

Edgar Filing: NOVARTIS AG - Form 6-K

NOVARTIS AG  
Form 6-K  
July 02, 2002

SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

FORM 6-K

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

Report on Form 6-K for the month of June 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    X  
   ---      ---  ---

Enclosures:

1. Steve Julius Award for Education in Hypertension presented to two pioneers in hypertension research
2. Federal District Court Rules in Favor of Wesley Jessen, Grants Injunction in Patent Infringement Case Filed Against Bausch & Lomb
3. Lescol(R) shown to reduce risk of serious cardiac events following surgery to open constricted coronary arteries
4. Novartis Ophthalmics teams with Carter Center to fight painful, blinding diseases
5. Novartis secures first marketing approval for breakthrough asthma drug as Australia approves Xolair(R)
6. Starlix(R) (nateglinide) significantly improves glycaemic control in metformin patients with type 2 diabetes

7. Data suggest that Prexige(TM) (lumiracoxib), a new COX-2 inhibitor, offers strong efficacy
8. Novartis announces recipients of Diabetes Award
9. Estalis(R)HRT patch demonstrates positive effects on sexual functioning in postmenopausal women in comparison with pills
10. New data show Glivec(R) as first-line treatment for chronic myeloid leukemia maintains quality of life
11. FDA grants marketing clearance for Ritalin(R)LA, a once-daily formulation of Ritalin(R) for ADHD that lasts through the entire school day
12. Novartis launches new educational ADHD web site
13. Novartis introduces S.T.A.R.T. (Straight Talk About Responsible Treatment) Now program to educate about appropriate use of ADHD medications
14. Novartis awarded 2002 international Galien Prize for innovative cancer therapy, Glivec(R)

[NOVARTIS LOGO]

Novartis International AG  
Novartis Communications  
CH-4002 Basel  
Switzerland

Tel +41 61 324 2200  
Fax + 41 61 324 3300  
Internet Address:  
<http://www.novartis.com>

MEDIA RELEASE o COMMUNIQUE AUX MEDIAS o MEDIENMITTEILUNG

Stevo Julius Award for Education in Hypertension presented to two pioneers in hypertension research

Prestigious Award presented by the International Society of Hypertension

Basel, 28 June 2002 - John Laragh, MD and Jeremiah Stamler, MD, both known worldwide for their significant contributions to the research and understanding of hypertension, and the leadership they have provided to many young scientists, have received the Stevo Julius Award for Education in Hypertension. Dr Laragh's role in understanding the renin-angiotensin-aldosterone system (RAAS) and its subsequent inhibition was a critical breakthrough and led to significant advances in the treatment of heart disease. Dr Stamler's landmark research into risk factors for coronary heart disease greatly influenced practice in terms of the prevention and control of cardiac disease. The award was supported by an educational grant from Novartis Pharma AG and presented by the International Society of Hypertension during the joint meeting of the International Society of Hypertension and the European Society of Hypertension.

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

"As a world leader in cardiovascular research and therapies, Novartis is honored to partner with the International Society of Hypertension in sponsoring the prestigious Stevo Julius Award for Education in Hypertension," said Joerg Reinhardt, Global Head of Development for Novartis Pharma AG. "We applaud Drs Laragh and Stamler for their outstanding achievements and discoveries in hypertension and other cardiovascular disease. Together, they have fundamentally changed our understanding of hypertension, which has led to improved survival and enhanced quality of life for millions who suffer from this disease."

The Stevo Julius Award for Education in Hypertension was established by the Executive Committee of the International Society of Hypertension to honor Dr Julius' critical contributions to hypertension education. The award is presented to individuals who demonstrate distinction in the education of scientists and specialists in hypertension or in hypertension education of the medical profession at large. Stevo Julius, MD, is Professor of Medicine and Physiology at the University of Michigan.

"I am delighted and honored by this year's choice of Drs. Stamler and Laragh as recipients of the Stevo Julius Award for Education in Hypertension," said Stevo Julius, MD. "Both Dr Stamler and Laragh are renowned figures in the field and have made early and seminal contributions to the understanding of hypertension. In addition, both have served as mentors to numerous scientists and remain deeply engaged in promoting public knowledge about hypertension."

Page 3 of 41 Total Pages

Dr Laragh discovered the renin-angiotensin-aldosterone endocrine control system and showed that it was a major factor in regulating normal blood pressure with body sodium and potassium content. He proved that excess plasma renin-angiotensin and aldosterone levels cause malignant hypertension and its fatal vascular damage to the eyes, brain, heart and kidneys. He then implicated milder excesses in plasma renin-angiotensin as the cause of most essential hypertension and also as the vascular-toxic agent causing heart attack, heart failure, or stroke in

them. Dr Laragh established three ways to block plasma renin system activity at three different sites: beta blockers, saralasin (the first angiotensin receptor blocker, or ARB), and teprotide (the first angiotensin converting enzyme inhibitor, or ACE inhibitor). Dr Laragh's research thus provided new understanding of the relationship between the renin system, high blood pressure and cardiovascular disorders -- and thereby also revolutionized treatments of these disorders.

Throughout his career, Dr Stamler has led several landmark studies in the causation and prevention of major cardiovascular diseases, and their key risk factors, including high blood pressure. Some of these are the Michael Reese estrogen trial, the Chicago Coronary Prevention Evaluation Program, the National Diet-Heart Study, the Multiple Risk Factor Intervention Trial, the Hypertension Detection and Follow-Up Program trial, the Systolic Hypertension in the Elderly trial, the Primary Prevention of Hypertension trial, and the DASH trials on the effects of dietary patterns and of salt on blood pressure. Dr Stamler spearheaded pivotal Chicago population studies, which have followed 4500 adult men and women for over 25 years and led to critical new understanding about the relationships among lifestyles, risk factors, and mortality from heart disease and stroke. Dr Stamler also developed the Chicago Coronary Prevention Evaluation Program, the first multi-factor primary prevention trial of cardiovascular disease ever conducted, and the international cooperative INTERSALT and INTERMAP studies of 15 000 adults elucidating the influences of multiple dietary factors on blood pressure.

"On behalf of the International Society for Hypertension and Novartis, I consider it an honor that Dr Laragh and Dr Stamler have accepted this year's

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

award. I cannot think of two more worthy individuals. Both Drs Laragh and Stamler have made discoveries which have paved the way to advancements in prevention and treatment, leading to improved longevity of human life. They uphold the values and leadership for which this award was originally established," said Professor A. Mimran, President of International Society of Hypertension.

Novartis, the maker of the antihypertensive Diovan(R) (valsartan), is committed to future developments in hypertension and cardiovascular conditions. To this end, Diovan is supported by the world's largest clinical trial programme for an ARB. The program includes the recently completed Val-HeFT trial (patients with heart failure) and three major ongoing multinational morbidity and mortality trials: VALUE (high risk hypertensive patients); VALIANT (post-myocardial infarction patients), and NAVIGATOR (patients with impaired glucose tolerance 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 "world leader in cardiovascular research and treatment" and "committed to future developments in hypertension and cardiovascular conditions", "world's largest clinical trial programme for an ARB" or similar expressions. Such forward looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results to be materially different from any future results, performance or achievements expressed or implied by such statements. There are no guarantees

Page 4 of 41 Total Pages

that the aforementioned data will result additional regulatory approvals for Diovan or in increased sales of Diovan. Any such commercialization 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 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 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 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 71,000 people and operate in over 140 countries around the world. For further information please consult <http://www.novartis.com>.

# # #

Notes to Editors:

John Laragh, MD  
John Laragh, MD, Professor of Medicine and Director of the Cardiovascular Center at the New York Presbyterian Hospital-Cornell Medical Center, founded the

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

American Society of Hypertension in 1985. In founding the Society, he was joined by 16 other world famous clinicians and scientists in an effort to evaluate the vast accumulation of data on hypertension and to provide an independent forum for those involved in high blood pressure research.

Dr Laragh also founded the first Hypertension Center and served as Chief of Nephrology and Vice-Chairman of the Board of Trustees at Columbia-Presbyterian Medical Center before returning to New York Hospital-Cornell in 1975. From 1986-1988, Dr Laragh also served as the president of the International Society of Hypertension.

Dr Laragh has been the recipient of a number of prestigious awards, including the Stouffer Prize of the American Heart Association (1969), the JP Peters Award of the American Society of Nephrology (1990), the Robert Tigerstedt Award from the American Society of Hypertension (1990), and the Distinguished Achievement Award from the Council for High Blood Pressure Research of the American Heart Association. Throughout the past 40 years, Dr. Laragh is among the most frequently cited scientists in cardiovascular disease. He has also published over 900 papers, including the two volume reference text, Hypertension: Pathophysiology, Diagnosis, and Management.

Dr Laragh earned his Medical Degree from Cornell University Medical College in 1948. He is married to his long time collaborator, Dr Jean Sealey, the distinguished biochemist. They spend leisure time at their homes in Florida and Southampton, New York.

Page 5 of 41 Total Pages

Jeremiah Stamler, MD

Jeremiah Stamler, MD, is an Emeritus Professor and Lecturer in the Department of Preventive Medicine at Northwestern University's Feinberg School of Medicine in Chicago. Dr Stamler served as the first Chair of the Department of Preventive Medicine at Northwestern University School of Medicine (1972-1986), held the distinguished position of Dingman Professor of Cardiology at the Medical School (1973-1990) and served as the Chairman of the Department of Community Health and Preventive Medicine at Northwestern Memorial Hospital (1973-1985).

Dr Stamler has been honored with several prominent awards, including the Distinguished Service Award from the American College of Cardiology (1985), the American Heart Association's Gold Heart Award (1992), and the David E. Rogers Award from the Association of American Medical Colleges (2000). In addition, he has published over 1000 articles in such leading journals as Circulation and Hypertension.

Dr Stamler earned his Medical Degree from State University of New York, Downstate Medical Center (Long Island College of Medicine) in 1943 and his undergraduate degree from Columbia University in 1940. He was married to the late Rose Stamler, internationally renowned researcher in cardiovascular epidemiology and prevention.

# # #

Page 6 of 41 Total Pages

[CIBA VISION LOGO]

News Release

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

CIBA Vision Corporation  
11460 Johns Creek Parkway  
Duluth, GA 30097-1556

### FOR MORE INFORMATION:

Kristie Madara (678) 415-3367  
Kristie.madara@cibavision.novartis.com

Federal District Court Rules in Favor of Wesley Jessen, Grants Injunction in Patent Infringement Case Filed Against Bausch & Lomb

Action Enjoins Sale of PureVision(TM) Contact Lenses

ATLANTA, June 26, 2002 - CIBA Vision Corporation, the eye care unit of Novartis AG (NYSE: NVS), announced today that the United States District Court for the District of Delaware ruled in favor of the company's wholly-owned subsidiary, Wesley Jessen Corporation, in a patent infringement lawsuit filed against Bausch & Lomb (NYSE: BOL).

The lawsuit, which was filed on May 3, 2001, claimed that Bausch & Lomb's PureVision product infringes Wesley Jessen's U.S. Patent No. 4,711,943, issued to Thomas Harvey III (the Harvey patent), which covers various silicone hydrogel materials for contact lenses.

The Court ruled in favor of Wesley Jessen and affirmed that the patent is valid, enforceable and infringed. The Court ordered Bausch & Lomb to discontinue the manufacture and sale of its PureVision contact lenses effective immediately in the United States. Bausch & Lomb cannot resume manufacture or sale of the product within the United States at least until 2005 when the Harvey patent expires.

Currently, PureVision lenses are only manufactured in the United States, which means Bausch & Lomb's ability to supply this product to its international markets may be affected.

-MORE-

"This is the outcome we expected," said Scott Meece, vice president and general counsel for CIBA Vision. "We were quite confident in the validity of this patent and the infringement by Bausch & Lomb and are extremely pleased with the speed with which this case was heard and resolved." In addition to this lawsuit filed on behalf of Wesley Jessen, CIBA Vision has had litigation pending against Bausch & Lomb since 1999 for infringement of four U.S. patents that protect its

Page 7 of 41 Total Pages

breakthrough Focus(R) NIGHT & DAY(TM) technology, which allows 30 nights of continuous wear. The cases in the U.S. were initially delayed because of Bausch & Lomb's attempts to invalidate CIBA Vision's patents in four reexamination proceedings before the United States Patent & Trademark Office (USPTO). After Bausch & Lomb exhausted all options with the USPTO, all four patents were issued again in November 2000, confirming the patents' validity and illustrating the pioneering nature of CIBA Vision's inventions. CIBA Vision has also initiated litigation against Bausch & Lomb in several other countries. If CIBA Vision prevails in the U.S. case, Bausch & Lomb's PureVision lenses will remain off the market until at least 2014.

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

"We are just as confident that we will prevail in our remaining patent infringement cases against Bausch & Lomb," added Meece. "We are eager to go to trial with our suits in the U.S., Australia and Germany, and to continue to protect CIBA Vision's breakthrough inventions."

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).

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 ongoing businesses achieved sales of CHF 32.0 billion (USD 19.1 billion) and a net income of CHF 7.0 billion (USD 4.2 billion). The Group invested approximately CHF 4.2 billion (USD 2.5 billion) in R&D. Headquartered in Basel, Switzerland, Novartis Group companies employ about 72,600 people and operate in more than 140 countries around the world. For further information, please consult [www.novartis.com](http://www.novartis.com).

### Forward-Looking Statement

The foregoing statement contains forward-looking statements that 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. The statement references patent litigation filed by CIBA Vision and our views on the nature and likelihood of success of that litigation. The statement reflects the view of the Company as of today. It is impossible to predict with certainty the outcome of patent litigation and the risks presented thereby. Should one or more of these risks or uncertainties materialize, actual results may vary materially from those described herein as anticipated, believed or expected.

# # #

Page 8 of 41 Total Pages

[NOVARTIS LOGO]

Novartis International AG  
Novartis Communications  
CH-4002 Basel  
Switzerland

Tel +41 61 324 2200  
Fax + 41 61 324 3300  
Internet Address:  
<http://www.novartis.com>

MEDIA RELEASE o COMMUNIQUE AUX MEDIAS o MEDIENMITTEILUNG

Lescol(R) shown to reduce risk of serious cardiac events following surgery to open constricted coronary arteries

Journal of the American Medical Association publishes landmark trial findings

Basel, Switzerland, 25 June, 2002 - Treatment with the cholesterol-lowering medication Lescol(R) 80 mg (fluvastatin sodium), routinely initiated shortly after a first angioplasty(a procedure to clear narrowed arteries), significantly reduced the chances of a second serious cardiac event by 22% - even in patients

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

with normal cholesterol levels, according to the results of the landmark Lescol Intervention Prevention Study (LIPS) published in today's edition of the Journal of the American Medical Association (JAMA). The results of LIPS, which was the first prospective statin study in this setting, may have major implications for the 1.8 million patients annually who undergo angioplasty procedures(i). Novartis plans to use the LIPS findings to broaden the indication for Lescol.

LIPS provides us with the scientific foundation to change the way we treat patients who undergo percutaneous coronary intervention (PCI), such as angioplasty or other similar procedures," commented lead author and principal investigator Patrick Serruys, MD, PhD, Professor of Interventional Cardiology at Erasmus Medical Centre, University Hospital, Rotterdam, The Netherlands.(ii) "The study supports early intervention with fluvastatin in post-PCI patients, regardless of cholesterol levels, to help prevent fatal and non fatal cardiac events such as heart attacks and coronary surgery."

LIPS demonstrated that, in every 19 people treated for four years, that Lescol prevented one fatal or non-fatal major adverse cardiac event. The study population had an average LDL cholesterol level of 132 mg/dL [3.4 mmol/L], at entry. Hence, half of the patients had a baseline cholesterol level within the normal range. The risk reduction following Lescol therapy was similar irrespective of baseline cholesterol levels. Because of this, the authors concluded that statin therapy after PCI should be based on an overall risk assessment of the patient, and not just baseline cholesterol levels.

LIPS is the first prospective, randomised, placebo-controlled trial to evaluate the effects of a statin - specifically Lescol - exclusively in patients who have had a first PCI. These patients represent a population with early-stage coronary heart disease, who are at high risk of a second major adverse cardiac event. While 90% of the 1.8 million patients who undergo PCI have immediate improvement in chest pain (angina), 66% of patients die or have a cardiac event within 10 years after surgery.(2)

Page 9 of 41 Total Pages

LIPS involved 1677 patients recruited from 57 centres in 10 countries (Europe, Canada and Brazil) for four years. The study examined the time to first major adverse cardiac event, following a first PCI. Major adverse cardiac events were defined as cardiac death, nonfatal heart attack, coronary artery bypass grafting or repeat PCI. Patients were randomised to receive either Lescol 80 mg/day (40 mg twice daily) or placebo before hospital discharge after their first PCI coronary surgical procedure.(1)

The study demonstrated that Lescol 80mg (40mg twice daily) significantly reduced the risk of major adverse cardiac events by 22%, as compared with placebo (p=0.01).(2) In addition, in certain high-risk patients, the benefits of Lescol were even more profound. Patients with diabetes, experienced a 47% reduction in the risk of a serious cardiac event,(2) as compared with placebo (p=0.04). The study also found high-risk patients with multi-vessel disease, experienced a 34% reduction in the risk of a major cardiac event, when compared with placebo (p=0.01).(2) Patients with or without a stent, experienced similar benefits when taking Lescol therapy.2 Of the patients treated with Lescol, those with unstable angina experienced a greater risk reduction than those with stable angina (28% versus 20%, respectively). Levels of harmful LDL cholesterol were significantly reduced with Lescol to mean levels below 100 mg/dL (2.6 mmol/L) throughout the course of the study. The LIPS data thus support the National Cholesterol Education Program Adult Treatment Panel III guidelines to lower LDL cholesterol to below the target level of 100 mg/dL (2.6 mmol/L) in all patients after a PCI.(2)

The data also underscored the excellent safety profile of Lescol: there were no



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

significant elevations of creatine phosphokinase (CPK) above 10x ULN over the three to four years of follow up. Elevated CPK is an indication of muscle breakdown and is a potential side effect of statin therapies. These safety data match those from a recent analysis involving more than 9000 patients of all randomised, controlled clinical trials with Lescol/ Lescol XL(R) administered as monotherapy, in which the rate of clinically relevant CPK elevations was not significantly different at any Lescol dose than in patients receiving placebo.(3)

Novartis introduced Lescol extended-release, once-daily 80 mg formulation in 2000 (Lescol XL), which has been shown in trials to provide effective lipid management, with reductions of 38% in harmful LDL-cholesterol, up to 31% in triglycerides and increases of up to 21% in favorable HDL-cholesterol.(4)

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 "may have major implications", "plans to use", "excellent safety profile", "provide effective lipid management" or similar expressions. Such forward looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results to be materially different from any future results, performance or achievements expressed or implied by such statements. There are no guarantees that the aforementioned data will result in the commercialisation or continued commercialisation or broadening of approved indication for Lescol in any market. Any such commercialization 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 20F 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.

Page 10 of 41 Total Pages

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

- 
- 1 Ruygrok PN, de Jaegere PT, van Domburg RT, et al. Clinical outcome 10 years after attempted percutaneous transluminal coronary angioplasty in 856 patients. J Am Coll Cardiol 1996;27:1669-77.
  - 2 Patrick WJC Serruys, MD, PhD, et al. Fluvastatin for Prevention of Cardiac Events Following Successful First Percutaneous Coronary Intervention. Draft Manuscript. JAMA. June 26, 2002.
  - 3 Benghozi et al. Frequency of creatinine kinase elevation during treatment with fluvastatin. Am J Card 2002, Jan 15.
  - 4 Ballantyne et al. Efficacy and Tolerability of Fluvastatin Extended-Releases Delivery System: A Pooled Analysis. Clinical Therapeutics 2001, No 2, Vol 23, p177-192.

# # #

Page 11 of 41 Total Pages

[NOVARTIS LOGO]

Novartis Ophthalmics, Inc.  
Media Relations  
11695 Johns Creek Parkway  
Duluth, Georgia 30097  
USA

Tel 770-905-1020  
Fax  
E-mail: jan.mcclure  
@pharma.novartis.com

MEDIA RELEASE

Novartis Ophthalmics teams with Carter Center to fight painful, blinding diseases

Atlanta, 19 June 2002 - Novartis Ophthalmics, North America, today announced a pilot program to aid former President Jimmy Carter and The Carter Center in their work to prevent trachoma, a chronic bacterial infection that is the world's leading cause of preventable blindness, and river blindness, caused by a parasite transmitted by the bite of black flies.

In addition to a \$50,000 donation to the Carter Center to fight blindness, Novartis Ophthalmics will donate supplies of Eye Scrub(R) cleanser, currently being used during and after trachoma surgeries in a pilot program in Ethiopia. The inflammation of trachoma leads to trichiasis, or in-turned eyelashes, which painfully abrade patients' corneas. If trichiasis is not surgically corrected, the disease leads to permanent blindness. The World Health Organization (WHO) estimates that trachoma already has blinded, or severely disabled 6 million people.

146 million people worldwide need medical treatment for trachoma, which flourishes where hygiene is poor. WHO and partner organizations have developed a strategy called SAFE (Surgery, Antibiotics, Face washing, Environmental hygiene) to combat the disease.

"In areas with limited access to clean, safe water, post-operative complications are common. Eye Scrub could improve the outcome of eye surgeries for the neediest patients," said Dan Myers, president of Novartis Ophthalmics. "These surgeries are done not only to save villagers from going blind, but also to end the painful irritation of trichiasis. Sterile equipment and supplies are limited in these countries. Eye Scrub is packaged as a sterile, individually wrapped pad that does not require water."

Novartis Ophthalmics, North America, which is based in Atlanta, will announce the pilot program at a dinner on Wednesday, June 19, at The Carter Center honoring President and Mrs. Carter and their commitment to vision-related health projects around the world. During the evening, President Carter will give Atlanta's leading ophthalmologists an overview of the Carter Center's health projects as well as an update on health conditions in Cuba, where he recently traveled.

Page 12 of 41 Total Pages

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

"Due to the efforts of President and Mrs. Carter, The Carter Center is a 'light of hope' beaming throughout the world for millions of impoverished people," Myers said. "Novartis Ophthalmics is very pleased to be able to join forces with The Carter Center in helping people retain their sight."

Novartis Ophthalmics, maker of Visudyne(R), Rescula(R), Zaditor(TM) and other ophthalmic pharmaceuticals, is also a partner with Prevent Blindness Georgia in outreach programs to test children for lazy eye and to screen the homeless for eye glasses.

### About 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, Ga. Novartis Ophthalmics has production sites in Switzerland, France and Canada. For more information, please go to the web site [www.novartisophthalmics.com/us](http://www.novartisophthalmics.com/us).

### About Novartis

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

# # #

### Contact

Jan McClure, Director, Corporate Communications, Novartis Ophthalmics

Phone: +1 770.905.1010

Fax: +1 770.905.1510

Email: [jan.mcclure@pharma.novartis.com](mailto:jan.mcclure@pharma.novartis.com)

Page 13 of 41 Total Pages

[NOVARTIS LOGO]

Investor Relations

Novartis International AG  
CH-4002 Basel  
Switzerland  
Karen J Huebscher, PH.D.  
Tel +41 61 324 8433  
Nafida Bendali  
Tel +41 61 324 3514  
Sabine Moravi, MBA  
Tel + 41 61 324 8989  
Silke Zenter  
Tel +41 61 324 8612  
Francisco Bouzas  
Tel +41 61 324 8444  
Fax + 41 61 324 8844  
Internet Address:

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

<http://www.novartis.com>

- Investor Relations Release -

Novartis secures first marketing approval for breakthrough asthma drug as Australia approves Xolair(R)

Basel, 18 June 2002 - Novartis has today welcomed a decision by the Therapeutic Goods Administration (TGA) in Australia to approve the new anti-IgE therapy Xolair(R) (omalizumab)\* for treating adults and adolescents with moderate allergic asthma. This represents the first marketing approval anywhere in the world so far for Xolair.

The decision comes after the Australian Drug Evaluation Committee agreed that Xolair should be indicated for the management of adult and adolescent patients with moderate allergic asthma who are already being treated with inhaled steroids and have raised levels of serum immunoglobulin E (IgE).

Thomas Ebeling, CEO of Novartis Pharma AG, said: "We are delighted by this approval, which means that asthma patients are a step closer to experiencing the benefits of this new treatment. Xolair seems to offer a unique method to enhance the control of their disease by targeting a root cause of allergic asthma."

Xolair - which was developed under an agreement between Novartis Pharma AG, Genentech, Inc. and Tanox, Inc. - is a monoclonal antibody and the first agent to specifically target IgE. It works by binding to circulating IgE and preventing it from attaching to mast cells. Without IgE bound to mast cells, the presence of an allergen will not cause the release of chemical mediators like histamine and leukotrienes, which lead to the symptoms and inflammation of allergic asthma. Xolair is administered every two to four weeks subcutaneously (i.e. by injection under the skin), at a dose depending on the patient's body weight and IgE level.

Meanwhile, submissions for the approval of Xolair are proceeding in a number of other important markets. In the US, Genentech and Novartis are planning to submit an amendment to the Biologics License Application for Xolair to the Food and Drug Administration in the fourth quarter of 2002. The content of this amendment will address requests for additional information made by the FDA in a Complete Response letter issued in July 2001, and the companies expect that data from ongoing trials will satisfy those requests.

-----  
\* In the US: Xolair(TM) (omalizumab)

Page 14 of 41 Total Pages

The foregoing press release contains forward-looking statements which can be identified by terminology such as "are proceeding", "planning to submit", "will address", "expect that", or similar expressions, or by discussion of potential additional approvals of Xolair. 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 certainty that Xolair will be approved in any other market. Management's expectation regarding the commercial potential of Xolair in any market 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 US Securities and Exchange Commission. Should one or more of these risks or

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

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 businesses achieved sales of CHF 32.0 billion (USD 19.1 billion) and a net income of CHF 7.0 billion (USD 4.2 billion). The Group invested approximately CHF 4.2 billion (USD 2.5 billion) in R&D. Headquartered in Basel, Switzerland, Novartis Group companies employ about 72 600 people and operate in over 140 countries around the world. For further information please consult <http://www.novartis.com>

# # #

Page 15 of 41 Total Pages

[NOVARTIS LOGO]

Novartis International AG  
Novartis Communications  
CH-4002 Basel  
Switzerland

Tel +41 61 324 2200  
Fax + 41 61 324 3300  
Internet Address:  
<http://www.novartis.com>

MEDIA RELEASE o COMMUNIQUE AUX MEDIAS o MEDIENMITTEILUNG

Starlix(R) (nateglinide) significantly improves glycaemic control in metformin patients with type 2 diabetes

Starlix(R) as an add-on to metformin significantly reduces HbA1c in a safe and well-tolerated manner

Basel, 17 June 2002 - New data presented today at the American Diabetes Association (ADA) annual meeting in San Francisco suggest that Starlix(R) (nateglinide) improves glycaemic control in a safe and well-tolerated manner in patients whose type 2 diabetes is inadequately controlled by taking metformin alone. These new data, obtained in a real-world setting, are in line with a double-blind clinical study published in May in Diabetes Obesity and Metabolism(1).

The new results are particularly significant because improved glycaemic control, as measured by a reduction of HbA1c levels, may lead to a dramatic lowering of deaths and complications from diabetes. Even a 1% reduction in HbA1c can correlate to a 21% decrease in deaths from diabetes and a 14% decrease in heart attacks(2). Since both fasting and post-meal blood glucose contribute to HbA1c, the combination of metformin (which acts on fasting blood glucose) and Starlix (which acts on post-meal blood glucose), reduces HbA1c more than either agent alone. In the new studies, reductions in HbA1c were even seen in patients who were close to their target blood glucose levels. This suggests that even those metformin patients near to target may benefit from the addition of Starlix to their regimen and the reduced risk of death and complications that is associated with improved glycaemic control.

"This study takes what we know about the efficacy of Starlix in clinical trials to where it matters most - a real-world setting," said Ken Hershon, MD, FACE, FACP, Director of Research, Northshore Diabetes and Endocrine Associates. "Here,

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

we found that nateglinide reduced mealtime glucose spikes and overall blood glucose just as well or even better than it did in controlled clinical trials."

The new US study(3) involved 83 type 2 diabetes patients inadequately controlled on metformin monotherapy (HbA1c 7.0-9.5%). For 12 weeks, these patients took 120 mg nateglinide before meals, in addition to their usual dose of metformin. The results showed that 70% of the patients responded to nateglinide therapy (decrease in HbA1c of at least 0.5%). The mean reduction in HbA1c over the 12 weeks was 0.8%. Plasma glucose two hours after a standard breakfast was reduced by a mean of 2.7 mmol/l. Nateglinide was well-tolerated and hypoglycaemia was confirmed by a low blood glucose level in only three patients (3.6%).

Page 16 of 41 Total Pages

These clinical data obtained in a real-world setting are in line with the results of a randomised controlled trial published in the current issue of *Diabetes, Obesity and Metabolism*. This trial involved 467 type 2 diabetes patients who were stabilised on high-dose metformin ( $\geq 1500$  mg/day) and who had an HbA1c of 6.8-11%. Patients were randomised to receive 60 mg nateglinide, 120 mg nateglinide, or placebo before main meals, in addition to taking 2000 mg metformin twice daily, for 24 weeks.

The trial results showed that the addition of Starlix to metformin monotherapy resulted in a significant reduction in HbA1c compared with placebo. At the end of the study HbA1c had been reduced by a mean of 0.6% in patients taking 120 mg nateglinide. Patients with high HbA1c at baseline had the greatest reduction in HbA1c (mean of -1.4%). Starlix was well tolerated with mild cases of hypoglycaemia being the only treatment-related event so far: hypoglycaemia was confirmed in only five patients (3.1%) taking the 120 mg dose and in none of the patients taking the 60 mg dose.

Similar findings were obtained in a study recently performed in clinical practice in the UK.(4) This UK study involved 214 patients whose type 2 diabetes was treated with metformin but poorly controlled (HbA1c 7.2-9.3%). These patients were given an additional 120 mg nateglinide before main meals for 12 weeks. At the end of the study, HbA1c had been reduced by a mean of 0.7% and plasma glucose two hours after a standard breakfast by a mean of 2.4 mmol/l. Starlix was well tolerated in patients, with symptoms suggestive of hypoglycaemia reported in 15% of patients.

The data from these three studies confirm that Starlix is effective and well-tolerated and can bring about a significant reduction in HbA1c in patients who are inadequately controlled on metformin alone. Many type 2 diabetes patients can initially achieve adequate glycaemic control with a single oral anti-diabetic drug like metformin, combined with diet and lifestyle changes. However, as type 2 diabetes progresses, most patients require the addition of a second agent. Starlix is a useful adjunct to metformin monotherapy as it is well-tolerated and has a complementary pharmacological action.

Type 2 diabetes is caused by a combination of reduced insulin secretion and reduced sensitivity of the body's cells to insulin (insulin resistance). Metformin reduces hepatic (liver) glucose production and insulin resistance and acts primarily to reduce fasting blood glucose. In contrast, nateglinide acts primarily on post-prandial blood glucose. When taken before a meal, nateglinide rapidly stimulates a short burst of insulin secretion from pancreatic (beta)-cells. This restores the early insulin secretion that is lost in people with type 2 diabetes and prevents the post-meal glucose spikes characteristic of the condition. Starlix duration of action is very short, minimizing the risk of severe or long-lasting hypoglycaemia. The combination of metformin and Starlix reduces HbA1c more than either agent alone.

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

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

Page 17 of 41 Total Pages

Novartis AG (NYSE: NVS) is a world leader in healthcare with core businesses in pharmaceuticals, consumer health, generics, eye-care, and animal health. In 2001, the Group's businesses achieved sales of CHF 32.0 billion (USD 19.1 billion) and a net income of CHF 7.0 billion (USD 4.2 billion). The Group invested approximately CHF 4.2 billion (USD 2.5 billion) in R&D. Headquartered in Basel, Switzerland, Novartis Group companies employ about 72 600 people and operate in over 140 countries around the world. For further information please consult <http://www.novartis.com>. For further information on type 2 diabetes, visit [www.diabetesandhealth.com](http://www.diabetesandhealth.com). Novartis in-licensed nateglinide from Ajinomoto Co., Inc. in 1993.

### References

1. Marre M, Van Gaal L, Usadel K-H, Ball M, Whatmough I, Guitard C. Nateglinide improves glycaemic control when added to metformin monotherapy: results of a randomized trial with type 2 diabetes patients. *Diabetes, Obesity and Metabolism* 2002; 4: 1-10.
2. Stratton IM, Adler AI, Neil AW, Matthews DR, Manley SE, Cull CA, Hadden D, Turner RC, Holman RR. Association of glycaemia with macrovascular and microvascular complications of type 2 diabetes (UKPDS 35): prospective observational study. *BMJ* 2000; 321: 405-412.
3. Baron M, Mager RR, Vyas KH, Purkayastha DD. Nateglinide (Starlix) effectively lowers HbA1c through reductions in post prandial glucose in subjects with type 2 diabetes mellitus. Abstract presented at ADA Annual Meeting, date, 2002.
4. Weaver JU, Robertson DA, Atkin SL. Nateglinide alone and as add-on therapy to metformin in UK clinical practice: a 12-week study. *Diabetic Medicine* 2002; 19 (Suppl 2): 112-115.

# # #

Page 18 of 41 Total Pages

[NOVARTIS LOGO]

Investor Relations

Novartis International AG  
CH-4002 Basel  
Switzerland  
Karen J Huebscher, PH.D.  
Tel +41 61 324 8433  
Nafida Bendali

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

Tel +41 61 324 3514  
Sabine Moravi, MBA  
Tel + 41 61 324 8989  
Silke Zenter  
Tel +41 61 324 8612  
Francisco Bouzas  
Tel +41 61 324 8444  
Fax + 41 61 324 8844  
Internet Address:  
<http://www.novartis.com>

- Investor Relations Release -

Data suggest that Prexige(TM) (lumiracoxib), a new COX-2 inhibitor, offers strong efficacy

Latest results additionally confirm Prexige(TM) is well-tolerated with gastrointestinal safety superior to NSAIDs

Basel, 13 June 2002 - Highlights from key Phase II studies presented for the first time at EULAR, the European League Against Rheumatism annual congress, Stockholm, demonstrate that Prexige(TM) (lumiracoxib, COX189), a new innovative investigational COX-2 selective inhibitor, has efficacy equal to the current European "gold standard", diclofenac, in the treatment of patients with arthritis and pain. Additional data presented at EULAR confirm Prexige(TM) is well tolerated, and its gastrointestinal safety profile is superior to non-steroidal anti-inflammatory drugs (NSAIDs) in this patient group. All results to date support the potential use of Prexige(TM) in the treatment of symptoms of arthritis and pain.

NSAIDs are commonly used for treating pain associated with arthritis. However, they are associated with gastrointestinal (GI) ulcers and bleeding, due to non-selective inhibition of cyclooxygenase (COX). The Phase II data with Prexige(TM) shows it to be highly effective in the treatment of the symptoms of arthritis and pain, while demonstrating improvements in safety and tolerability, including GI safety, beyond traditional NSAIDs.

Results of an exploratory analysis of a large multinational study of 583 patients(iii) confirm the clinical relevance of the findings previously presented by Schnitzer, et al.(iv) The assessment of the responder rate of Prexige(TM) in osteoarthritis (OA) pain show that Prexige(TM) at 400mg once daily (od) is highly effective for the treatment of patients with OA. These findings suggest that Prexige(TM) provides the same strong efficacy as high doses of diclofenac (75mg twice a day) in treatment response defined as a 20% reduction in OA pain intensity based on the visual analog scale measure.

Commenting on the results, Jorg Reinhardt, Head of Development, Novartis Pharma AG, said: "These data suggest that Prexige(TM) is a highly efficacious COX-2 selective inhibitor. Prexige(TM) has been shown to be as efficacious as the "gold standard" treatment for arthritis, which is very encouraging news in the development of new treatments in this therapy area."

Page 19 of 41 Total Pages

A second study, by Codreanu, et al.(v), compared the safety and tolerability of Prexige(TM) to ibuprofen and celecoxib, over 3 months. The study investigated upper gastrointestinal safety and tolerability in 1042 OA patients treated over 13 weeks. The results indicate that at both doses (200 mg od and 400 mg od) Prexige(TM) showed a superior GI safety and tolerability profile compared with



Edgar Filing: NOVARTIS AG - Form 6-K

ibuprofen. With respect to the occurrence of gastroduodenal ulcers, Prexige (TM) was statistically superior to ibuprofen (p