

NOVARTIS AG
Form 6-K
January 07, 2011

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 January 7, 2011

(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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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:** ☒

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- Investor Relations Release -

Novartis gains new indication for Lucentis® in EU for vision loss due to Diabetic Macular Edema, a leading cause of blindness

- *Lucentis® (ranibizumab) is the first licensed therapy to improve vision and vision-related quality of life in patients with visual impairment due to diabetic macular edema (DME)*
- *Pivotal data showed Lucentis provides rapid, superior and sustained vision gains compared to laser therapy, the current standard of care*
- *About half of Lucentis-treated patients gained 10 letters or more in visual acuity in two clinical trials; Such improved vision can restore independence and function*
- *Diabetic macular edema is a leading cause of blindness in most developed countries in the working-age population*

Basel, January 7, 2011 The European Commission has granted Novartis a new indication for Lucentis® (ranibizumab) to treat patients with visual impairment due to diabetic macular edema (DME), a leading cause of blindness in the working-age population in most developed countries.

Laser therapy, the current standard of care, has provided stabilization of vision in many patients, but generally does not improve vision. Lucentis is the first licensed therapy to significantly improve both vision and vision-related quality of life in patients with visual impairment due to DME.

Similarly to wet age related macular degeneration, diabetic macular edema can cause disabling vision loss. While vision loss as a consequence of diabetes affects only a very small proportion of people with the disease, it is one of the most feared complications, said Don Curran, Chair, AMD Alliance International. Visual impairment impacts everything from managing social interactions to the ability to work thus, for most people it means a loss of independence.

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The approval of Lucentis was based on data from two Novartis-sponsored clinical trials, RESTORE and RESOLVE, which showed that Lucentis was superior in providing rapid and sustained visual acuity gain versus sham (dummy) therapy or laser therapy, the current standard of care.

In the clinical trials, Lucentis-treated patients began to recover their vision as early as eight days after the first injection on average, and vision improvement was maintained at one year, said Gabriele E. Lang, Professor, University Eye Hospital, University of Ulm, Germany. The vision improvement for many of these patients was clinically significant, meaning that they regained the ability to carry out day-to-day activities such as driving.

The RESTORE study showed patients treated with Lucentis alone or with Lucentis plus laser therapy gained an average of 6.8 letters and 6.4 letters, respectively, in visual acuity at 12 months

compared to baseline, while laser-treated patients gained an average of 0.9 letters as measured on a standard ETDRS eye chart.

The RESOLVE study showed that Lucentis-treated patients gained an average of 10.3 letters in visual acuity at 12 months compared to baseline while sham-treated patients, some of whom also received laser treatment, lost an average of 1.4 letters.

Since its first launch in the EU in 2007, Lucentis has become the gold standard treatment of wet AMD and its use has stimulated research into other ocular conditions, said David Epstein, Division Head of Novartis Pharmaceuticals. Our continued investment in the clinical development of Lucentis means that another group of patients who are at risk of losing their eyesight will have the option of a licensed therapy that could help save their vision.

The pivotal data from RESTORE and RESOLVE studies are further supported by results of an independent US study examining Lucentis for the treatment of DME compared to standard of care. Conducted by the Diabetic Retinopathy Clinical Research Network (DRCR.net), this study showed that at 12 months patients treated with Lucentis plus laser gained an average of nine letters in visual acuity compared to baseline while patients treated with laser therapy alone gained an average of three to four letters. In addition, the study demonstrated superior gains in visual acuity among Lucentis-treated patients up to two years, with a reduced number of Lucentis injections required the second year compared to the first. Specifically, there was a median of only two to three injections required in the second year of treatment compared to a median of eight to nine injections required in the first year.

Diabetic macular edema (DME) is a consequence of diabetic retinopathy, the most common diabetic eye complication. DME is characterized by changes in the blood vessels of the retina, which is the light-sensitive layer at the back of the eye. In patients with DME, leakage from these abnormal blood vessels occurs in the central portion of the retina, called the macula. Because this part of the eye is responsible for sharp central vision, DME can lead to significant visual impairment. Visual impairment due to DME affects approximately 1-3% of patients with diabetes, and DME is a leading cause of blindness in the working-age population in most developed countries.

Lucentis offers an entirely new pharmacological approach to treatment for visual impairment due to DME compared to the current standard of care, which involves the use of laser burns to stop capillary leakage and reduce swelling. Lucentis is an antibody fragment that is injected into the eye and neutralizes vascular endothelial growth factor (VEGF), a protein that is known to increase vascular permeability, resulting in capillary leakage and macular edema in patients with diabetes.

Lucentis was generally well tolerated in DME clinical studies, either when given as monotherapy or when combined with laser treatment. Its safety profile was consistent with the well established profile in patients with wet age-related macular degeneration (wet AMD). There was an incidence of arterial thromboembolic events ($\leq 3.5\%$) observed in the DME clinical trials, consistent with what was seen in the wet AMD clinical trials, with no significant difference between the groups treated with Lucentis compared to sham or laser therapy. Ocular adverse events were similar to those seen in the wet AMD trials, with an incidence of 1.4% endophthalmitis in the pooled pivotal studies.

Lucentis is currently licensed in more than 85 countries for the treatment of wet AMD. It receives continuous safety monitoring via a systematic pharmacovigilance system and there is more than 750,000 patient-treatment years of exposure to date for Lucentis.

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Lucentis was developed by Genentech and Novartis. Genentech has the commercial rights to Lucentis in the United States, where Lucentis is also approved for the treatment of macular edema following retinal vein occlusion (RVO). In addition, Genentech is conducting two Phase III

studies, RISE and RIDE, in patients with diabetic macular edema with results expected in 2011. Novartis has exclusive rights in the rest of the world and has filed in the European Union for approval of Lucentis for the treatment of visual impairment due to macular edema secondary to RVO.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as can, will, could, expected, or similar expressions, or by express or implied discussions regarding potential new indications or labeling for Lucentis or regarding potential future revenues from Lucentis. 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 Lucentis to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Lucentis will be submitted or approved for any additional indications or labeling in any market. Nor can there be any guarantee that Lucentis will achieve any particular levels of revenue in the future. In particular, management's expectations regarding Lucentis 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; competition in general; government, industry and general public pricing pressures; the company's ability to obtain or maintain patent or other proprietary intellectual property protection; 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>.

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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: January 7, 2011

By: /s/ MALCOLM B. CHEETHAM

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