

NOVARTIS AG
Form 6-K
June 02, 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 May 22nd, 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:

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Yes: ☐ **No:** ☒

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- Investor Relations Release -

Ranibizumab significantly more effective than standard of care in treating vision loss due to DME, a serious complication of diabetes

- *Study shows around 40% of ranibizumab patients substantially improved vision by 10 letters or more on an eye-chart, compared to 16% with laser therapy alone(1)*
- *Ranibizumab, given alone or with laser, provided average vision gain of six letters sustained over a year compared to 0.8 letters with laser therapy alone(1)*
- *Diabetic macular edema (DME) with visual impairment affects 1-3% of people with diabetes worldwide(2) with potentially disabling impact on patients' lives*
- *New data support current submission for EU approval of ranibizumab for visual impairment caused by DME*

Basel, May 22, 2010 First results of the RESTORE Phase III study show that ranibizumab is significantly more effective than laser treatment, the current standard of care, at treating visual impairment due to diabetic macular edema (DME), a serious complication of diabetes(1).

Results at one year show that 37% of patients treated with ranibizumab 0.5 mg alone, and 43% of those treated with ranibizumab plus laser therapy, gained a substantial vision improvement of 10 letters or more on an eye-chart compared to 16% of patients treated with laser alone(1). Ranibizumab had a favorable safety profile when used as monotherapy with no new safety risks observed when combined with laser therapy(1).

These new data add to the body of evidence showing that treatment with ranibizumab produced a rapid improvement in visual acuity with sustained benefit, and may offer patients the prospect of regaining vision they have lost due to this disabling disease, said Professor Gabriele Lang, Head of the Division of Medical Retina and Laser Surgery, Department of Ophthalmology, University of Ulm, Germany. Professor Lang today presented initial results from the RESTORE Phase III study at the meeting of the European Association for the Study of Diabetic Eye Complications (EASDec) in Paris.

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Ranibizumab has been approved in more than 80 countries for the treatment of wet age-related macular degeneration (AMD) under the brand name Lucentis®. It is not currently licensed in any market for the treatment of visual impairment due to DME. An application for marketing approval in this indication was submitted to EU health authorities in December 2009.

The RESTORE study showed that over one year, patients treated with ranibizumab plus laser were able to read an additional 5.9 letters on a standard eye-chart, while those treated with ranibizumab alone could read 6.1 letters more than at the start of the study. This compared with patients receiving laser therapy alone who could read an additional 0.8 letters. All figures are

mean averages for the year. The study met its primary endpoint (both ranibizumab arms $p < 0.0001$ vs. laser alone)(1).

The safety profile of ranibizumab in RESTORE was consistent with that previously observed in large controlled clinical trials, with no new safety risks observed. No cases of endophthalmitis were reported. Ranibizumab showed a low incidence (less than 1%) of increased intra-ocular pressure (IOP). In terms of systemic safety, there was a low incidence of hypertension (5-8%) and arterial thromboembolic events (3-4%) in all treatment groups(1).

These efficacy and safety data support the results of the pivotal RESOLVE study comparing ranibizumab to sham (or dummy) treatment. This demonstrated that 61% of ranibizumab-treated patients gained 10 letters or more in visual acuity, and formed the basis of the EU submission(3). The results from RESTORE also follow a US study conducted by the Diabetic Retinopathy Clinical Research Network (DRCR.net) showing that after one year, nearly 50% of eyes treated with ranibizumab and laser therapy showed an improvement in vision of 10 letters or more, compared to 28% with laser alone(4).

Ranibizumab was specifically designed and licensed for use in the eye, and has already been shown in robust, randomized controlled trials to improve vision and vision-related quality of life in patients with wet AMD, said Trevor Mundel, MD, Global Head of Development at Novartis AG. We are committed to exploring its potential in other ophthalmic diseases where there is an unmet medical need, and these results confirm that it could provide an important new therapeutic option for visually impaired patients with DME.

Diabetes is a disease associated with high levels of blood sugar which can damage many organs over time, including the eyes. Long-term diabetes can result in diabetic retinopathy, an eye disease characterized by changes in the blood vessels of the retina – the light-sensitive layer at the back of the eye. Diabetic retinopathy is a leading cause of blindness in people of working age.

One manifestation of diabetic retinopathy is DME or retinal swelling, which is caused by leakage of fluid in the central portion of the retina called the macula. Because this is the part of the eye responsible for sharp central vision, patients with visual impairment due to DME can find it hard to recognize faces and carry out everyday activities such as reading and driving. DME with visual impairment affects 1-3% of people with diabetes worldwide(2).

Ranibizumab works by neutralizing a protein called vascular endothelial growth factor (VEGF), which is believed to cause abnormal blood vessel growth and leakage beneath the macula.

The randomized, double-masked, multicenter RESTORE study involved 345 DME patients with an average age of 63 years randomized into three treatment arms: ranibizumab 0.5 mg plus sham laser treatment, ranibizumab plus active laser treatment, and sham injection plus active laser treatment. The primary endpoint was the mean change in best corrected visual acuity (BCVA) from baseline to the average level from months one to 12. Key secondary endpoints were the mean change in BCVA over time, and safety(1).

Ranibizumab was developed by Genentech and Novartis. Genentech has the commercial rights to ranibizumab in the US, while Novartis has exclusive rights in the rest of the world.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as potentially, may, committed, potential, could, can, believed, or similar expressions, or by express or implied discussions regarding potential new indications or labeling for ranibizumab or regarding potential future revenues from ranibizumab. 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 ranibizumab to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that ranibizumab will be approved for any additional indications or labeling in any market. Nor can there be any guarantee that ranibizumab will achieve any particular levels of revenue in the future. In particular, management's expectations regarding ranibizumab could be affected by, among other things, unexpected regulatory actions or delays or government regulation generally; unexpected clinical trial results, including unexpected new clinical data and unexpected additional analysis of existing clinical data; 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) Lang, G. on behalf of the RESTORE study group. Safety and efficacy of ranibizumab as monotherapy or adjunctive to laser photocoagulation in diabetic macular edema: 12-month results of the RESTORE study. Late-breaker presentation at EASDec Meeting. May 22, 2010.
- (2) R Klein, et al. The Wisconsin Epidemiologic Study of Diabetic Retinopathy: IV Diabetic Macular Edema. Ophthalmol 91:1464-1474, 1984.
Early Treatment Diabetic Retinopathy Study Research Group. Photocoagulation for diabetic macular edema: Early Treatment Diabetic Retinopathy Study Report No 1. Arch Ophthalmol 103, Dec 1985.
- (3) Data on file. Novartis Pharma AG.
- (4) The Diabetic Retinopathy Clinical Research Network. Randomized trial evaluating ranibizumab plus prompt or deferred laser or triamcinolone plus prompt laser for diabetic macular edema. Ophthalmology 2010, in press.

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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: May 22nd, 2010

By: /s/ MALCOLM B. CHEETHAM

Name: Malcolm B. Cheetham

Title: Head Group Financial Reporting and Accounting
