NOVARTIS AG
Form 6-K
August 03, 2004

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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 July 2004
(Commission File No. 1-15024)

Novartis AG

(Name of Registrant)

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(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: ý Form 40-F: o

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Yes: o **No:** ý

Enclosures:

1. Emselex® Receives Positive CHMP Opinion for the Treatment Of Overactive Bladder (Basel, 30 July, 2004)

2. Approval recommended for use of Zelnorm® in chronic constipation by FDA Advisory Committee (Basel, 15 July, 2004)

3. Novartis Institute for Tropical Diseases opens in Singapore's state-of-the-art Biopolis research facility (Basel, Switzerland and Singapore, 5 July, 2004)

4. Novartis seeks European approval for Xolair® as first-in-class treatment for severe allergic asthma (Basel, 2 July, 2004)

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Investor Relations Release

Emselex® Receives Positive CHMP Opinion for the Treatment Of Overactive Bladder

Basel, 30 July 2004 Novartis Pharma AG announced today that the Committee for Medicinal Products for Human Use (CHMP), adopted a positive opinion recommending that the European Commission (EC) grant a Marketing Authorisation for Emselex® (darifenacin hydrobromide), 7.5mg and 15mg, for the treatment of overactive bladder (OAB) in all 25 European Union (EU) countries as well as Norway and Iceland. Upon receipt of the EC approval, Novartis will be able to market Emselex throughout these countries.

"We are delighted by the CHMP's positive opinion for Emselex, to provide overactive bladder sufferers with a new safe and effective treatment option", said Jörg Reinhardt, Global Head of Development Novartis Pharma AG. "Due to its M3 selectivity, Emselex provides effective overactive bladder symptom relief while decreasing the potential risk of safety issues such as cognitive impairment or effects on cardiac function."

OAB affects almost one in six adults in Europe(1). Symptoms of overactive bladder are urinary urgency (a sudden compelling desire to pass urine, which is difficult to defer) with or without urge incontinence (involuntary leakage accompanied by urgency), urinary frequency (voiding the bladder too often), and nocturia (waking at night one or more times to void the bladder).

The CHMP based its positive opinion on Emselex's comprehensive data package for OAB. The safety and efficacy of Emselex has been extensively studied in over 90 pre-clinical studies and clinical trials, involving more than 5,000 patients. Pivotal studies explored key endpoints including the reduction in the number of incontinence episodes per week, the reduction in the number of voluntary urination episodes (micturition) per day, the reduction in the episodes and severity of urgency and an increase in the average volume of urine passed per micturition.

The phase III clinical trials demonstrated the efficacy, safety and tolerability of Emselex. A pooled analysis of three multicentre, double-blind, placebo-controlled studies included a population of 1,049 adults with OAB symptoms for more than 6 months. Results demonstrated that Emselex reduces the number of weekly incontinence episodes by up to 77%(1). Emselex was well tolerated and discontinuation rates due to dry mouth or constipation were very low with each dose of Emselex compared to placebo(2). Also, central nervous system (CNS) and cardiovascular safety of Emselex were comparable to placebo at both doses1. Another study showed Emselex does not impair cognitive function such as memory, choice reaction time and word recognition, compared to placebo(3).

About Novartis

Novartis AG (NYSE: NVS) is a world leader in pharmaceuticals and consumer health. In 2003, the Group's businesses achieved sales of USD 24.9 billion and a net income of USD 5.0 billion. The Group invested approximately USD 3.8 billion in R&D. Headquartered in Basel, Switzerland, Novartis Group companies employ about 80 000 people and operate in over 140 countries around the world. For further information please consult *http://www.novartis.com*.

Disclaimer

This release contains certain forward-looking statements that can be identified by the use of forward-looking terminology, such as "upon receipt of ... approval", "will be able to market", "potential", "may be"

or similar expressions, or by express or implied discussions regarding potential marketing approvals or future sales of Emselex. Such forward looking statements reflect the current views of the Company regarding future events, and involve known and unknown risks, uncertainties and other factors that may cause the actual results with Emselex to be materially different from any future results, performance, or achievements expressed or implied by such statements. There can be no guarantee that Emselex will be approved for sale in any new market or that it will reach any particular sales levels. Any such commercialisation can be affected by, amongst other things, uncertainties relating to clinical trials, regulatory actions or delays or government regulation generally, the ability to obtain or maintain patent or other proprietary intellectual property protection and competition in general, government, industry, and general public pricing pressures, 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. Novartis is providing the information in this press release as of this date and does not undertake any obligation to update any forward-looking statements contained in this press release as a result of new information, future events or otherwise.

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Investor Relations Release

Approval recommended for use of Zelnorm® in chronic constipation by FDA Advisory Committee

When approved, Zelnorm will be first Rx therapy for chronic constipation

Basel, Switzerland July 15, 2004 Novartis Pharma AG announced today that Zelnorm® (tegaserod maleate) was recommended for approval for the treatment of chronic constipation (CC) by the Gastrointestinal Drugs Advisory Committee to the U.S. Food and Drug Administration (FDA). The Committee's recommendation was subject to specific labelling regarding age and gender. Novartis will work with the FDA to address the issues raised by the Committee.

The supplemental new drug application (sNDA) for Zelnorm for chronic constipation was filed in October 2003. The FDA generally follows the advice of its advisory committees, although the agency is not bound by its recommendations. A decision by the FDA is expected next month. If approved, Zelnorm would be the first prescription medication for the treatment of chronic constipation.

The sNDA is supported by data from the two largest randomized, double-blind, placebo-controlled, multi-national Phase III clinical trials ever conducted in the treatment of chronic constipation in more than 2,600 male and female patients. One of the studies included a 13-month extension safety study of nearly 842 patients. Zelnorm was found to significantly increase the frequency of complete spontaneous bowel movements as well as relief of the multiple symptoms patients complain about most straining, hard stool, incomplete evacuation and infrequent defecation.

To enroll in the studies, patients had to have CC for at least six months, which was defined as less than three bowel movements per week, accompanied by at least one of the following additional symptoms: straining, incomplete evacuation and/or hard/very hard stools.

"We are pleased the Advisory Committee has recognized Zelnorm's ability to address the needs of chronic constipation sufferers," said Bo Joelsson, MD, PhD, VP, Global Head, Gastroenterology Therapeutic Area, Clinical Development of Novartis Pharmaceuticals Corporation. "We look forward to working with the FDA on label discussions to secure approval for Zelnorm for the treatment of CC, so this novel therapy can be made available to patients at the earliest possible opportunity."

Zelnorm was approved by the FDA in July 2002 as the first and only prescription medication for the short-term treatment of women with irritable bowel syndrome whose primary bowel symptom is constipation.

Zelnorm Clinical Trial Results

The studies demonstrated that Zelnorm-treated patients experienced significantly more complete spontaneous bowel movements (CSBMs) than patients on placebo during 12 weeks. Zelnorm demonstrated early onset of action, with the majority of the Zelnorm-treated patients experiencing a spontaneous bowel movement within the first 24 hours. The response rate for the first four weeks of treatment (primary efficacy variable) was 42 percent in the group receiving 6 mg twice-a-day of Zelnorm significantly higher than the 26 percent in the placebo group ($p < 0.0001$). Over the 12-week period, the response rate for the 6 mg twice-a-day treated group continued to be significantly superior to placebo (44 percent vs. 29 percent).

Significant weekly improvements were observed in Zelnorm-treated patients for stool frequency, consistency and straining compared to placebo. Zelnorm-treated patients also reported less bothersome

constipation, abdominal pain/discomfort and bloating/distension. In addition, satisfaction with bowel habits significantly improved with Zelnorm compared to placebo.

In the studies, the incidence of adverse events with Zelnorm was similar to that of placebo. The only adverse event reported more often with Zelnorm 6 mg twice-a-day than placebo was diarrhea (6.6 percent). Diarrhea rarely led to discontinuation of the study (0.9 percent). Typically, diarrhea was transient, lasting two days, and generally resolved without rescue medication or interruption of treatment.

Data from one of the studies which incorporated a 13-month extension study showed Zelnorm to be generally safe and well tolerated long term.

About Chronic Constipation

Constipation affects nearly 18 percent of the population, or 37 million people, with more than 4.5 million Americans saying they are constipated most of the time. The condition is evenly distributed across all ages. CC is treated most frequently by primary care physicians, accounts for more than 5.7 million annual visits to emergency rooms and doctors' offices each year, and leads to more than 282,000 in-patient hospitalizations.

About Zelnorm

Zelnorm is indicated for the short-term treatment of women with IBS whose primary bowel symptom is constipation. The safety and effectiveness of Zelnorm in men with IBS with constipation has not been established.

Zelnorm is the first agent proven to provide women with relief of the abdominal discomfort or pain, bloating and constipation of IBS, and it is the first in a novel class of drugs. Zelnorm acts an agonist at 5HT4 (serotonin type 4) receptors in the GI tract. Zelnorm mimics the natural effects of serotonin by activating 5HT4 receptors, which normalizes impaired motility in the GI tract, inhibits visceral sensitivity and stimulates intestinal secretion.

In IBS with constipation clinical trials, tolerability to Zelnorm was similar to placebo. The only adverse event reported notably more often with Zelnorm than with placebo was diarrhea (nine vs. four percent). The majority of patients reporting diarrhea had a single episode and in most cases, diarrhea occurred in the first week of treatment. Typically, it resolved with continued therapy. Serious consequences of diarrhea, including hypovolemia, hypotension and syncope, have been reported in the clinical studies (0.04 percent) and during marketed use of Zelnorm. In some cases, these complications have required hospitalization for rehydration. Overall, safety data is now available in more than 11,600 patients who have enrolled in clinical trials assessing Zelnorm's safety and efficacy in various GI conditions.

Zelnorm was developed by Novartis and is also known in some countries as Zelmac®. It is approved in more than 55 countries for IBS with constipation. Approximately three million patients worldwide have been treated with Zelnorm for IBS with constipation. Zelnorm also is approved for use in chronic constipation in 10 countries, including Mexico and Latin America. Zelnorm is being studied as a potential treatment for other important GI disorders, including gastroesophageal reflux disease (GERD) and dyspepsia.

This release contains certain forward-looking statements relating to the Company's business, which can be identified by the use of forward-looking terminology such as "if approved", "might benefit", "would be", "look forward", or similar expressions, or by express or implied discussions regarding the potential approval of Zelnorm for any chronic constipation or for any other new indications, or regarding potential future sales of Zelnorm. Such forward-looking 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 Zelnorm will be approved for chronic constipation or for any other new indications by the FDA or in any other country. Nor can there be any guarantee regarding potential future revenues from Zelnorm. In particular, management's expectations could be

affected, among other things, uncertainties relating to unexpected regulatory actions or delays, government regulation generally, new clinical data, unexpected clinical trial results, the ability to obtain or maintain patent or other proprietary intellectual property protection, competition in general, government pricing pressures, and other risks and factors referred to in the Company's current Form 20-F on file with the Securities and Exchange Commission of the United States. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those described herein as anticipated, believed, estimated or expected. Novartis is providing the information in this press release as of this date and does not undertake any obligation to update any forward-looking statements contained in this press release as a result of new information, future events or otherwise.

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MEDIA RELEASE COMMUNIQUE AUX MEDIAS MEDIENMITTEILUNG

Novartis Institute for Tropical Diseases opens in Singapore's state-of-the-art Biopolis research facility

Unique non-profit initiative in drug discovery for neglected diseases

Basel, Switzerland and Singapore, July 5, 2004 Novartis announced today the official opening of the Novartis Institute for Tropical Diseases (NITD) in Singapore's new Biopolis research facility. The Institute is focused on advanced biomedical research for neglected diseases, initially dengue fever and drug resistant tuberculosis (TB). The incidence of both these diseases is accelerating rapidly, particularly in the developing world. Today, more than one-third of the world's population is infected with TB and more than two million people die each year. In addition, 2.5 billion people worldwide are at risk from dengue fever.

"Every second someone is newly infected with TB, which has grown to be the third leading cause of death globally for people aged 15-59, while dengue fever infects as many as 50 million people a year, and is endemic in over 100 countries," said Dr. Daniel Vasella, Chairman and CEO of Novartis. "The relentless spread across the developing world of these diseases makes the discovery of new treatments critical. We will make a scientific contribution with the NITD, bringing together excellent researchers and world class advisors to help solve these problems."

The World Health Organization (WHO) has declared drug-resistant TB an urgent health matter, with more than 300,000 new cases per year occurring mainly in Eastern Europe and Central Asia. Unfortunately, TB has become resistant to most of the antibiotics used today to treat the disease. Currently, more than 79 percent of cases are identified as "super strains" resistant to three of the four current treatments, and there has been little research into new treatment options for many years.

In the case of dengue fever, there has been no major discovery effort directed to new treatments despite significant unmet medical need. According to the WHO, there have been 58,000 new cases of dengue fever in Indonesia alone during 2004, resulting in 650 deaths. Worldwide, there are about 500,000 hospitalizations to treat dengue patients each year.

The NITD is a public-private partnership between Novartis and the Singapore Economic Development Board (EDB). The Institute's goals are to have at least two compounds in clinical trials by 2008 and two novel and attractive compounds available to patients by 2013. Novartis intends to make these treatments available without profit for countries where these diseases are endemic.

"The NITD is a unique research institute dedicated to reducing the affliction of tropical diseases through the application of Novartis' leading edge drug discovery skills," said Professor Paul Herrling, Chairman of the Board of the NITD, and Head of Corporate Research at Novartis. "The NITD is simultaneously educating young scientists, and helping people in the developing world learn how to continue to address these problems in their own countries. We want this institute to stand as a role model for public-private partnerships in South East Asia."

The discovery technology available at NITD is state-of-the-art and the scope of its activities ranges from target discovery and screen development, to compound optimization, resulting in potential treatments ready for clinical testing.

The NITD is located in the 2 million square feet Biopolis research complex, an integrated biomedical research hub located in Singapore. Opened in October 2003, Biopolis boasts state-of-the-art

scientific facilities, including nuclear magnetic resonance and DNA sequencing and hosting all of the biomedical research bodies, namely the Institute of Molecular and Cell Biology (IMCB), the Genome Institute of Singapore (GIS), the Bioprocessing Technology Institute (BTI), the Bioinformatics Institute (BII) and the Institute for Bioengineering and Nanotechnology (IBN) of the Agency for Science, Technology and Research (A*STAR).

"The Biopolis development underlines Singapore's commitment to the biomedical sciences. We are confident that the research done by our community of public research institutes and R&D laboratories of biomedical companies will contribute significantly to advancing human healthcare around the world," said Mr. Philip Yeo, Chairman A*STAR and Co-Chairman, EDB in charge of the EDB Biomedical Sciences Group (EDB BMSG). "Our partnership with Novartis through the establishment of the NITD is one example of how we are moving towards that goal. We are delighted to be part of this important initiative to discover and develop new ways to prevent and treat these life threatening diseases."

The NITD is directed by Professor Alex Matter who is supported by a strong scientific advisory board. Board members include Nobel Laureate Professor Sidney Brenner of The Salk Institute in California; Nobel Laureate Professor Rolf Zinkernagel, Head of the Institute of Experimental Immunology in Zurich, Switzerland; Professor Barbara Imperiali of the Massachusetts Institute of Technology in Cambridge, Massachusetts; Professor Stefan Kaufmann of the Max-Planck-Institute for Infection Biology in Berlin, Germany; and Professor Duane Gubler, Head of the Pacific Center for Emerging Infectious Diseases Research, University of Hawaii Medical School, Honolulu, Hawaii.

The NITD was established in 2002 with support from the EDB Biomedical Sciences Group (EDB BMSG) and was housed temporarily in the Capricorn Research Center in 2003.

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Additional media information can be found at:

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Investor Relations Release

Novartis seeks European approval for Xolair® as first-in-class treatment for severe allergic asthma

Basel, 2 July 2004 Novartis Pharma AG yesterday submitted its application for the European approval of Xolair® (omalizumab), a novel therapy which targets a root cause of allergic disease and offers an entirely new approach to the treatment of allergic asthma. The file, submitted to the Committee for Medicinal Products for Human Use (CHMP), is based on clinical trial experience in around 5,500 patients demonstrating Xolair's efficacy in controlling symptoms and reducing asthma exacerbations (or "attacks"), even in patients with severe allergic asthma that is uncontrolled by existing medication.

Allergic asthma is a chronic disorder of the airways that affects nearly 150 million people worldwide and causes more than 180,000 deaths annually.[(1)] The symptoms include difficulty in breathing, wheezing, coughing, chest tightness and shortness of breath. Allergies are a contributory factor in a majority of cases of asthma. In these patients, the symptoms are triggered by contact with allergens such as pollen, house dust mites or particles of animal hair.

Unique mode of action

Xolair is conveniently administered by subcutaneous injection every two or four weeks, and is unique in blocking the action of IgE (immunoglobulin E), the antibody responsible for triggering the cascade of symptoms in patients who suffer from allergy-induced diseases. Xolair is a humanised monoclonal antibody which is designed to bind to the IgE circulating in the bloodstream, inhibiting the release of inflammatory chemicals that cause the symptoms of asthma. Reducing IgE levels also helps to improve inflammation of the airways, making Xolair the first non-steroidal therapy that is proven to have a major anti-inflammatory effect in allergic asthma.

Xolair was developed jointly by Novartis Pharma AG, Genentech, Inc., and Tanox, Inc., and was approved by the US Food and Drug Administration in June 2003. In the US, Xolair is indicated for adults and adolescents (12 years of age and above) with moderate to severe persistent asthma who have a positive skin test or *in vitro* reactivity to a perennial aeroallergen and whose symptoms are inadequately controlled with inhaled corticosteroids. Xolair is also approved in Australia. To date, more than 15,000 patients have been prescribed Xolair in the US. In Europe the proposed indication will focus on the prevention of asthma exacerbations and control of symptoms in adults and adolescents with severe persistent allergic asthma, who remain inadequately controlled despite use of inhaled corticosteroids and long-acting beta-2 agonists.

The submission is supported by a comprehensive programme of more than 30 clinical trials demonstrating Xolair's efficacy in reducing asthma exacerbations and the need for emergency medical treatment, and improving patients' quality of life. Among them is a recently completed 28-week randomised, double-blind, placebo-controlled study in 419 adults and adolescents with inadequately-controlled severe allergic asthma, results from which will be presented at the European Respiratory Society meeting in September 2004.

Clinical benefits

Data from a clinical trial published in the latest edition of *Allergy*[(2)] show that the number of asthma exacerbations was significantly lower with Xolair than with best standard care alone (1.12 and 2.86 per patient-year respectively, $p < 0.001$), equivalent to a reduction of 60.8%. Significantly more

patients treated with Xolair remained exacerbation-free than those on best standard care alone (49.5% [102/206] vs. 26.4% [28/106], p = 0.001).

This randomised, open-label, multicentre parallel-group study of 312 patients (aged 12 73) with poorly-controlled moderate-to-severe allergic asthma was designed to investigate Xolair's efficacy and tolerability in a "real-life" clinical setting.

Prof. Jean Bousquet of the Service des Maladies Respiratoires, Hôpital Arnaud de Villeneuve, Montpellier, France, who is the editor of *Allergy*, said: "These results confirm that this therapy has the potential to transform the way we treat patients with severe allergic asthma, who remain at risk of serious and sometimes life-threatening symptoms despite receiving the best treatment currently available. For patients with severe and uncontrolled disease, Xolair has the potential to provide a major breakthrough in treatment".

Anti-inflammatory effect

The anti-inflammatory properties of Xolair are highlighted in a further recently-published study[(3)] involving 43 patients (aged 19 48) with mild-to-moderate disease, whose airways have not been modified by treatment with corticosteroids. This 16-week randomised, double-blind, placebo-controlled, multicentre parallel-group study showed that Xolair led to a reduction in many types of cells involved in airway inflammation, especially the white blood cells called eosinophils. An increase of eosinophils in the sputum is a typical feature of asthma, and this is associated with a greater risk of exacerbation and broadly correlates with disease severity.

The study showed that the mean sputum eosinophil count decreased significantly (p <0.001) from 6.6% to 1.7% in the Xolair group, a reduction significantly (p 0.05) greater than with placebo (8.5% to 7.0%). The authors conclude: "The findings of the present study are significant in that they show omalizumab to be the first nonsteroidal agent with major anti-inflammatory activity in the airways of allergic asthmatics."

Safety information

Xolair treatment is generally well-tolerated. The most frequent adverse events included injection site reactions (45%), viral infections (23%), upper respiratory tract infections (20%), sinusitis (16%), headache (15%), and pharyngitis (11%). These events were observed at similar rates in Xolair-treated patients and control patients.

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(1) World Health Organization. In the US, Xolair is indicated for adults and adolescents (12 years of age and above) with moderate to severe persistent asthma who have a positive skin test or *in vitro* reactivity to a perennial aeroallergen and whose symptoms are inadequately controlled with inhaled corticosteroids. Xolair is also approved in Australia.

(2) J. Ayres, B. Higgins, E. Chilvers, et al. Efficacy and tolerability of anti-immunoglobulin E therapy with omalizumab in patients with poorly controlled (moderate-to-severe) allergic asthma. Allergy 2004 Jul; 59(7): 701-8.

(3) R. Djukanoviæ, S. Wilson, M. Kraft, N. Jarjour, M. Steel, K. Fan Chung, W. Bao, A. Fowler-Taylor, J. Matthews, W. Busse, S. Holgate, J. Fahy. The Effects of Anti-IgE (Omalizumab) Treatment on Airways Inflammation in Allergic Asthma. Am. J. Respir. Crit. Care Med. 2004 Jun 1 (published online ahead of print).

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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: August 2, 2004

By: /s/ MALCOLM B. CHEETHAM

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

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