

NOVARTIS AG
Form 6-K
July 23, 2003

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SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 6-K

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

Report on Form 6-K dated July 23, 2003
(Commission File No. 1-15024)

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 if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):

Yes: No:

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7):

Yes: No:

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:

New Novartis transplant drug Certican® approved in first European market

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Investor Relations Release

New Novartis transplant drug Certican® approved in first European market

Novel proliferation inhibitor increases treatment choice for renal and heart transplant recipients

Basel, 23 July, 2003 Novartis announced today that the Swedish Medical Products Agency (MPA) has granted marketing authorization for Novartis' new immunosuppressant drug Certican® (everolimus) for use in kidney and heart transplantation. Sweden will be the Reference Member State in the Mutual Recognition Process for Certican within the European Union.

Certican is a novel proliferation signal inhibitor that is designed to target the primary causes of chronic allograft dysfunction or late graft loss, including acute rejection, cytomegalovirus (CMV) infection, calcineurin inhibitor (CNI) nephrotoxicity and vascular remodeling^{1,2,3}. Preventing chronic allograft dysfunction or late graft loss is a major unmet medical need in transplantation.⁴

The Novartis Transplantation and Immunology Team is committed to developing a new and innovative range of therapeutic products for the prevention of organ rejection in order to provide an extensive choice of drugs to the transplant community and to maintain Novartis' role as a global market leader in this field of medicine.

This release contains certain "forward-looking statements," relating to the Company's business, which can be identified by the use of forward-looking terminology such as "increases treatment choice", "will be", "is committed to developing", "to maintain", or similar expressions, or by express or implied discussions regarding potential future sales and approvals of Certican. Such statements reflect the current views of the Company with respect to future events and are subject to certain risks, uncertainties and assumptions. Many factors could cause the actual results to be materially different from any future results, performances or achievements that may be expressed or implied by such forward-looking statements. There can be no guarantees that Certican will be approved for use in any other market or that it will reach any particular sales level. Any such commercialisation can be affected by, among other things, uncertainties relating to product development and clinical trials, regulatory actions or delays or government regulation generally, the ability to obtain or maintain patent or other proprietary intellectual property protection, competition in general, increased government price pressures, as well as factors discussed in the Company's Form 20-F filed with the US Securities and Exchange Commission. Should one or more of these risks or uncertainties 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 pharmaceuticals and consumer health. In 2002, the Group's businesses achieved sales of CHF 32.4 billion (USD 20.9 billion) and a net income of CHF 7.3 billion (USD 4.7 billion). The Group invested approximately CHF 4.3 billion (USD 2.8 billion) in R&D. Headquartered in Basel, Switzerland, Novartis Group companies employ about 78 200 people and operate in over 140 countries around the world. For further information please consult <http://www.novartis.com>.

References

1. Vitko S, Margreiter R, Weimar W *et al.* International, double-blind, parallel group study for the safety and efficacy of Certican (RAD) versus mycophenolate mofetil (MMF) in combination with Neoral® and steroids. Am J Transplant 2001 (Suppl 1):474. Abstract 1337.

- 2. Curtis J, Nashan B, Ponticelli C *et al.* One-year results of a multicenter, open-label trial on safety and efficacy of Certican (RAD) used in combination with Simulect®, corticosteroids and full or reduced dose Neoral® in renal transplantation. *Am J Transplant* 2001 (Suppl 1): 474. Abstract 1335.
- 3. Nishimura T *et al.* 40-0-(2-hydroxyethyl-) rapamycin attenuates pulmonary arterial hypertension and neointimal formation in rats. *Am J Respir Crit Care Med* 2001; 163:498-502.
- 4. Kaplan B, Srinivas TR, Meier-Kriesche HU. Factors associated with long-term renal allograft survival. *The Drug Monitor* 2002 Feb; 24 (1):36-9

NOTES TO EDITORS

Patients receiving organ transplants depend on immunosuppressive drugs to stop their immune systems from attacking and rejecting the transplanted organ (graft). The drug Neoral® (cyclosporin for microemulsion) is a mainstay of immunosuppression in transplant patients, permitting long-term survival, but the risk of acute and chronic graft rejection persists. Rates of chronic allograft dysfunction or late graft loss in particular have been barely influenced by standard regimens. Identifying additional immunosuppressive agents which can act synergistically with Neoral® is therefore an urgent priority in transplantation research.

For further information, please access the Virtual Press Office on <http://www.transplantsquare.com>

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SIGNATURES

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

Novartis AG

Date: July 23, 2003

By: /s/ MALCOLM B. CHEETHAM

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

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