

# SHEARMAN & STERLING

FAX: (44 20) 7655-5500

BROADGATE WEST  
9 APPOLD STREET  
LONDON EC2A 2AP, ENGLAND  
(44-20) 7655-5000

ABU DHABI  
BEIJING  
BRUSSELS  
DÜSSELDORF  
FRANKFURT  
HONG KONG  
LONDON  
MANNHEIM  
MENLO PARK  
MUNICH  
NEW YORK  
PARIS  
SAN FRANCISCO  
SINGAPORE  
TOKYO

WRITER'S DIRECT NUMBER:

+44 (0)20-7655-5558

October 4, 2001

## VIA EDGAR

Securities and Exchange Commission  
450 Fifth Street, N.W.  
Washington, D.C. 20549

### **Novartis AG** **Current Report on Form 6-K (Commission File No. 1-15024)**

Ladies and Gentlemen:

On behalf of Novartis AG, please find enclosed a copy of a Report on Form 6-K for the month of September 2001, submitted electronically through EDGAR, under the Securities Exchange Act of 1934, as amended.

If the Staff wishes to discuss this matter at any time, please telephone (collect) any of James M. Bartos, Louis Lehot or the undersigned in our London office at (44-207) 655-5000.

Very truly yours,

Eurydice Goulet  
Legal Assistant

Enclosure

cc: New York Stock Exchange (Listed Securities Library)  
George Miller (Novartis AG)  
James M. Bartos (Shearman & Sterling)  
Louis Lehot (Shearman & Sterling)

**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 2001**

**Novartis AG**  
(Name of Registrant)

Lichtstrasse 35  
4056 Basel  
Switzerland

(Address of Principal Executive Offices)

Indicate by check mark whether the registrant files or will file annual reports under cover of  
Form 20-F or Form 40-F.

Form 20-F ☒ Form 40-F ☐

Indicate by check mark whether the registrant by furnishing the information contained in this  
form is also thereby furnishing the information to the Commission pursuant to Rule 12g3-2(b)  
under the Securities Exchange Act of 1934.

Yes ☐ No ☒

Enclosures:

- (1) Novartis' Foradil® gains FDA approval for the treatment of chronic obstructive pulmonary disease (COPD) (September 27, 2001);
- (2) Novartis Ophthalmics supports worldwide education campaign to fight blindness (September 25, 2001);
- (3) International survey reveals that one in five smokers who have signs of irreversible lung damage attribute their breathlessness to other causes (September 24, 2001);
- (4) Omalizumab controls symptoms, reduces hospital visits and decreases steroid use in patients with severe asthma (September 24, 2001);
- (5) CIBA Vision signs agreement with Wound Healing of Oklahoma to license Glaucoma Device (September 19, 2001);

- (6) Novartis' Foradil® demonstrates superior efficacy in chronic obstructive pulmonary disease over gold standard treatment (September 19, 2001);
- (7) Novartis' Expo project "Biopolis" gets underway (September 18, 2001);
- (8) Novartis research symposium reports advances in genomics, disease knowledge, technologies and modeling tools (September 14, 2001);
- (9) New analysis underscores safety and efficacy of Novartis' cholesterol-lowering drug Lescol®/Lescol XL® (September 10, 2001);
- (10) Novartis launches largest diabetes prevention trial to date (September 10, 2001);
- (11) Novartis Ophthalmics and QLT file Canadian submission for expansion of Visudyne® approval (September 10, 2001);
- (12) New non-steroid cream Elidel® could change the treatment of eczema (September 7, 2001);
- (13) Novartis Ophthalmics and QLT file submission with the EMEA to expand the use of Visudyne® in AMD (September 7, 2001).

**- Investor Relations Release -****Novartis' Foradil<sup>®</sup> gains FDA approval for the treatment of chronic obstructive pulmonary disease (COPD)**

Basel, 27 September 2001 – Novartis announced today that its fast-acting, long-lasting bronchodilator Foradil<sup>®</sup> Aerolizer<sup>™</sup> (formoterol fumarate inhalation powder) has received approval from the US Food and Drug Administration (FDA) for long term administration in the maintenance treatment of bronchoconstriction in patients with COPD, including chronic bronchitis and emphysema. This is a new indication for Foradil, which gained approval from the FDA in February for use in the maintenance of asthma and prevention of exercise-induced bronchospasm.

“This second US approval for Foradil within a year is important for Novartis, as the long-acting beta<sub>2</sub>-agonist is a key product in our respiratory portfolio,” said Thomas Ebeling, CEO of Novartis Pharma AG. “Foradil provides COPD patients with better 24-hour symptom relief compared with the current gold standard treatment, ipratropium bromide, and allows patients to be less dependent on rescue medications.”

In the USA, 16 million people have been diagnosed with COPD, but it is estimated that twice as many - 30 to 35 million - could be affected. It is a slowly progressive disease that causes irreversible damage to the lungs, including chronic bronchitis and emphysema. Symptoms include shortness of breath, cough and sputum production.<sup>1</sup> The main risk factor for COPD is smoking. COPD is the world's fourth-biggest cause of death, killing about the same number of people per year as HIV/AIDS, according to the World Health Organisation.

Foradil is already available in 87 countries around the world and is recognised by national and international clinical guidelines as a highly effective treatment for COPD and asthma.

The foregoing press release contains forward-looking statements which can be identified by terminology such as “better symptom relief”, “allows”, “to be less dependent”, or similar expressions. Such forward looking statements include descriptions of Foradil<sup>®</sup> Aerolizer<sup>™</sup> and reflect the current views of the Company with respect to future events concerning that product and are subject to certain risks, uncertainties and assumptions and 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 commercialisation of the fast-acting, long-lasting bronchodilator Foradil<sup>®</sup> Aerolizer<sup>™</sup> will be successful in any market. Any such commercialisation 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. Please refer to the Form 20-F filed by Novartis AG with the US Securities & Exchange Commission for further information.

Novartis (NYSE: NVS) is a world leader in healthcare with core businesses in pharmaceuticals, consumer health, generics, eye-care, and animal health. In 2000, the Group's ongoing businesses achieved sales of CHF 29.1 billion (USD 17.2 billion) and a net income of CHF 6.5 billion (USD 3.9 billion). The Group invested approximately CHF 4.0 billion (USD 2.4 billion) in R&D. Headquartered in Basel, Switzerland, Novartis employs about 70 000 people and operates in over 140 countries around the world. For further information please consult <http://www.novartis.com>

# # #

## References

<sup>1</sup> Global Initiative on Obstructive Lung Disease fact sheet. [www.goldcopd.com](http://www.goldcopd.com)

## **Novartis Ophthalmics supports worldwide education campaign to fight blindness**

*Retina Week for the Prevention of Blindness to raise awareness of devastating eye conditions such as age related macular degeneration*

Basel, 25 September 2001 — Novartis Ophthalmics, the eye health unit of Novartis AG, confirmed today its strong commitment to fight blindness by announcing its sponsorship of “Retina Week for the Prevention of Blindness”, a multinational educational campaign launched this week (Sept. 23 - 29) by the AMD Alliance International, a non-profit alliance of vision and seniors’ organizations. Novartis Ophthalmics is founding global sponsor of the AMD Alliance International.

The campaign, held in conjunction with Retina International and the European Blind Union, spans five continents and is targeted at informing government officials, eye care professionals and consumers about age-related macular degeneration (AMD), the leading cause of blindness in people over the age of 50, and retinal degeneration, in general.

“We are very pleased to support this worldwide educational campaign to fight blindness,” said Luzi von Bidder, head of Novartis Ophthalmics. “A survey, conducted by the AMD Alliance in the European Union, illustrates the dire circumstances confronting the blind and visually impaired in many EU countries. Many individuals have either limited or no access to needed treatment and rehabilitation unless they can afford to pay out-of-pocket. In supporting this campaign, we hope to help raise the awareness for devastating eye conditions such as AMD.”

Bruce Rosenthal, O.D., FAAO, chairman of the AMD Alliance International and chief of Low Vision Programs at Lighthouse International, said, “We are grateful to Novartis Ophthalmics for its support of this inaugural global initiative. It targets thousands of patients who face life every day with vision impairment and are unaware of the many options available to them for treatment, rehabilitation and support services.”

Local actions planned this week range from workshops for eye care professionals to inform them about treatment and rehabilitation options for patients with AMD and other forms of retinal degeneration, to consumer initiatives, such as free eye screenings or public exhibitions and direct mail campaigns to raise the awareness of AMD. Pre-launch activities by the sponsoring organizations at the European Parliament last week included a week-long exhibition and an information briefing to inform government decision-makers about retinal degeneration.

Novartis Ophthalmics provides operational funding for the expansive educational programs of the AMD Alliance International as well as specific financial contributions at local country levels for AMD awareness campaigns.

### **About AMD**

AMD is the leading cause of blindness in people over the age of 50 and is caused by a growth of abnormal blood vessels (CNV) under the central area of the retina or macula. The vessels leak fluid and cause scar tissue that destroys central vision, resulting in a deterioration of sight over a period ranging anywhere from two months to three years. Although the wet form (the form Visudyne is used to treat) represents an estimated 15% of all AMD cases, it accounts for approximately 90% of the severe vision loss associated with the diseases. Worldwide, approximately 500,000 new cases of wet AMD occur each year and this estimate is expected to grow dramatically as the population ages.

### **About Visudyne**

Novartis Ophthalmics and QLT Inc. have developed Visudyne® (verteporfin for injection) <sup>1</sup> therapy, the only drug therapy approved for the treatment of some forms of wet AMD. Visudyne therapy is a two-step procedure that can be performed in a doctor's office. First, the drug is injected intravenously into the patient's arm. A non-thermal laser light is then shone into the patient's eye to activate the drug. For more information, visit [www.visudyne.com](http://www.visudyne.com).

### **Background on Novartis Ophthalmics, QLT, AMD Alliance and Retina International**

Novartis Ophthalmics: With worldwide headquarters in Bulach, Switzerland, Novartis Ophthalmics is a global leader in research, development and manufacturing of leading ophthalmic pharmaceuticals that assist in the treatment of glaucoma, age-related macular degeneration, eye inflammation, ocular allergies and other diseases and disorders of the eye. Novartis Ophthalmics products are available in more than 110 different countries. The North American headquarters is based in Atlanta, Georgia. Novartis Ophthalmics has production sites in Switzerland, France and Canada. For more information, visit [www.novartisophthalmics.com](http://www.novartisophthalmics.com) or [www.novartisophthalmics.com/us](http://www.novartisophthalmics.com/us).

Novartis (NYSE: NVS) is a world leader in healthcare with core businesses in pharmaceuticals, consumer health, generics, eye-care, and animal health. In 2000, the Group's ongoing businesses achieved sales of CHF 29.1 billion (USD 17.2 billion) and a net income of CHF 6.5 billion (USD 3.9 billion). The Group invested approximately CHF 4.0 billion (USD 2.4 billion) in R&D. Headquartered in Basel, Switzerland, Novartis employs about 70 000 people and operates in over 140 countries around the world. For further information please consult <http://www.novartis.com>.

QLT Inc. (NASDAQ:QLTI; TSE:QLT) is a world leader in photodynamic therapy, a field of medicine utilizing light-activated drugs in the treatment of disease. QLT's innovative science has led to the development and commercialization of breakthrough treatments utilizing this technology for applications in ophthalmology and oncology and is exploring the potential in other diseases. For more information, you are invited to visit QLT's web site at <http://www.qltinc.com>.

<sup>1</sup> Outside the US: Visudyne®; in the US: Visudyne™

AMD Alliance International is a non-profit alliance of vision and seniors' organizations working to raise awareness of AMD and an understanding of available options for treatment,

rehabilitation and support services. It is the only international organization that concentrates solely on AMD. Globally launched in Geneva in September 1999, the Alliance has representations in over 20 countries around the world. For more information on AMD, please consult <http://www.amdalliance.org>.

Retina International is an umbrella organization of 50 voluntary self help support groups around the world dedicated to promoting research into all forms of Retinal Degenerative Disease including AMD. It also promotes research into genetic Retinal Degeneration such as Retinitis Pigmentosa (RP), Ushers Syndrome, Stargardts Disease and several other forms of retinal disorder. It was founded in 1982 and since then has been responsible for establishing a very significant amount of research in many different countries around the world. While it has had much success in this area, it badly needs State and Corporate support to build on the huge advances achieved so far and rapidly turn the great hope that now exists into treatments.

### **European Blind Union**

The European Blind Union is a non-governmental and non profit-making European organization founded in 1984. It is one of the seven regional bodies of the World Blind Union, and it is the only organization representing the interests of blind and partially-sighted people in Europe. EBU aims to protect and promote the interests of blind and partially-sighted people in Europe [www.euroblind.org](http://www.euroblind.org).





## **International survey reveals that one in five smokers who have signs of irreversible lung damage attribute their breathlessness to other causes**

Aberdeen, 24 September 2001 — Many smokers already have early signs of the incapacitating lung condition chronic obstructive pulmonary disease (COPD) without realising they have a serious problem that can benefit from medical treatment, an international survey has revealed.

In the survey – the first of its kind to look at breathlessness among people at risk from the lung disease – one in five smokers over age 40 reported that they suffered from breathlessness when walking up a short flight of stairs. Breathlessness is a major symptom of COPD.

Up to a third of the survey respondents did not attribute their breathlessness to smoking in any way, believing it had other causes such as growing older, being unfit or an unrelated illness.

“The problem with COPD is that it has a very slow onset. Many people do not recognise the telltale signs, they just cut back on their activities so that they don’t become breathless,” said David Price, GPIAG Professor of Primary Care Respiratory Medicine at Aberdeen University, Scotland, who developed the survey. “It is not normal to get breathless when you walk up a flight of stairs. This survey gives some idea of just how serious breathlessness is in this population.”

Professor Price said he was surprised at the severity of breathing problems that people in the survey admitted to. More than one in 10 said breathlessness prevented them from coping with everyday tasks, such as dressing and leaving the house.

MORE/



## News Release

[www.abdn.ac.uk/newsreleases](http://www.abdn.ac.uk/newsreleases)

International survey reveals that one in five smokers who have signs of irreversible lung damage attribute their breathlessness to other causes....page 2 of 4

About a quarter of those said that their breathlessness either completely or frequently dictated their daily activities. Problems caused by the breathlessness included being unable to sleep, panicking when unable to breathe, being embarrassed in public, and having problems taking part in exercise, sport and even sex.

The survey – entitled BREATH (Breathlessness Research: Expectations and Treatment Hopes) – questioned about 2,300 people in the UK, USA, France and Germany who were smokers or ex-smokers and aged over 40.

“Although the survey sampled a relatively small group, I think the findings really do show that a lot of people’s lives are severely affected by breathlessness,” Prof Price said.

COPD, sometimes known as “smoker’s lung”, is a slowly progressive disease that causes irreversible damage to the lungs. Symptoms include shortness of breath, cough and sputum production. Tobacco smoking is the biggest risk factor for the condition, which is the world’s fourth-biggest cause of death, killing about the same number of people per year as HIV/AIDS, according to the World Health Organisation (WHO).

Relieving symptoms such as breathlessness is one of the main COPD treatment goals advocated by guidelines, including the recent Global Initiative on Chronic Obstructive Lung Disease (GOLD) report from the WHO and the US National Health Institutes. Bronchodilators are considered to be first line therapy for the relief of symptoms in COPD.<sup>1</sup> Studies have also indicated that some bronchodilators, such as the long-acting beta2-agonist Foradil® (formoterol fumarate), can positively affect daily living and improve quality of life.<sup>2</sup>

In the survey, sufferers also reported mixed success when seeking medical advice. According to the BREATH survey, almost two-thirds of those with breathlessness had consulted a doctor about it, but only about half of those had been given a diagnosis.

MORE/



## News Release

[www.abdn.ac.uk/newsreleases](http://www.abdn.ac.uk/newsreleases)

International survey reveals that one in five smokers who have signs of irreversible lung damage attribute their breathlessness to other causes....page 3 of 4

"There were large country variations in the diagnosis given, but it is difficult to know whether this is a result of cultural or languages differences in disease terminology or whether some diagnoses were inaccurate," commented Professor Price.

But the survey did show that those people who had not consulted their doctor were more likely to expect to be told to stop smoking.

Among its other findings, the survey highlighted some interesting national differences:

- Twice as many people in Germany as in the other three countries thought smoking had nothing to do with their breathing problems
- Doctors in the USA gave the largest number of diagnoses of COPD
- The French were the least likely to consult a doctor about their breathing problems
- The British reported the most severe problems with mobility caused by breathlessness.

The BREATH survey was sponsored by an unrestricted educational grant from Swiss-based pharmaceutical group Novartis Pharma AG.

ENDS

## NOTES TO EDITORS

For more information about the BREATH survey, contact Janet Morgan or Camilla Bull at Chandler Chicco Agency on + 44 20 7318 8300, out of hours + 44 7778 055 109.

COPD is a slowly progressive airway disease that reduces lung function. The loss of lung function (airflow limitation) is associated with an abnormal inflammatory response of the lungs to noxious particles or gases. The characteristic symptoms of COPD - cough, sputum production and shortness of breath (dyspnoea) on exertion - often precede the development of COPD by many years.

MORE/



# News Release

[www.abdn.ac.uk/newsreleases](http://www.abdn.ac.uk/newsreleases)

International survey reveals that one in five smokers who have signs of irreversible lung damage attribute their breathlessness to other causes....page 4 of 4

COPD is a significant cause of chronic morbidity and mortality throughout the world. It caused an estimated 2.74 million deaths in 2000. The most important risk factor for COPD is cigarette smoking. Pipe, cigar and other types of tobacco smoking are risk factors. Passive exposure to cigarette smoke also contributes to respiratory symptoms and COPD.

More information about COPD is available from: [www.goldcopd.com](http://www.goldcopd.com)

### References

1. Global Initiative for Chronic Obstructive Lung Disease Executive Summary. National Institutes of Health. 2001
2. Dahl R, et al. Inhaled formoterol dry powder versus ipratropium bromide in chronic obstructive pulmonary disease. Am J Respiratory and Critical Care Medicine, 2001; 164 (5): 778-784.



# News Release

[www.abdn.ac.uk/newsreleases](http://www.abdn.ac.uk/newsreleases)

**MEDIA RELEASE - COMMUNIQUE AUX MEDIAS - MEDIENMITTEILUNG****Omalizumab controls symptoms, reduces hospital visits and decreases steroid use in patients with severe asthma**

*Studies emphasise serious financial burden of treating patients whose lives are at risk from their asthma*

Basel, 24 September 2001 – Omalizumab, the new anti-IgE agent from Novartis, has been shown to control symptoms and reduce hospitalisations in patients with severe asthma while enabling them to decrease their daily use of inhaled corticosteroids, according to studies presented at the European Respiratory Society meeting in Berlin.

In one study, 60 per cent of severe allergic asthma patients on omalizumab reduced their steroid intake to 500µg per day or less over 16 weeks, compared to only 46 per cent of those on placebo<sup>1</sup>. During this time, the placebo group experienced worsening symptoms and an increase in the use of rescue medication, whereas those on omalizumab maintained control.

A separate preliminary analysis of data from this and other Phase III clinical trials has shown that in 254 patients whose lives were at risk from their asthma, omalizumab reduced the mean number of exacerbations by 55 per cent compared to placebo. An exacerbation is the worsening of asthma symptoms that can lead to patients making emergency visits, needing oral steroid therapy or being admitted to hospital. Full details of this new analysis are currently being prepared and will be presented shortly to the medical community.

“This new analysis indicates that omalizumab could become an exciting treatment option for patients at risk from their asthma,” said Stephen Holgate, study author and Professor of Immunopharmacology at the University of Southampton School of Medicine. “Patients are defined as being at risk if they have had a hospital or intensive care stay or made an emergency visit in the previous year due to their asthma, and/or been intubated at any time to assist with their breathing. While these patients only make up around 5 per cent of all cases, they account for 50 per cent of the resources spent on asthma.”

Additional studies presented at ERS show that the costs of asthma are directly associated with the severity of disease and the effectiveness of symptom control.<sup>2,3,4</sup> A UK study showed that poorly-controlled asthma patients can cost up to three times as much in terms of use of hospital and staff resources.<sup>2</sup> The study analysed data from 13,241 patients and defined ‘poor control’ as the need for a hospital or emergency visit for asthma.

Omalizumab is a monoclonal antibody to IgE in development by Novartis Pharma AG in collaboration with Genentech Inc and Tanox Inc. It is the first product to target IgE and acts at an early stage in the allergic cascade. By binding to IgE antibodies, omalizumab prevents IgE from attaching to mast cells. Without IgE bound to mast cells, the presence of allergen will not cause the release of chemical mediators like histamine and leukotrienes, which lead to the symptoms and inflammation of allergic asthma. In trials to date, omalizumab has been administered as a subcutaneous injection every two to four weeks, at a dose depending on patients' body weight and IgE levels.

The foregoing press release contains forward-looking statements which can be identified by terminology such as "provide effective symptom control", "has shown to be", "help prevent", 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 commercialisation of any product in any market. Any such commercialisation 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.

#### **About Novartis**

Novartis (NYSE: NVS) is a world leader in healthcare with core businesses in pharmaceuticals, consumer health, generics, eye-care, and animal health. In 2000, the Group's ongoing businesses achieved sales of CHF 29.1 billion (USD 17.2 billion) and a net income of CHF 6.5 billion (USD 3.9 billion). The Group invested approximately CHF 4.0 billion (USD 2.4 billion) in R&D. Headquartered in Basel, Switzerland, Novartis employs about 70 000 people and operates in over 140 countries around the world. For further information please consult <http://www.novartis.com>

#### **About Genentech**

Genentech, Inc. (NYSE: DNA) is a leading biotechnology company that discovers, develops, manufactures and markets human pharmaceuticals for significant unmet medical needs. Fourteen of the currently approved biotechnology products stem from Genentech science. Genentech markets nine biotechnology products directly in the United States. The company has headquarters in South San Francisco, California and is traded on the New York Stock Exchange under the symbol DNA.

# # #

---

#### **References**

<sup>1</sup> Holgate S, Chuchalin A, Herbert J, et al. Omalizumab, a novel therapy for severe allergic asthma. ERS.

<sup>2</sup> McCowan C, Hoskins G, Thomas G, et al. Does 'poor asthma control' influence morbidity and cost of care in the following year? ERS.

<sup>3</sup> Schramm B, Berger K, Ehlken B, et al. Cost of illness study of patients with allergic asthma and seasonal allergic rhinitis in Germany. ERS.

<sup>4</sup> Schwenkglens M, Szucs T D, Everhard F. Costs of asthma of adults in Switzerland: associations with severity and degree of control. ERS

## News Release



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

### **FOR MORE INFORMATION:**

#### **CIBA Vision**

**Kristie Madara (678) 415-3646**

#### **WHO**

**Robert Nordquist (405) 528-1303**

## **CIBA Vision Signs Agreement with Wound Healing of Oklahoma to License Glaucoma Device**

**ATLANTA, 19 September 2001** – CIBA Vision, the eye care unit of Novartis AG (NYSE: NVS), announced today that is has signed an agreement with Wound Healing of Oklahoma, Inc. (WHO) that gives CIBA Vision exclusive worldwide marketing and distribution rights for CellPlant™, a device designed to be inserted during standard filtration surgery in glaucoma patients.

The device is designed to relieve intraocular pressure in the eye by allowing fluid egression evenly through fibrovascular channels surrounding the device.

WHO began development of the device in 1995 and has conducted long-term preclinical studies of the product, as well as early phase clinical trials. As part of the agreement, CIBA Vision will complete the US and European clinical submissions and have exclusive rights to sell the product globally.

“We are delighted that a company with the reputation of CIBA Vision for outstanding contributions in ophthalmic products has undertaken the clinical development of the glaucoma device pioneered by Wound Healing of Oklahoma,” said Robert Nordquist, PhD, WHO president. “We anticipate that this project will dramatically impact the treatment of glaucoma and result in the preservation of vision for many patients.”

“We are pleased at the potential of adding CellPlant to CIBA Vision’s growing surgical product portfolio,” said Robin Terrell, president of CIBA Vision’s Surgical Business Unit. “While we must still complete clinical trials and the regulatory approval process, we are confident that this product will provide a valuable alternative to physicians when treating glaucoma patients.”

CIBA Vision expects to complete the regulatory process for this product by mid-2003 in Europe and early 2004 in the United States.

The Magnum Group, a firm specializing in business development services for ophthalmic medical device companies, facilitated the transaction between WHO and CIBA Vision.

#### **About CIBA Vision**

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 website at [www.cibavision.com](http://www.cibavision.com).

CIBA Vision is the eye care unit of Novartis (NYSE: NVS), a world leader in healthcare with core businesses in pharmaceuticals, consumer health, generics, eye care and animal health. In 2000, the Group's ongoing businesses achieved sales of CHF 29.1 billion (USD 17.2 billion) and a net income of CHF 6.5 billion (USD 3.9 billion). The Group invested approximately CHF 4.0 billion (USD 2.4 billion) in R&D. Headquartered in Basel, Switzerland, Novartis employs about 70,000 people and operates in over 140 countries around the world. For further information please consult [www.novartis.com](http://www.novartis.com).

#### **About WHO**

Founded in 1994, Oklahoma City, OK based Wound Healing of Oklahoma, Inc. is a privately held research and development company specializing in cancer research and ophthalmic devices and materials. The company has performed contract research and licensed refractive surgery and glaucoma technologies for numerous companies.

###



**MEDIA RELEASE · COMMUNIQUE AUX MEDIAS · MEDIENMITTEILUNG****Novartis' Foradil® demonstrates superior efficacy in chronic obstructive pulmonary disease over gold standard treatment**

Basel, 19 September 2001 – New results just published show Novartis' fast-acting, long-lasting bronchodilator Foradil® (formoterol fumarate) to be significantly better than the current gold standard therapy, ipratropium bromide\*, in reducing clinical symptoms of chronic obstructive pulmonary disease (COPD) and their impact on patients' lives.<sup>1</sup>

Results from a head-to-head clinical trial, published in the current issue of the *American Journal of Respiratory and Critical Care Medicine* demonstrate that the bronchodilating action of Foradil was significantly better than that of ipratropium bromide as early as five minutes after dosing and was still evident up to 12 hours later. While similar improvements in lung function were seen with each drug, only Foradil demonstrated a statistically significant improvement in all domains of patients' quality of life, as measured by the St George's Respiratory Questionnaire. By contrast, the effect of ipratropium bromide was similar to that of placebo.

"We conclude that formoterol is more effective than ipratropium bromide in the treatment of COPD, since the efficacy of ipratropium on airflow obstruction does not translate into a clinical benefit that patients can perceive," wrote the study authors. "The twice-daily dosing schedule of formoterol, its fast onset of action and the perception of benefit by the patients, should enhance compliance and minimise the possibility of overdosing. The clinically significant improvement in quality of life by treatment with formoterol could reduce disability, lost productivity and medical care costs."

The improvement in pulmonary function produced by Foradil was associated with a reduction in daily symptoms, less use of rescue medication, and fewer 'bad days' - defined as days where patients scored two or more on at least two of the marked individual symptoms and/or had a reduction in the peak expiratory flow rate from baseline of more than 20 %.

The double-blind parallel-group study compared the effects of Foradil (12 or 24 µg twice daily), ipratropium (40 µg four times daily) and placebo over 12 weeks on 780 patients who were diagnosed as having COPD, according to the American Thoracic Society Guidelines. The primary efficacy assessment related to lung function was evaluated by FEV<sub>1</sub> (forced expiratory volume in the first second) measurements over 12 hours following the morning dose and after 12 weeks of therapy. Secondary assessments included symptom scores health status measurements, as evaluated by the St George's Respiratory Questionnaire. The safety and tolerability of treatment with both Foradil and ipratropium was good and similar.

\* Ipratropium bromide is also marketed under the brand name Atrovent.

Although this study did not compare Foradil with salmeterol, the other available long-acting beta<sub>2</sub>-agonist, previous studies have shown that Foradil produced a more rapid onset of bronchodilation than salmeterol.<sup>2,3</sup>

Foradil, which is available in most major markets, was launched in the US earlier this year and is currently under review for approval by the US Food & Drug Administration (FDA) in the treatment of COPD. It is already available in several European countries.

The foregoing press release contains forward-looking statements which can be identified by terminology such as “could reduce disability”, “perception of benefit”, “should enhance compliance”, 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 commercialisation of any product in any market. Any such commercialisation 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.

#### **About Novartis**

Novartis (NYSE: NVS) is a world leader in healthcare with core businesses in pharmaceuticals, consumer health, generics, eye-care, and animal health. In 2000, the Group's ongoing businesses achieved sales of CHF 29.1 billion (USD 17.2 billion) and a net income of CHF 6.5 billion (USD 3.9 billion). The Group invested approximately CHF 4.0 billion (USD 2.4 billion) in R&D. Headquartered in Basel, Switzerland, Novartis employs about 70 000 people and operates in over 140 countries around the world. For further information please consult <http://www.novartis.com>

# # #

#### **References**

1. Dahl R et al. Inhaled formoterol dry powder versus ipratropium bromide in chronic obstructive pulmonary disease. *Am J Respiratory and Critical Care Medicine*, 2001; 164 (5): 778-784.
2. Celik G et al. Formoterol and salmeterol in partially reversible chronic obstructive pulmonary disease: A crossover, placebo -controlled comparison of onset and duration of action. *Respiration* 1999; 66 (5): 434 -439
3. Kottakis J et al. Superior spirometric efficacy of single dose formoterol compared to single dose salmeterol during the first hour post dose in moderate and severe COPD patients. *Eur Respir J* 2001, abstract in press.

**MEDIA RELEASE - COMMUNIQUE AUX MEDIAS - MEDIENMITTEILUNG****Novartis' Expo project "Biopolis" gets underway**

*Over the next few days, work is to begin in Neuchâtel on the construction of Novartis "Biopolis" pavilion for the Expo.02. Today's ceremony at the "arteplage" exhibition area in Neuchâtel is to be accompanied by the project's virtual launch on the Internet.*

Basel, September 18, 2001 – Today saw the turning of the construction start at the "arteplage" exhibition area in Neuchâtel for Novartis' Expo.02 project "Biopolis". The pavilion, designed by Zurich-based architect Barbara Holzer, is due to be completed and ready for installation work by the end of the year.

The pavilion is to house "Biopolis" – both a city of life and a city of the future. "Biopolis" is intended to give visitors an impression of what life could be like in the future as modern biology develops – with genomic analysis or innovative "personalized" treatments. The city of "Biopolis", which is located in 2022, communicates visions and possible scenarios for patients and the healthy in an interactive way. At the same time, the exhibition offers insights into the world of biomedical research.

The exhibition is intended to encourage visitors to engage personally with the future and in particular with the future of human health. Heinz Boller, Head of Novartis Switzerland, commented: "Our Expo involvement is also a contribution toward an open dialog on new technologies." To stimulate and provide a forum for long-term discussions, a website has already been established at [www.biopolis.ch](http://www.biopolis.ch) which also includes background information and the latest updates on the Expo.02 project.

Novartis (NYSE: NVS) is a world leader in healthcare with core businesses in pharmaceuticals, consumer health, generics, eye-care, and animal health. In 2000, the Group's ongoing businesses achieved sales of CHF 29.1 billion (USD 17.2 billion) and a net income of CHF 6.5 billion (USD 3.9 billion). The Group invested approximately CHF 4.0 billion (USD 2.4 billion) in R&D. Headquartered in Basel, Switzerland, Novartis employs about 70 000 people and operates in over 140 countries around the world. For further information please consult <http://www.novartis.com>.

# # #

**MEDIA RELEASE - COMMUNIQUE AUX MEDIAS - MEDIENMITTEILUNG****Novartis research symposium reports advances in genomics, disease knowledge, technologies and modelling tools**

*Investment increase in early phase research to increase new drug leads and shorten discovery times*

Florence, 14 September 2001 – Novartis scientists from around the world gathered at a research conference in Florence, Italy this week to report on new advances in genomics and disease knowledge and how the newest high-throughput technology, knowledge management and modeling tools are being used to improve and accelerate the drug discovery process. These programs are part of a three-year, multi-million dollar research initiative that aims to dramatically increase the quantity and quality of drug leads.

“In this dawning era of unprecedented scientific opportunity, the best way to stay ahead of the competition is to ensure that the necessary expertise, technologies and resources are available in-house,” said Paul Herrling, Head of Global Research at Novartis Pharma AG. “Our research talent includes some of the best and brightest scientists in the world, and their work reflects a level of innovation and rapid, aggressive exploration that is setting the standard for the post-genomic world.”

Dr Herrling said that Novartis met the challenge of the Human Genome Project completion with a massive increase in early phase research investment. The initiative includes the creation of a new drug discovery center, biology platforms for immunology and angiogenesis, and target platform proteases, as well as expansion of groups for Central Technologies and Information & Knowledge Management. In addition, a global recruitment drive is underway to add staff to new and expanded units. Approximately 450 new hires are expected, representing a 15-20% increase in research personnel.

New approaches to selecting potential targets for medicines, including broad *in-vitro* biological profiling of compounds will increase the number and quality of early therapeutic drug candidates – and shorten discovery times. This pace is expected to enhance Novartis Research’s profile for high-quality external collaborations and alliances.

Novartis' research and development spans therapeutic areas including: cardiovascular diseases; metabolism/endocrinology; arthritis/inflammation; bone metabolism; oncology; neurology/psychiatry; dermatology; transplantation/immunology and respiratory diseases. The highlights of new approaches and genomics targets for drug discovery were summarized as follows:

### **Central nervous system**

GABA<sub>B</sub> is an important [amino acid](#), as it is the [most common inhibitory neurotransmitter](#) in the [central nervous system](#). Novartis researchers were among the first to recognize that the GABA<sub>B</sub> receptor is not a single molecule, but instead consists of two different proteins. Novartis researchers were the first to clone these GABA<sub>B</sub> receptor proteins – and are now screening for drugs that can enhance the physiological effects of GABA in the brain.

Drugs acting at the GABA<sub>B</sub> receptor, called allosteric modulators, could be used to treat neurological disorders ranging from anxiety to epilepsy, and Alzheimer's disease. This fall, Novartis researchers will publish data on the first allosteric modulators of GABA<sub>B</sub> receptors in molecular pharmacology.

### **Cancer**

Novartis Oncology research is focusing on specific drug targets for malfunctioning cancer cells. Molecules are being investigated that target pathways involved in: cell growth; apoptosis (programmed cell death); senescence (aging); and angiogenesis (the development of blood vessels that feed the growing tumor). For example, recent in vitro studies show that Zometa® (zoledronic acid) also reduces human tumor cell proliferation and promotes their death. An anti-angiogenic effect has also been demonstrated in animal studies.

Zometa, a bisphosphonate compound, is a highly potent inhibitor of bone cells known as osteoclasts. Zometa is already approved in several countries for the treatment of hypercalcemia of malignancy (HCM), which is caused through abnormal activity of osteoclasts in cancer patients.

### **Immunology**

Novartis researchers are studying a novel compound that displays a mode of action never before observed in any immunosuppressive agent. Whereas traditional immunosuppressants block the immune function of lymphocytes, FTY720, an immunomodulator, instead only traffics the lymphocytes out of circulation into local lymph nodes, until they need to be returned. Therefore, treatment with FTY720 does not impair the immune system's ability to remember and fight off viral infections—and, therefore, may reduce the risk of opportunistic infections and malignancies—in striking contrast to conventional immunosuppressants. FTY720 offers potential for preventing acute and chronic rejection of transplanted organs as well as for the treatment of autoimmune diseases such as multiple sclerosis, Crohn's disease, and rheumatoid arthritis.

### **Dermatology**

A few months ago, Novartis completed the first dermatological therapeutic study to include pharmacogenetic profiling (analysis of gene expression) when it clinically evaluated Elidel® (pimecrolimus) as an oral drug for psoriasis. Elidel was shown to strongly down-regulate expression of the genes that trigger the immunological responses underlying psoriasis. A derivative of a natural product, Elidel also demonstrated clinical efficacy with a favorable safety profile, even up to the highest dose tested (30 mg bid). The drug has already shown high efficacy for short and long-term treatment of atopic dermatitis in adults, children and babies as young as three months. Filing for regulatory approval for this indication was completed last year in the US last year, and last June in Europe.

This release contains certain “forward-looking statements”, relating to the Group's business, which can be identified by the use of forward-looking terminology such as “expects”, “estimates”, “promising”, “will”, “anticipates” or similar expressions, or by discussions of strategy, plans or intentions. Such statements include descriptions of new products expected to be introduced or have been introduced by the Group and anticipated customer demand for such

products. Such statements reflect the current views of the Group with respect to future events and are subject to certain risks, uncertainties and assumptions. Many factors could cause the actual results, performance or achievements of the Group to be materially different from any future results, performances or achievements that may be expressed or implied by such forward-looking statements. Some of these are 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 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.

Novartis (NYSE: NVS) is a world leader in healthcare with core businesses in pharmaceuticals, consumer health, generics, eye-care, and animal health. In 2000, the Group's ongoing businesses achieved sales of CHF 29.1 billion (USD 17.2 billion) and a net income of CHF 6.5 billion (USD 3.9 billion). The Group invested approximately CHF 4.0 billion (USD 2.4 billion) in R&D. Headquartered in Basel, Switzerland, Novartis employs about 70 000 people and operates in over 140 countries around the world. For further information please consult <http://www.novartis.com>

###

**MEDIA RELEASE - COMMUNIQUE AUX MEDIAS - MEDIENMITTEILUNG****New analysis underscores safety and efficacy of Novartis' cholesterol-lowering drug Lescol®/Lescol XL®**

Basel, 10 September, 2001 – Novartis announced today, at the Drugs Affecting Lipid Metabolism (DALM) meeting in New York, the results of its analysis of data pooled in nearly 200 centers in fifteen countries, representative of the use of Lescol® (fluvastatin) and Lescol® XL in 9000 patients<sup>1</sup>. The analysis focused on the frequency of elevations in creatine phosphokinase (CPK), an indication of muscle breakdown.

This analysis of the data confirms that the frequency of clinically relevant CPK elevations with 20 mg and 40 mg Lescol and 80 mg Lescol XL doses, was not significantly different to that in patients receiving placebo. No cases of rhabdomyolysis were observed. The studies also demonstrate that Lescol/Lescol XL is highly effective in lowering blood lipids to the levels specified in international treatment guidelines.

In addition, several studies involving approximately 700 patients treated with Lescol in combination with either gemfibrozil, fenofibrate, bezafibrate or niacin did not show safety concerns<sup>2</sup>. However, the combined use of any statin, including Lescol and Lescol XL, and fibrates should be avoided, unless the benefit on lipid levels outweighs the increased risk of this combination.

Lescol XL, the once-daily Lescol formulation, has shown in trials to provide effective and comprehensive lipid management, with excellent lipid reductions of up to 38% in harmful LDL-cholesterol, up to 31% in triglycerides combined, and top-in-class elevations of up to 21% in favourable HDL-cholesterol.

These data underscore the favourable efficacy/safety profile of Lescol/Lescol XL for patients who need effective, comprehensive lipid management.

This press release contains forward looking statements which can be identified by the use of forward looking terminology such as “considered”, “did not show safety concerns”, “provides”, 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. In particular, management’s ability to ensure satisfaction of the FDA’s further requirements is not guaranteed and management’s expectations regarding commercialization of Lescol/Lescol XL could be affected by, among other things, additional analysis of data; new data; unexpected findings; 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 Securities and Exchange Commission of the United States. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those anticipated, believed, estimated or expected.

Novartis (NYSE: NVS) is a world leader in healthcare with core businesses in pharmaceuticals, consumer health, generics, eye-care, and animal health. In 2000, the Group's ongoing businesses achieved sales of CHF 29.1 billion (USD 17.2 billion) and a net income of CHF 6.5 billion (USD 3.9 billion). The Group invested approximately CHF 4.0 billion (USD 2.4 billion) in R&D. Headquartered in Basel, Switzerland, Novartis employs about 70 000 people and operates in over 140 countries around the world. For further information please consult <http://www.novartis.com>

# # #

1. Abstract accepted by Drugs Affecting Lipid Metabolism (DALM) NY, September 2001
2. Smit et al, Am J Cardiol 1995; 76:126A-128A; Farnier et al 1995;76:76A-79A; Cortellario et al 2000, Thrombosis and Haemostasis;83 (4):549-553; Jacobson et al 1994, Am J Cardiol; 73:25D-29D.



- Investor Relations Release -

## **Novartis launches largest diabetes prevention trial to date**

*NAVIGATOR study to determine benefit of early administration of Starlix® and Diovan® in people with impaired glucose tolerance who have high cardiovascular risk*

Basel, 10 September 2001 – Novartis today announced the launch of NAVIGATOR (Nateglinide And Valsartan in Impaired Glucose Tolerance Outcomes Research), the largest-ever diabetes prevention clinical trial to date, which aims to determine whether long-term administration of Starlix® (nateglinide) or Diovan® (valsartan) reduce or delay the development of type 2 diabetes and cardiovascular (CV) disease in people who have impaired glucose tolerance (IGT) and are at high cardiovascular risk. Recent studies suggest that people with IGT are 34% more likely to die from CV disease than people with normal blood glucose control.

IGT is an intermediate state between normal blood glucose control and type 2 diabetes. IGT is characterised by an excessive rise in blood glucose following consumption of 75g glucose. People with IGT show abnormalities in both insulin secretion and response to insulin (insulin sensitivity), and are at high risk of progressing to type 2 diabetes, with a 40-50% chance of developing the disease within ten years. IGT is also a major risk factor for CV disease.

“With as many as one in seven people over 40 being affected by IGT, it is essential that we evaluate strategies to improve the outlook of people with this condition. We believe that collaborative research in these two fields will ultimately lead to treatment strategies that can prevent type 2 diabetes and cardiovascular disease in high-risk populations,” said Thomas Ebeling, Chief Executive Officer, Novartis Pharma AG.

Speaking at the launch of the NAVIGATOR trial, Professor Paul Zimmet of the WHO Collaborating Centre in Melbourne, Australia, and a world expert on IGT, noted, “although we have clear evidence that weight control and physical activity substantially reduce the risk of developing diabetes and CV disease, it’s equally clear that many people do not respond to lifestyle advice”

NAVIGATOR will be the largest diabetes prevention trial to date, involving 7500 subjects recruited from 600-800 centres in 40 countries. Participants will be aged at least 50 with at least one cardiovascular disease, or 55 years and older with at least one CV risk factor. In the four arm study, subjects will be randomised to receive Starlix (60mg before main meals), Diovan (160mg daily), both, or placebo. The effects of the two drugs will be assessed

independently. The NAVIGATOR protocol is under review with the U.S. Food and Drug Administration and European health authorities.

The study will be carried out in two phases. In the first phase, designed to run for three years after the last subject is enrolled, the effect of Starlix and Diovan on progression to diabetes will be evaluated. In the second, or 'extension' phase, the drugs' effects on CV disease will be evaluated. This phase will last until 1000 subjects have had a cardiovascular event. The total duration of NAVIGATOR follow-up is estimated at five years and nine months. It is expected that the first patient visit will take place in November 2001 and that recruitment will last 18 months.

Mealtime glucose spikes have been identified as an important risk factor for CV disease and mortality in people with type 2 diabetes. Starlix is an oral anti-diabetic drug which, when taken before main meals, rapidly stimulates a short-acting burst of insulin secretion, thereby reducing post-meal hyperglycaemia with minimal risk of subsequent hypoglycaemia. The pattern of insulin secretion produced by Starlix is similar to the physiological pattern of insulin secretion that is progressively lost in people with IGT and type 2 diabetes. Thus, in theory, Starlix is an ideal drug to use in the treatment of IGT.

Diovan is an angiotensin II receptor blocker (ARB) indicated for treatment of high blood pressure. Studies have shown that drugs that block the effects of angiotensin II reduce the incidence of cardiovascular disease in high-risk groups. Evidence is also emerging that these drugs may improve insulin sensitivity and reduce the risk of developing type 2 diabetes. Diovan is supported by the world's largest clinical trial program with an ARB, including several studies besides NAVIGATOR that are investigating its effects beyond blood pressure lowering. Diovan is also undergoing regulatory review worldwide for treatment of heart failure.

"The NAVIGATOR trial, which is nearly twice the size of any comparable trial, will show us whether restoration of early phase insulin secretion and improvements in insulin sensitivity can arrest decline to type 2 diabetes and prevent cardiovascular disease in this high-risk group" says Rury Holman, Professor of Diabetic Medicine, University of Oxford, UK, one of the trial's lead investigators. "Half of the people who develop type 2 diabetes already have complications by the time they are diagnosed. If we are to manage the growing tidal wave of type 2 diabetes, it is essential that we tackle the problem upstream".

### **Forward-looking statement**

The forgoing press release contains forward-looking statements which can be identified by terminology such as "aims to determine", "will be", "will receive", "will evaluate", "will be carried out", "is estimated", "it is expected", "will take place", "will last", "may improve", "may reduce", "will show" 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 commercialisation of any product in any market. Any such commercialisation 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.

**About Novartis**

Novartis (NYSE:NVS) is world leader in healthcare with core businesses in pharmaceuticals, consumer health, generics, eye-care, and animal health. In 2000, the Group's ongoing businesses achieved sales of CHF 29.1 billion (USD 17.2 billion) and invested approximately CHF 4.0 billion (USD 2.4 billion) in R&D. Headquartered in Basel, Switzerland, Novartis employs about 67 600 people and operates in over 140 countries around the world. For further information please consult <http://www.novartis.com>.

For further product information please consult [www.starlix.com](http://www.starlix.com), [www.diovan.com](http://www.diovan.com), [www.diabetesandhealth.com](http://www.diabetesandhealth.com), and [www.hypertensionandhealth.com](http://www.hypertensionandhealth.com)



## MEDIA RELEASE

### **Novartis Ophthalmics and QLT file Canadian submission for expansion of Visudyne® approval**

#### **For Immediate Release**

**September 10, 2001**

ATLANTA, GEORGIA and VANCOUVER, CANADA — Novartis Ophthalmics, the eye health unit of Novartis AG (NYSE: NVS), and QLT Inc. (NASDAQ:QLTI; TSE:QLT) today announced the filing of Visudyne® (verteporfin for injection) therapy with the Canadian Therapeutics Products Directorate (TPD) for the treatment of a select group of patients with occult subfoveal choroidal neovascularization (CNV) caused by wet age-related macular degeneration (AMD). AMD is the leading cause of blindness in people over the age of 50.

This submission is based on favorable two-year results from a phase III clinical trial showing Visudyne has a significant treatment benefit in AMD patients with occult CNV. The results were published in the May 2001 issue of the peer-reviewed American Journal of Ophthalmology. The submission specifically seeks approval for patients with occult AMD with smaller lesions or lower visual acuity.

“In our efforts to make Visudyne therapy available to all wet AMD patients, today’s filing brings us one step closer to fulfilling that goal as occult CNV represents a significant portion of the total wet AMD market,” said Dr. Julia Levy, president and CEO of QLT.

“We look forward to the agency’s review of this important therapy as there is currently no approved treatment for patients suffering from the occult form of this devastating eye disease,” said Dan Myers, president of Novartis Ophthalmics, North America.

Visudyne is commercially available in 50 countries for the treatment of predominantly classic subfoveal CNV caused by AMD. It is also approved in over 20 countries, including the EU, U.S. and Canada, for the treatment of subfoveal CNV due to pathologic myopia (severe near-sightedness). In the U.S., Visudyne has received an additional approval for CNV due to presumed ocular histoplasmosis. Approximately 80,000 patients have undergone Visudyne therapy worldwide.

Occult and classic are terms used to describe different patterns of CNV leakage as seen on fluorescein angiography. Together, the occult and predominantly classic form of the disease account for approximately two-thirds of all wet AMD cases at diagnosis. Annually, it is estimated that 500,000 new patients develop wet AMD worldwide.

As part of the Canadian submission, Novartis Ophthalmics and QLT also filed for approval of Visudyne for presumed ocular histoplasmosis, a condition characterized by CNV resulting from a fungal infection of the retina. The condition is caused by inhaling the fungus *Histoplasma capsulatum* and can lead to severe, irreversible vision loss. The fungus generally remains in a dormant stage but tends to become more active when a person’s immune system is compromised.

**About Visudyne**

Visudyne therapy is a two-step procedure that can be performed in a doctor's office. First, the drug is injected intravenously into the patient's arm. A non-thermal laser light is then shone into the patient's eye to activate the drug. Visudyne therapy uses a specially designed laser that produces the low level, non-thermal 689nm light required to activate the drug. Visudyne is generally well tolerated and has an excellent safety profile. Potential side effects include injection site reactions, infusion related pain, back pain, headaches, blurring, decreased sharpness and gaps in vision, and in 15 % of patients a substantial decrease in vision with partial recovery in some patients. People should avoid direct sunlight for five days to avoid sunburn. People with porphyria should not be treated. For more information, visit [www.visudyne.com](http://www.visudyne.com).

The foregoing press release contains forward-looking statements that can be identified by terminology such as "look forward," "could significantly expand the current market," "potential," or similar expressions. Such forward-looking statements involve known and unknown risks, uncertainties and other factors, which may cause the actual results and assumptions to be materially different from any future results, performance or achievements expressed or implied by such statements. Such factors include, but are not limited to: risks associated with the development and commercialization of the treatment, including uncertainties relating to manufacturing, clinical trials, registration, patient enrollment, pricing and reimbursement; patient and physician demand for the treatment; competition; any uncertainty regarding patents and proprietary rights; outcome of litigation claims, product liability claims and insurance; government regulation; dependence on corporate relationships; volatility of share prices; QLT Inc.'s access to capital; and any additional information and other factors as described in detail in QLT Inc.'s Annual Information Form on Form 10-K and recent and forthcoming quarterly reports on Form 10Q, Novartis AG's Form 20-F on file, and other filings with the US Securities and Exchange Commission.

**Background on Novartis Ophthalmics and QLT**

Novartis Ophthalmics: With worldwide headquarters in Bulach, Switzerland, Novartis Ophthalmics is a global leader in research, development and manufacturing of leading ophthalmic pharmaceuticals that assist in the treatment of glaucoma, age-related macular degeneration, eye inflammation, ocular allergies and other diseases and disorders of the eye. Novartis Ophthalmics products are available in more than 110 different countries. The North American headquarters is based in Atlanta, Georgia. Novartis Ophthalmics has production sites in Switzerland, France and Canada. For more information, visit [www.novartisophthalmics.com](http://www.novartisophthalmics.com) or [www.novartisophthalmics.com/us](http://www.novartisophthalmics.com/us).

Novartis (NYSE: NVS) is a world leader in healthcare with core businesses in pharmaceuticals, consumer health, generics, eye-care, and animal health. In 2000, the Group's ongoing businesses achieved sales of CHF 29.1 billion (USD 17.2 billion) and a net income of CHF 6.5 billion (USD 3.9 billion). The Group invested approximately CHF 4.0 billion (USD 2.4 billion) in R&D. Headquartered in Basel, Switzerland, Novartis employs about 70,000 people and operates in over 140 countries around the world. For further information please consult <http://www.novartis.com>.

QLT Inc. (NASDAQ:QLTI; TSE:QLT) is a world leader in photodynamic therapy, a field of medicine utilizing light-activated drugs in the treatment of disease. QLT's innovative science has led to the development and commercialization of breakthrough treatments utilizing this technology for applications in ophthalmology and oncology and is exploring the potential in other diseases. For more information, you are invited to visit QLT's web site at [www.qltinc.com](http://www.qltinc.com).

*Visudyne® is a registered trademark of Novartis AG*

**Contacts:**

Novartis Ophthalmics, North America:

Duluth, Georgia, USA

Jan McClure, Telephone: 770-905-1020      Fax: 770-905-1510

Novartis Ophthalmics, Worldwide:

Bulach, Switzerland

Kathrin Wyss, Telephone: +41 1 864 16 19      Fax: +41 1 862 03 86

QLT Inc.:

Vancouver, Canada

Elayne Wandler or Tamara Hicks, Telephone: 604-707-7000      Fax: 604-707-7001

**MEDIA RELEASE - COMMUNIQUE AUX MEDIAS - MEDIENMITTEILUNG****New non-steroid cream Elidel® could change the treatment of eczema**

*Studies presented at international symposium demonstrate effective relief from eczema in children without the use of steroids*

Basel, Switzerland, 7 September 2001 – A new steroid-free approach to controlling the itching skin disease eczema in children was outlined today to the world's leading specialists at the International Symposium on Atopic Dermatitis in Portland, Oregon, US. Thomas Luger, Professor of Dermatology at the University of Muenster, Germany, reported that six out of ten children, enrolled in clinical trials, who used the new non-steroid cream Elidel® (primecrolimus) at the first sign of itching or other signs of eczema, did not have any flares and did not use any topical corticosteroids.

“Until now, the conventional treatment for eczema has been emollients for the dry skin stage, and intermittent use of topical corticosteroids to treat flares,” Professor Luger said. “While topical corticosteroids are effective, their long-term use has been linked to side-effects such as skin thinning and growth retardation, and many parents are reluctant to use corticosteroids on their children. This study shows an alternative way of successfully managing eczema, without the side-effects of steroids, for many patients. We can expect that more than half of the children treated with Elidel will not need any topical corticosteroids.”

In the international study, the first of its kind and one of the largest ever performed in children with eczema, 713 patients aged 2-17 received either an Elidel-based regimen or a conventional treatment. In the first group, Elidel was applied at the first signs of itching, redness or skin thickening, in order to prevent the eczema progressing to a flare. If needed, topical corticosteroids were allowed as rescue therapy for flares. The conventional treatment group was allowed to use emollients and topical corticosteroids.

The study showed that the Elidel-based regimen offered more effective control: 61% of patients in the Elidel-treated group completed six months without a flare, compared with only 35% in the conventional treatment group.

Another study showed that Elidel is also effective in treating eczema in babies aged 3-23 months. Itching - the most troublesome symptom of eczema - was reported to have stopped or to be merely mild in 70% of the Elidel-treated babies within the first week.

In studies to date, approximately 1700 patients have been treated with Elidel and the cream has been well-tolerated, with no clinically important systemic side effects reported. The most frequent side-effect, occurring in approximately 10% of children, is a transient feeling of warmth or mild sensation of burning on the skin where the cream is applied, but this usually disappears within a few days of treatment.

Elidel, which is being developed by Novartis, is the first treatment proven to reduce the incidence of eczema flares and the need for topical corticosteroids. As a skin-selective inflammatory cytokine inhibitor, Elidel works by selectively targeting those cells which release the pro-inflammatory mediators in atopic eczema.

Novartis has filed applications for marketing authorization in the US, Canada, Switzerland and Denmark (the reference member state for the European Union).

This press release contains forward looking statements which can be identified by the use of forward looking terminology such as “new,” “alternative way,” “can expect,” 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 commercialisation of Elidel in any market. Any such commercialisation 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. Any of these and other factors can cause the actual results to differ materially from the expected or predicted results.

Novartis (NYSE: NVS) is a world leader in healthcare with core businesses in pharmaceuticals, consumer health, generics, eye-care, and animal health. In 2000, the Group's ongoing businesses achieved sales of CHF 29.1 billion (USD 17.2 billion) and a net income of CHF 6.5 billion (USD 3.9 billion). The Group invested approximately CHF 4.0 billion (USD 2.4 billion) in R&D. Headquartered in Basel, Switzerland, Novartis employs about 70 000 people and operates in over 140 countries around the world. For further information please consult <http://www.novartis.com>



**MEDIA RELEASE - COMMUNIQUE AUX MEDIAS - MEDIENMITTEILUNG****Novartis Ophthalmics and QLT file submission with the EMEA to expand the use of Visudyne® in AMD**

Basel, 7 September 2001 – Novartis Ophthalmics, the eye health unit of Novartis AG and QLT Inc. today announced the filing of Visudyne® (verteporfin)<sup>1</sup> therapy with the European Medicines Evaluation Agency (EMA) for marketing clearance in the European Union (EU) for the treatment of occult subfoveal choroidal neovascularization (CNV) secondary to wet age-related macular degeneration (AMD). AMD is the leading cause of blindness in people over the age of 50.

This submission is based on favorable two-year results from a phase III clinical trial showing Visudyne has a significant treatment benefit in AMD patients with occult CNV. The results were published in the May 2001 issue of the peer-reviewed *American Journal of Ophthalmology*.

Luzi von Bidder, head of Novartis Ophthalmics said, “We look forward to the European agency’s assessment of this important therapy and the potential benefit to the many patients who suffer from this devastating condition for which there is currently no approved drug treatment available.”

“This EU submission is a very important milestone,” said Dr. Julia Levy, president and CEO of QLT. “Occult CNV represents a considerable portion of the total wet AMD population and if approved this indication could significantly expand the current market for Visudyne.”

Visudyne is commercially available in 50 countries for the treatment of predominantly classic subfoveal CNV caused by AMD. It is also approved in over 20 countries, including the EU, US and Canada, for the treatment of subfoveal CNV due to pathologic myopia (severe near-sightedness). In the US, Visudyne has received an additional approval for CNV due to presumed ocular histoplasmosis. Approximately 80,000 patients have undergone Visudyne therapy worldwide. In May, Visudyne was awarded the prestigious Prix Galien for therapeutic innovation in France, Belgium and Portugal.

Occult and classic are terms used to describe different patterns of CNV leakage as seen on fluorescein angiography. Together, the occult and predominantly classic forms of the disease account for approximately two-thirds of all wet AMD cases at diagnosis. Annually, it is estimated that 500,000 new patients develop wet AMD worldwide.

---

<sup>1</sup> Outside the US: Visudyne®; in the US: Visudyne™

**About Visudyne**

Visudyne therapy is a two-step procedure that can be performed in a doctor's office. First, the drug is injected intravenously into the patient's arm. A non-thermal laser light is then shone into the patient's eye to activate the drug. Visudyne therapy uses a specially designed laser that produces the low level, non-thermal 689nm light required to activate the drug. Visudyne is the only drug therapy approved for the treatment of some forms of wet AMD.

For more information, visit [www.visudyne.com](http://www.visudyne.com).

The foregoing press release contains forward-looking statements that can be identified by terminology such as "look forward," "could significantly expand the current market," "potential," or similar expressions. Such forward-looking statements involve known and unknown risks, uncertainties and other factors, which may cause the actual results and assumptions to be materially different from any future results, performance or achievements expressed or implied by such statements. Such factors include, but are not limited to: risks associated with the development and commercialization of the treatment, including uncertainties relating to manufacturing, clinical trials, registration, patient enrollment, pricing and reimbursement; patient and physician demand for the treatment; competition; any uncertainty regarding patents and proprietary rights; outcome of litigation claims, product liability claims and insurance; government regulation; dependence on corporate relationships; volatility of share prices; QLT Inc.'s access to capital; and any additional information and other factors as described in detail in QLT Inc.'s Annual Information Form on Form 10-K and recent and forthcoming quarterly reports on Form 10Q, Novartis AG's Form 20-F on file, and other filings with the US Securities and Exchange Commission.

**Background on Novartis Ophthalmics and QLT**

Novartis Ophthalmics: With worldwide headquarters in Bulach, Switzerland, Novartis Ophthalmics is a global leader in research, development and manufacturing of leading ophthalmic pharmaceuticals that assist in the treatment of glaucoma, age-related macular degeneration, eye inflammation, ocular allergies and other diseases and disorders of the eye. Novartis Ophthalmics products are available in more than 110 different countries. The North American headquarters is based in Atlanta, Georgia. Novartis Ophthalmics has production sites in Switzerland, France and Canada. For more information, visit [www.novartisophthalmics.com](http://www.novartisophthalmics.com) or [www.novartisophthalmics.com/us](http://www.novartisophthalmics.com/us).

Novartis (NYSE: NVS) is a world leader in healthcare with core businesses in pharmaceuticals, consumer health, generics, eye-care, and animal health. In 2000, the Group's ongoing businesses achieved sales of CHF 29.1 billion (USD 17.2 billion) and a net income of CHF 6.5 billion (USD 3.9 billion). The Group invested approximately CHF 4.0 billion (USD 2.4 billion) in R&D. Headquartered in Basel, Switzerland, Novartis employs about 70,000 people and operates in over 140 countries around the world. For further information please consult <http://www.novartis.com>.

QLT Inc. (NASDAQ:QLTI; TSE:QLT) is a world leader in photodynamic therapy, a field of medicine utilizing light-activated drugs in the treatment of disease. QLT's innovative science has led to the development and commercialization of breakthrough treatments utilizing this technology for applications in ophthalmology and oncology and is exploring the potential in other diseases. For more information, you are invited to visit QLT's web site at <http://www.qltinc.com>.

# # #

## **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 4, 2001

By: /s/ Raymund Breu

Name: Raymund Breu

Title: Chief Financial Officer