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NOVARTIS AG
Form 6-K
July 25, 2002

SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 6-K

REPORT OF FOREIGN PRIVATE ISSUER
PURSUANT TO RULE 13a-16 or 15d-16 OF
THE SECURITIES EXCHANGE ACT OF 1934

Report on Form 6-K dated July 25, 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. Zometa(R) receives EU approval for the prevention of cancer-related bone complications
2. FDA approves Zelnorm(TM), a novel treatment for irritable bowel syndrome in women with constipation

Page 1 of 7 Total Pages

Novartis

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- Investor Relations Release -

Zometa(R) receives EU approval for the prevention of cancer-related bone complications

Zometa is the first and only bisphosphonate demonstrating efficacy across a broad range of solid tumors

Basel, 24 July 2002 - Novartis today announced that the European Agency for the Evaluation of Medicinal Products (EMA) has granted marketing authorization in the European Union (EU) for Zometa(R) (zoledronic acid) 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. This is the broadest range of tumor types in which a bisphosphonate has ever demonstrated efficacy. Zometa offers patients and clinicians a highly effective treatment with a convenient 15-minute infusion time.

"We are pleased to see that medical and regulatory authorities around the world are recognizing the value of Zometa in treating the debilitating bone complications associated with advanced cancer," said David Epstein, President, Novartis Oncology.

Advanced malignancies in a broad range of solid tumors, including breast, lung, prostate, bladder and renal cancers often spread (metastasize) to bones, while multiple myeloma is a type of cancer that originates in the bones. Zometa is an intravenous bisphosphonate newly indicated to prevent these complications - or skeletal related events (SREs) - which represent a significant problem for cancer patients in the advanced stages of the disease. They include pathological fractures, spinal compression, radiation or surgery to bone, or tumor-induced hypercalcaemia.

In February, the US Food and Drug Administration granted approval for the use of Zometa in treating patients with multiple myeloma and patients with documented bone metastases from solid tumors, in conjunction with standard antineoplastic therapy. Additionally, recent clinical practice guidelines from The American Society of Clinical Oncology support the use of Zometa in the treatment of bone lesions in multiple myeloma. The guidelines will be published in the September issue of the Journal of Clinical Oncology and are currently available online (JCO July 1, 2002).

Clinical Data

The approval for Zometa is based on data from three large international clinical trials evaluating more than 3000 patients with myeloma, prostate cancer, breast cancer, lung cancer and other solid tumor types studied in the clinical trials. This is the largest set of clinical trials ever conducted to

Page 2 of 7 Total Pages

evaluate the efficacy and tolerability of a bisphosphonate in preventing skeletal complications in patients with bone metastases.

Zometa has been shown in clinical trials to decrease the skeletal complications of patients with multiple myeloma and with bone metastases from solid tumors. Results have also demonstrated that Zometa delays the initial onset of bone complications by more than two months in patients with non-small cell lung cancer and other solid tumors. In two placebo-controlled clinical studies conducted in patients with bone metastases from prostate cancer or other solid tumors, there was a decrease in the number of patients with skeletal related events, whereas the time to first skeletal related event was delayed.

About Zometa

To date, Novartis has received marketing authorisation for Zometa in the multiple myeloma and bone metastases indication in more than 35 countries, including the EU. Previously, Novartis received marketing clearance for Zometa in the treatment of hypercalcaemia of malignancy, also known as tumor-induced hypercalcaemia, 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 bisphosphonates. The most commonly reported adverse events included flu-like syndrome (fever, arthralgias, myalgias, bone 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; single doses of Zometa should not exceed 4 mg and the duration of infusion should be no less than 15 minutes. Caution is advised when Zometa is administered with other potentially nephrotoxic drugs.

Novartis AG (NYSE: NVS) is a world leader in healthcare with core businesses in pharmaceuticals, consumer health, generics, eye-care, and animal health. In 2001, the Group's businesses achieved sales of CHF 32.0 billion (USD 19.1 billion) and a net income of CHF 7.0 billion (USD 4.2 billion). The Group invested approximately CHF 4.2 billion (USD 2.5 billion) in R&D. Headquartered in Basel, Switzerland, Novartis Group companies employ about 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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Page 3 of 7 Total Pages

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- Investor Relations Release -

FDA approves Zelnorm(TM), a novel treatment for irritable bowel syndrome in women with constipation

Zelnorm(TM) is first and only prescription therapy in the US for the relief of the common symptoms of abdominal pain and discomfort, bloating, and constipation in women with IBS

Basel, 24 July 2002 - The Novartis drug Zelnorm(TM) (tegaserod maleate)* today became the first and only prescription medication approved by the US Food and Drug Administration (FDA) for the short-term treatment of women with irritable bowel syndrome (IBS) whose primary bowel symptom is constipation. Until now, no prescription medication has been approved in the United States to treat the multiple symptoms of abdominal pain and discomfort, bloating, and constipation associated with IBS. The medical community has recognized that therapies traditionally used to treat these symptoms have been generally ineffective or poorly tolerated.

"Zelnorm marks a breakthrough for the millions of women who have suffered for years with IBS with constipation waiting for a safe and effective therapy to relieve their symptoms," said Daniel Vasella, MD, Chairman and CEO, Novartis AG. "As with our discoveries in oncology, heart disease and transplantation, Zelnorm reflects our commitment to bring innovative treatments to patients with significant unmet needs. We will rapidly make Zelnorm available to patients, and plan for an early fall market introduction. "

About IBS

IBS is characterized by abdominal pain and discomfort, bloating, and altered bowel function (constipation and/or diarrhea). IBS affects up to one in five Americans. Second only to the common cold as a leading cause of workplace absenteeism in the US, IBS costs the US healthcare system up to an estimated \$30 billion annually in direct and indirect costs.

"Patients suffering from abdominal pain and discomfort, bloating, and constipation associated with IBS endure a great deal of distress, often preventing them from participating in such simple everyday activities as going to work or school, participating in sports, or enjoying a vacation with their family," said Nancy Norton, President and Founder of the International Foundation for

* In the US, Canada, and South Africa: Zelnorm(TM) (tegaserod maleate), all other countries: Zelmac(R) (tegaserod)

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Functional Gastrointestinal Disorders. "The approval of Zelnorm is very exciting news for millions of women who suffer from this condition."

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 have a lower GI tract that may be more sensitive and work more slowly than it should. This may be due to the way their lower GI tract reacts to changes in a naturally occurring chemical in their body that regulates mobility in the intestinal system, and the perception of pain and discomfort.

About Zelnorm

Zelnorm is the first agent in a new class of drugs called serotonin-4 receptor agonist (5HT4 agonist) developed to target the GI tract. By activating 5HT4 receptors, Zelnorm stimulates the peristaltic reflex and normalizes impaired mobility in the GI tract. Zelnorm is the first agent proven to provide relief of the abdominal pain and discomfort, bloating and constipation caused by IBS.

"IBS with constipation is a very real medical disorder that has frustrated patients and physicians due to the obvious lack of any safe and effective prescription medications to treat the painful symptoms," said Pete Peterson, MD, University of Texas, Southwestern School of Medicine in Dallas. "Zelnorm is an important advancement in IBS therapy. We can now provide safe and effective symptom relief to a significant number of patients for whom this was not possible before."

The FDA approval of Zelnorm is based on clinical trials that show Zelnorm provides relief of the abdominal pain and discomfort, bloating and constipation in women with IBS. Three multicenter, double blind, placebo-controlled studies involved 2,470 women with at least a three-month history of IBS symptoms prior to the study baseline period. Patients received either Zelnorm 6 mg/b.i.d. or a placebo over a three-month period.

Each week, participants rated their responses to the "Subject's Global Assessment of Relief," a measurement tool which takes into account overall well being, symptoms of abdominal pain and discomfort, and constipation. Based on this assessment, more patients on Zelnorm experienced relief than patients on placebo. In addition, Zelnorm was shown to provide relief of the individual symptoms of abdominal pain and discomfort, bloating, and constipation.

In clinical studies, Zelnorm was generally well tolerated. The side effects that occurred more often with Zelnorm than with placebo were headache (15% vs. 12%) and diarrhea (9% vs. 4%). The majority of the Zelnorm patients reporting diarrhea had a single episode. In most cases, diarrhea occurred within the first week of treatment. Typically, diarrhea resolved with continued therapy. Zelnorm is not indicated for patients who are currently experiencing or frequently experience diarrhea. The safety and effectiveness of Zelnorm in men have not been established.

Zelnorm was discovered and developed by Novartis. Zelnorm, known internationally as Zelmac, is approved in more than 30 countries including Australia, Switzerland, Canada and Brazil. Novartis also is conducting clinical assessments of Zelnorm as a potential treatment for other important gastrointestinal disorders such as chronic constipation and functional dyspepsia. It is the tenth Novartis product to receive FDA approval since January 2000.

The foregoing press release contains forward-looking statements that can be identified by terminology such as "will rapidly make Zelnorm available", "plan for an early fall market

introduction", "also is conducting", "potential treatment", or similar expressions, or by statements regarding the potential sales of Zelnorm in the US, or by discussions of potential additional indications for 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 are no guarantees of the commercial success of Zelnorm in the US or elsewhere, or that the aforementioned clinical assessments will result in the commercialization of any additional indications for Zelnorm in any market. Any such commercial success or commercialization of additional indications, or other results, performance or achievements expressed or implied in such statements, 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, uncertainties relating to pharmaceutical production, 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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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: July 25, 2002

By: /s/ MALCOLM B. CHEETHAM

Name: Malcolm B. Cheetham

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Title: Head Group Financial
Reporting and Accounting

Page 7 of 7 Total Pages