NOVARTIS AG
Form 6-K
April 22, 2010

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 April 22, 2010

(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: x Form 40-F: o

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: o **No**: x

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Yes: o **No**: x

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: o **No**: x

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- Investor Relations Release -

Novartis receives US FDA approval for Zortress® (everolimus) to prevent organ rejection in adult kidney transplant recipients

- *Zortress offers kidney transplant recipients a new option for preventing organ rejection and preserving kidney function with reduced doses of cyclosporine(1)*

- *Preventing organ rejection while reducing the side effects of treatment regimens containing cyclosporine is a major challenge in kidney transplantation(2)*

- *Zortress inhibits the proliferation of cells that play a key role in transplant rejection(3)*

- *First approved outside the US over six years ago as Certican®, everolimus is an established transplant immunosuppressant therapy in more than 70 countries*

Basel, April 22, 2010 The US Food and Drug Administration (FDA) has approved Zortress (everolimus) oral tablets for the prevention of organ rejection of kidney transplants in adult patients at low-to-moderate immunologic risk. Zortress is to be given in combination with reduced doses of the calcineurin inhibitor (CNI) cyclosporine, as well as basiliximab and corticosteroids(4).

Under the brand name Certican®, everolimus is already an established part of the immunosuppressive regimen for transplant patients in more than 70 countries outside the US.

For patients who require a kidney transplant, the limited availability of organs underscores the urgent need for effective medicines that can help protect the survival of the transplanted organ for the patient, said David Epstein, Division Head of Novartis Pharmaceuticals. Our commitment to transplant patients exceeds 25 years, and Zortress is the latest addition to our growing portfolio. This includes five medications that enable clinicians to provide various treatment options to help manage their individual kidney transplant patients.

FDA approval of Zortress was based on results from the largest single Phase III registration study ever conducted in kidney transplant recipients. In the study, Zortress prevented acute organ rejection and preserved kidney function while allowing, on average, 60% lower doses of the CNI cyclosporine to be used compared with the control regimen of mycophenolic acid (MPA) with full dose cyclosporine and corticosteroids. Use of Zortress led to a reduction in CNI-associated side effects while maintaining good efficacy(1).

Calcineurin inhibitors, which are part of the typical immunosuppressive regimen, have been associated with injury to the kidneys and, when used in a combination-immunosuppressant regimen, increase the risk of infections and malignant tumors(3).

Following transplantation, immunosuppressive medicines are required to protect the transplanted organ from being rejected by the recipient s immune system. Antigen-activated T cells play a key role in transplant rejection by recognizing foreign substances and multiplying in an attempt to

protect the body. Zortress acts as an immunosuppressant by binding to a protein called mammalian target of rapamycin (mTOR) and preventing the proliferation of these antigen-activated T cells(3).

Transplant recipients require lifelong immunosuppression, so there is a critical need for treatment regimens that protect the transplanted kidney, and also reduce the side effects and infections associated with calcineurin inhibitors, said Diane M. Cibrik, MD, Associate Professor of Medicine and Medical Director of Transplant Clinical Research Trials at the University of Michigan. Based on its different mode of action, Zortress offers the ability to reduce calcineurin inhibitors, and may help to address this unmet need.

In 2009, an estimated 16,800 kidney transplants were performed in the US, and an estimated 4,500 kidney transplant candidates died while awaiting organ donation. As of March 2010, there were more than 83,000 patients awaiting kidney transplantation in the US(5).

Organ survival rates one year after a successful kidney transplant range from 89% when the organ comes from a deceased donor to 95% when the donor is living. However, percentages drop five years after transplantation with survival rates of approximately 67% and 80% respectively(5).

Zortress has been approved in the US with a Risk Evaluation and Mitigation Strategy (REMS) to help guide patients and healthcare providers on the safe use and risks of Zortress following kidney transplantation. The approved REMS includes a medication guide, a communications plan and a timetable for submission of assessments.

The most common ($\geq$ 20%) adverse events observed with Zortress are peripheral edema, constipation, hypertension, nausea, anemia, urinary tract infection and hyperlipidemia. Events such as peripheral edema, dyslipidemia and hyperlipidemia were at least 5% higher in patients given Zortress with reduced-dose cyclosporine than in those given mycophenolic acid and full-dose cyclosporine(4).

Increased susceptibility to infection and possible development of malignancies may result from immunosuppression. Potential serious adverse events associated with Zortress include lymphoma and other malignancies, as well as serious infections. Increased risk of kidney graft thrombosis has also been reported with Zortress. Therapeutic drug monitoring of everolimus and cyclosporine is recommended for all patients receiving these products.

The active ingredient in Zortress is everolimus, which was first approved in 2003 under the brand name Certican and is used for kidney and heart transplantation in more than 70 countries outside the US. A Phase III study using everolimus in heart transplant is under way to support US filing, and a worldwide Phase III liver transplant study is ongoing.

Everolimus is also available in different dosage strengths under the brand name Afinitor® for the treatment of advanced renal cell carcinoma (RCC) after failure of treatment with sunitinib or sorafenib. Afinitor was approved in the US in 2009.

About Novartis Transplant Medicines

As a company committed to research, development and the marketing of therapies that improve health, ease suffering and enhance patients quality of life, Novartis is a leader in transplantation and immunology. With the discovery and introduction of cyclosporine more than 25 years ago, Novartis has contributed to improving treatment options for transplant patients and now has the broadest portfolio of immunosuppressants on the market.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as commitment, risk, may, potential, or similar expressions, or by express or implied discussions regarding potential new indications or labeling for medicines containing the active ingredient everolimus or regarding potential future revenues from everolimus. You should not place undue reliance on these statements. Such forward-looking statements reflect the current views of management regarding future events, 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 can be no guarantee that everolimus will be approved for any additional indications or labeling in any market. Nor can there be any guarantee that everolimus will achieve any particular levels of revenue in the future. In particular, management s expectations regarding everolimus could be affected by, among other things, unexpected clinical trial results, including unexpected new clinical data and unexpected additional analysis of existing clinical data; 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; government, industry and general public pricing pressures; the impact that the foregoing factors could have on the values attributed to the Novartis Group s assets and liabilities as recorded in the Group s consolidated balance sheet, and other risks and factors referred to in Novartis AG s current Form 20-F on file with the US 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 anticipated, believed, estimated or expected. Novartis is providing the information in this press release as of this date and does not undertake any obligation to update any forward-looking statements contained in this press release as a result of new information, future events or otherwise.

About Novartis

Novartis provides healthcare solutions that address the evolving needs of patients and societies. Focused solely on healthcare, Novartis offers a diversified portfolio to best meet these needs: innovative medicines, cost-saving generic pharmaceuticals, preventive vaccines, diagnostic tools and consumer health products. Novartis is the only company with leading positions in these areas. In 2009, the Group s continuing operations achieved net sales of USD 44.3 billion, while approximately USD 7.5 billion was invested in R&D activities throughout the Group. Headquartered in Basel, Switzerland, Novartis Group companies employ approximately 100,000 full-time-equivalent associates and operate in more than 140 countries around the world. For more information, please visit http://www.novartis.com.

References

(1) Tedesco Silva H., et al. Everolimus with reduced-dose cyclosporine as a strategy for optimizing long-term renal function: Results from a randomized study in 833 de novo renal transplant recipients. ESOT poster presentation; ESOT 2009.

(2) Cibrik D. et al. Everolimus plus reduced-exposure CsA vs mycophenolic acid plus standard exposure CsA in renal-transplant recipients. Novartis internal document; 2009.

(3) Mange K., Lee L. Briefing Book for Cardiovascular and Renal Drugs Advisory Committee Meeting. Novartis Internal Document; 2009.

(4) Zortress® Prescribing Information. April 2010.

(5) OPTN Organ Procurement and Transplant Network Database. http://optn.transplant.hrsa.gov/latestData/rptData.asp. Accessed: April 20, 2010.

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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: April 22, 2010

By: /s/ MALCOLM B. CHEETHAM

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