NOVARTIS AG
Form 6-K
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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 February 15, 2013

(Commission File No. 1-15024)

Novartis AG

(Name of Registrant)

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(Address of Principal Executive Offices)

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

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MEDIA RELEASE • COMMUNIQUE AUX MEDIAS • MEDIENMITTEILUNG

Novartis drug Zortress® is first in over a decade approved by FDA to prevent organ rejection in adult liver transplant patients

- *Zortress is the first mTOR inhibitor approved to prevent organ rejection in adult liver transplant patients in the US, where it is already approved for kidney transplantation*

- *Approval based on positive outcomes from largest liver transplant study ever, comparing Zortress plus reduced-exposure tacrolimus to standard tacrolimus(1)*

- *Under trade name Certican®, the drug was approved by European Health Authorities for use in adult liver transplant patients in the fourth quarter of 2012*

Basel, February 15, 2013 Novartis announced today that the US Food and Drug Administration (FDA) has approved Zortress® (everolimus) for the prophylaxis of organ rejection in adult patients receiving a liver transplant. Zortress is the first mammalian target of rapamycin (mTOR) inhibitor approved for use following liver transplantation. It is also the first immunosuppressant approved by the FDA in over a decade for use following liver transplantation(1).

Novartis has been a leading innovator in the transplant field for 30 years, and this FDA approval for liver transplantation marks an important milestone for patients and their transplant physicians in the US, said David Epstein, Division Head of Novartis Pharmaceuticals. This second indication for Zortress in just three years in the US follows the recent European approval, further underscoring Novartis continued commitment to bringing much needed treatment options to the transplant community worldwide.

The approval was based on the largest liver transplant study to date, which showed that Zortress plus reduced tacrolimus led to comparable efficacy and 10mL/min higher renal function as measured by estimated glomerular filtration rate (eGFR) for Zortress compared to standard tacrolimus at 12 months(1).

A large independent registry study of nearly 70,000 patients who received a non-renal solid organ transplant between 1990 and 2000 showed that the incidence of chronic renal failure was greater in liver transplant recipients than in recipients of all other solid organ transplants, except intestinal transplants(2). Calcineurin inhibitors (CNIs), such as tacrolimus, are part of the standard-of-care treatment regimen for immunosuppression in liver transplantation, but they can contribute to adverse reactions, including impaired renal function(3),(4). Zortress works by binding to a protein called mTOR, and acts synergistically with CNIs, offering an opportunity to lower CNI exposure(1),(5).

European Health Authorities approved Certican® (everolimus) for the prophylaxis of organ rejection in adult patients receiving a liver transplant in the fourth quarter of 2012. In most EU member countries, Certican is also approved in kidney and heart transplantation. In the US, Zortress is already approved for use in adult kidney transplant patients(1).

Pivotal Study Details: Zortress Plus Reduced-Exposure Tacrolimus

The US approval was based on 12-month results from a Phase III, multicenter, open-label, randomized, controlled study conducted in 719 liver transplant patients starting 30 days post-transplant. In the study, during the first 30 days after transplant and prior to randomization, patients received tacrolimus and corticosteroids, with or without mycophenolate mofetil. No induction antibody was administered(1).

Thirty days following liver transplantation, patients were randomized to one of three groups: Zortress (C0 3-8ng/mL) plus reduced-exposure tacrolimus (C0 3-5ng/mL) (n=245), Zortress (C0 6-10ng/mL) followed by tacrolimus withdrawal at four months (n=231) or standard-exposure tacrolimus (C0 6-10ng/mL) only (control, n=243). All three study arms included twice-daily treatment. Additionally, all arms included corticosteroids for at least six months post-transplant. Enrollment into the tacrolimus withdrawal arm was prematurely halted due to a higher incidence of acute rejection episodes and adverse reactions leading to treatment discontinuation, clustered around the time of tacrolimus elimination at four months post randomization. Therefore, a treatment regimen of Zortress with tacrolimus elimination is not recommended(1),(6).

The efficacy failure endpoint at 12 months included treated biopsy proven acute rejection (tBPAR), graft loss, death or loss to follow-up by month 12. Loss to follow-up represented patients who did not experience tBPAR, death or graft loss, and whose last contact date was prior to the 12-month visit. Study results showed that Zortress plus reduced-exposure tacrolimus was comparable to standard-exposure tacrolimus with respect to efficacy failure. The incidence of efficacy failure was lower in the Zortress plus reduced-exposure tacrolimus group compared to the tacrolimus control group at month 12 (9% vs. 13.6%, respectively). The difference in rates (Zortress vs. control) with 97.5% CI for the efficacy failure endpoint was -4.6% (-11.4%, 2.2%) and the difference in rates for the graft loss, death or loss to follow-up endpoint was -0.1% (-5.4%, 5.3%)(1).

The main safety objective was evolution of renal function. The estimated mean glomerular filtration rate for the Zortress plus reduced-exposure tacrolimus group was 80.9 mL/min/1.73m(2) and the tacrolimus control group was 70.3 mL/min/1.73m(2) at 12 months post-transplant in the intent-to-treat (ITT) population(1).

Please see US prescribing information at: http://www.pharma.us.novartis.com/product/pi/pdf/zortress.pdf.

About Zortress (everolimus)

Everolimus is one of the most-extensively studied immunosuppressants in solid organ transplantation with more than 10,000 transplant recipients enrolled in Novartis-sponsored clinical trials worldwide(7). Under the trade name Certican®, it is approved in more than 90 countries to prevent organ rejection for renal and heart transplant patients, and in addition, is approved in the EU and other countries worldwide to prevent organ rejection for liver transplant patients. In the US, under the trade name Zortress®, the drug is approved for the prophylaxis of organ rejection in adult patients at low-moderate immunologic risk receiving a kidney transplant, and is also approved in adult patients following a liver transplant.

Everolimus is also available from Novartis in different dosage strengths and for different uses in non-transplant patient populations under the brand names Afinitor® and Votubia®. It is also exclusively licensed to Abbott and sublicensed to Boston Scientific for use in drug-eluting stents.

Not all indications are available in every country. As an investigational compound, the safety and efficacy profile of everolimus has not yet been established outside the approved indications. Because of the uncertainty of clinical trials, there is no guarantee that everolimus will become commercially available for additional indications anywhere else in the world.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as commitment, will, or similar expressions, or by express or implied discussions regarding potential new indications or labeling for 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 with everolimus 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 submitted or approved for any additional indications or labeling in any market, or at any particular time. 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; unexpected manufacturing issues; 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 innovative healthcare solutions that address the evolving needs of patients and societies. Headquartered in Basel, Switzerland, Novartis offers a diversified portfolio to best meet these needs: innovative medicines, eye care, cost-saving generic pharmaceuticals, preventive vaccines and diagnostic tools, over-the-counter and animal health products. Novartis is the only global company with leading positions in these areas. In 2012, the Group achieved net sales of USD 56.7 billion, while R&D throughout the Group amounted to approximately USD 9.3 billion (USD 9.1 billion excluding impairment and amortization charges). Novartis Group companies employ approximately 128,000 full-time-equivalent associates and operate in more than 140 countries around the world. For more information, please visit http://www.novartis.com.

Novartis is on Twitter. Sign up to follow @Novartis at http://twitter.com/novartis.

References

(1) Zortress® (everolimus) US Prescribing Information, February 2013.

(2) Ojo, A., Held, P., Port, F., et al. Chronic Renal Failure after Transplantation of a Nonrenal Organ. *New Eng J Med*, 2003;349:931-940.

(3) McGuire B.M., Rosenthal P., Brown C.C., et al. Long-term Management of the Liver Transplant Patient: Recommendations for the Primary Care Doctor. *Am J Transplant,* 2009;9:1988 2003.

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(5) Schuurman, HJ., Cottens, S., Fuchs, S., et al. SDZ RAD, A New Rapamycin Derivative: Synergism with Cyclosporine. *Trans,* 1997;64,1;32-35.

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(7) Novartis Data on File. July 2012.

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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:	February 15, 2013	By:	/s/ MALCOLM B. CHEETHAM
		Name:	Malcolm B. Cheetham
		Title:	Head Group Financial Reporting and Accounting