBS). "The decision to allow the reimbursement of Zelmac by the health insurance companies, is a welcome acknowledgement of the value of this novel treatment for Irritable Bowel Syndrome from the Swiss Federal Department for Social Security," said Thomas Ebeling, CEO Novartis Pharma. Known in the USA and Canada as Zelnorm , Zelmac® has been shown in clinical studies to relieve the symptoms abdominal pain and discomfort, bloating and constipation for women suffering with IBS.

**About Irritable Bowel Syndrome (IBS)**

IBS is characterized by abdominal pain and discomfort, bloating, and altered bowel function (constipation and/or diarrhoea). 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**

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.<sup>1</sup> In most patients, the onset of relief occurred within just one week.<sup>2</sup> The medicine was well tolerated and showed a profile of side effects similar to that of placebo. Zelmac was discovered and developed by Novartis. Apart from Switzerland, it is already approved in more than 30 countries today, including the USA, Australia, Canada, Brazil and Mexico.

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Mueller-Lissner S, et al. Tegaserod, a 5-HT<sub>4</sub> partial agonist, relieves symptoms in irritable bowel syndrome with abdominal pain, bloating and constipation. *Aliment Pharmacol Ther* 2001; 16:1655-66

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Integrated summary of efficacy. January 2000. Novartis, data on file.

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**MEDIA RELEASE**

**COMMUNIQUE AUX MEDIAS**

**MEDIENMITTEILUNG**

### **Novartis and Compugen expand collaboration for identification, prioritization and validation of new drug targets**

*Agreement includes new research collaboration in the field of RNAi and continued licensing of Compugen's LEADS platform*

Basel / Tel Aviv, 4 September 2002 Novartis and Compugen today announced the expansion of their multimillion-dollar collaboration, for the accelerated identification of drug targets, to include target validation. Under the expanded agreement, the two companies will collaborate on the research and development of a large-scale RNA interference (RNAi) platform.

The RNAi collaboration is based on Compugen's expertise in transcriptome analysis, which takes into account alternative splicing. The platform is intended for the design of a large-scale library of transcript-specific inhibiting molecules, to be synthesized by Novartis and to be used for evaluation of gene function and target validation. Under the terms of the agreement, Novartis is entitled to use the RNAi platform for its internal research and will own the derived results. Compugen will own the RNAi platform and will be entitled to use it for both internal and commercialization purposes.

This original collaboration for the completion of Novartis' human transcriptome database began in August 2001, and includes the licensing by Novartis of Compugen's LEADS computational biology platform for the creation of a comprehensive genome, transcriptome and proteome database. The database is derived from an analysis of all public genomic and expressed sequence data, as well as Novartis' proprietary and third party data. Please see backgrounder for more information on RNAi.

"Through this partnership we aim to set the standard for how the pharmaceutical industry can swiftly translate the promise of the new science of computational biology into meaningful therapies," said Prof. Paul Herrling, Head of Corporate Research at Novartis. "We believe that Compugen's technology is the best suited to analyze the vast amount of data represented in our sequence databases."

Mor Amitai, PhD., President and Chief Executive Officer of Compugen Ltd., commented, "We are delighted that in the past year we have successfully established a fruitful partnership with Novartis, a global leader in cutting-edge technologies for drug discovery and development. We are honored that Novartis chose to involve us in their internal research and development efforts in the emerging and promising field of RNAi, bringing a new level of collaboration to our relationship. For Compugen, this agreement marks a significant milestone in our efforts to establish alliances and co-develop novel technologies with market leaders."

#### About Compugen

Compugen (NASDAQ: CGEN) is a pioneer in the merging of computational technologies with biology, chemistry and medicine to enhance drug discovery and development. This unique capability is a proven basis for providing high value products and services to leading biotechnology and pharmaceutical companies and for in-house discovery. For additional information, please visit Compugen's Corporate Website at [www.cgen.com](http://www.cgen.com) and the Company's Internet research engine for molecular biologists at [www.LabOnWeb.com](http://www.LabOnWeb.com).

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## About Novartis

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This press release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. These statements include words like "will collaborate," "aim to," "can swiftly translate," "believe," "offers the promise of creating," and "could be crucial," and describe opinions or predictions about future events, including the possible development of new drugs or new drug targets as a result of the collaboration between Compugen and Novartis. These forward-looking statements involve known and unknown risks and uncertainties that may cause the actual results, performance or achievements of Compugen or Novartis to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. Some of these risks are: changes in relationships with collaborators; the impact of competitive products and technological changes; risks relating to the development of new products; the likelihood or ability to develop a commercially viable product deriving from any of the targets identified from this collaboration and then to obtain registration thereof with applicable authorities, the ability to implement technological improvements; and the ability of Compugen to obtain and retain customers. In particular, there can be no guarantee that any new drug will be commercialized in any market as a result of this collaboration. These and other applicable risk factors are identified and more fully explained, in Compugen's case, under the heading "Risk Factors" in Compugen's Registration Statement on Form F-1 and its annual reports filed with the Securities and Exchange Commission and in Novartis' case, in the Group'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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## Backgrounder for Novartis/Compugen Press Release

**RNA interference (RNAi)** is a biological phenomenon that involves the silencing or "knockdown" of genes in a sequence-specific manner. RNAi is currently being used as a potent tool for evaluation of gene function and target validation. In addition, it is particularly exciting as it offers the promise of creating a brand new class of gene-specific medicines (RNAi-based therapeutics) with high potency and specificity.

First discovered in 1998 in worms, RNAi is a naturally occurring process that can silence the expression of a specific gene by destroying its messenger RNA (mRNA), which encodes its protein product. The process is triggered by a double stranded RNA (dsRNA) molecule, and is thought to be a natural cellular defense mechanism against RNA viruses. Since its discovery, RNAi has been found in a number of organisms such as drosophila (fruit flies) and nematodes (worms), and in fungi and plants. More recently, it was shown that this mechanism is also active in mammals, including human cells, and that it can be artificially induced and employed for gene-specific silencing.

The common way of triggering the RNAi silencing mechanism starts with the introduction of dsRNA into cells. Once inside cells, the dsRNA is shredded into short fragments by an enzyme known as "Dicer" and then rendered single stranded. Next, each resulting single-stranded RNA fragment, in conjunction with a complex of proteins, seeks out and destroys the mRNA that is complementary to it. By selecting the sequence of the dsRNA to target specific mRNAs, the relevant genes can be silenced. In mammals, the dsRNA has to be specifically designed as short fragments of about 21 nucleotides in length to avoid triggering a general toxic cellular response to dsRNA.

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The collaboration between Novartis and Compugen is based on Compugen's prediction of **alternative splicing**. Alternative splicing is the phenomenon in which a single gene may produce a number of variant protein products through the transcription of multiple RNAs encoded by different parts of the gene. A deep understanding of alternative splicing patterns could be crucial for the design of dsRNA for optimal gene silencing. For instance, a gene can be completely silenced only if the sequence of the dsRNA used is common to all splice variants. If silencing of a specific gene product is desired, the dsRNA sequence has to correspond to regions that are specific to the splice variant. Thus, an understanding of splicing pattern is of great importance for modeling RNAi in mammals, where over 50% of the genes are known to have alternative splicing, and very short dsRNA are employed.

By using its proprietary LEADS technology, Compugen researchers have developed a profound understanding of alternative splicing and of the transcriptome, the bridge between genes and their coded proteins. Using LEADS, Compugen has developed a comprehensive genome, transcriptome and proteome database, enabling in-depth, accurate understanding of underlying biological processes for drug target discovery and

therapeutic research.

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3

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**MEDIA RELEASE**

**COMMUNIQUE AUX MEDIAS**

**MEDIENMITTEILUNG**

**New data from Val-HeFT shows Diovan (valsartan) is highly cost-effective in treating heart failure patients not taking ACE inhibitors**

Basel, 2 September 2002 A new study presented at the European Society of Cardiology (ESC) Congress 2002 shows that Diovan® (valsartan), the angiotensin II receptor blocker (ARB), is a highly cost-effective treatment for heart failure patients not taking angiotensin-converting-enzyme (ACE) inhibitors, currently the most widely-prescribed drugs for this disease. Based on new data from the landmark Valsartan Heart Failure Trial (Val-HeFT), the study shows 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. The study was presented by Eric Velazquez, MD, Professor of Cardiology, Duke University Medical Center, Durham, North Carolina, USA.

Val-HeFT previously established that Diovan significantly improves mortality by 33% and reduces hospitalizations for heart failure by 57% in-patients who do not take ACE inhibitors. Based on these findings, Diovan recently became the only ARB approved in the US for treatment of heart failure patients who cannot tolerate ACE inhibitors. Treatment guidelines by the ESC and other prestigious organizations already recommend the use of ARBs such as Diovan for these patients.

"The cost-effectiveness of Diovan in heart failure patients who do not take ACE inhibitors has important implications for clinical practice. Despite their known benefits, ACE inhibitors are not prescribed to as many as 54% of heart failure patients because of side effects or other reasons," said Professor Velazquez.

Val-HeFT was one of the largest studies ever conducted in heart failure patients and involved 5010 patients from 302 centers in 16 countries. Patients were randomized to receive placebo or Diovan along with standard heart failure therapy already prescribed by their physicians. The new data presented at ESC are based on a multinational economic analysis conducted throughout the Val-HeFT trial on resource utilization and clinical outcomes in the 366 patients who did not take ACE inhibitors as part of their prescribed treatment at baseline. The average period of follow-up was 23 months. Direct medical costs were computed using unit costs from all 16 countries participating in the trial, converted to 1999 US dollars, the most currently available figures.

The study showed that Diovan was not only more effective but also less costly than placebo in treating heart failure patients not receiving an ACE inhibitor. Mortality was significantly reduced and at the same time, costs were USD 929 lower on average during the period studied [95% CI: -3243 to USD 1533]. In particular, costs for heart failure hospitalizations were lower by more than USD 2000 per patient.

Heart failure is reaching epidemic proportions in most developed countries, partly due to the rapidly growing aging population and scientific advances that have helped heart attack patients to survive for longer. It 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. In the US alone, costs for treating heart failure are estimated to exceed USD 50 billion a year.

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"Val-HeFT demonstrates that Diovan is not only a safe and effective substitute for ACE inhibitors for the management of heart failure but is an economically attractive treatment as well," said Joerg Reinhardt, Head of Development, Novartis Pharma AG. "Novartis is also studying the cost-efficacy of Diovan in other diseases spanning the cardiovascular continuum as part of our major ongoing clinical trial program."

Diovan is supported by the world's largest and most innovative clinical trial program with an ARB involving over 40 000 patients including over 8000 with diabetes. Besides Val-HeFT, trials examining the effects of Diovan beyond its indications for hypertension and heart failure include VALUE (high-risk patients with hypertension), VALIANT (post-myocardial infarction patients), and NAVIGATOR (patients with impaired glucose tolerance also called pre-diabetes at high risk for cardiovascular events).

Diovan is 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 antihypertensives, an estimated three million patients worldwide take Diovan for high blood pressure.

The foregoing press release contains forward-looking statements that can be identified by terminology such as "fastest growing" 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, including the results of clinical trials, regulatory actions or delays or government regulation generally, the ability to obtain or maintain patent or other proprietary intellectual property protection and competition in general, as well as factors discussed in the Company's Form 20-F filed with the 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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### SIGNATURES

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

#### Novartis AG

Date: October 2, 2002

By: /s/ MALCOLM B. CHEETHAM

Name: Malcolm B. Cheetham

Title: Head Group Financial Reporting and Accounting

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