

NOVARTIS AG  
Form 6-K  
September 05, 2012

# 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 September 5, 2012**

**(Commission File No. 1-15024)**

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**Novartis AG**

(Name of Registrant)

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**4056 Basel**

**Switzerland**

(Address of Principal Executive Offices)

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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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**MEDIA RELEASE • COMMUNIQUE AUX MEDIAS • MEDIENMITTEILUNG**

**New data for Novartis drug Lucentis® confirms long-term efficacy and safety profile and benefits of individualized treatment**

- *REPAIR study shows an average of three Lucentis® injections improve visual acuity in patients with myopic choroidal neovascularization*
- *RESTORE extension study demonstrates DME patients fully maintained initial vision gains with an average of 13.9 Lucentis injections over three years*
- *Retrospective analysis reinforces Lucentis well-characterized safety profile in wet AMD; ongoing LUMINOUSTM program now involves over 10,000 patients*

**Basel, September 5, 2012** New data for Lucentis® (ranibizumab), the only anti-VEGF therapy licensed across three ocular indications, show that individualized treatment with Lucentis provides sustained improvement in vision with a low number of injections. It is estimated that over 80% of visual impairment is preventable when due to conditions such as wet age-related macular degeneration (wet AMD), diabetic macular edema (DME), and visual impairment due to macular edema secondary to retinal vein occlusion (RVO)(1). These conditions can eventually lead to blindness if left untreated.

Lucentis has become the standard of care in wet AMD and has helped to significantly improve vision in a majority of patients with this disease, said Tim Wright, Global Head of Development, Novartis Pharma. These new data confirm that an individualized treatment approach can lead to optimal improvements in vision with a low average number of treatments, thus ensuring that patients with retinal diseases are not over- or under-treated. In addition, these data add to the well-characterized safety profile of Lucentis .

Lucentis also demonstrated benefits in visual acuity outcomes in patients with visual impairment due to choroidal neovascularization (CNV) secondary to pathological myopia (PM). Lucentis is currently not approved to treat this condition. Novartis will submit for regulatory approval in this indication in the European Union in the third quarter of this year and in Japan by the end of 2012.

Novartis is dedicated to the research, development and manufacturing of ophthalmic pharmaceuticals. The mission of Novartis in the field of ophthalmology is to discover, develop and manufacture innovative products to improve eye health and enhance people's lives.

Lucentis study highlights at the 12th European Society of Retina Specialists (EURETINA) Congress in Milan, Italy include(2)-(4):

**REPAIR**

This one year study performed in twelve centers in the United Kingdom explored the efficacy and safety profile of 0.5 mg Lucentis administered on an individualized basis in 65 patients with myopic CNV. After six months of treatment, mean visual acuity improved by twelve letters. Patients received an average of three Lucentis injections with 29 %

requiring no further treatment beyond the first injection. This analysis shows that Lucentis therapy leads to improvement in visual acuity in patients with this condition. The six month interim results and the full one year data will be presented at Euretina. Currently, photodynamic therapy with Visudyne® (verteporfin) is the only approved medical treatment for this condition.

## **RESTORE**

In the RESTORE extension study, 240 patients with DME received individualized treatment with Lucentis according to a regimen consistent with the European Union label. Results showed that patients who were originally treated with Lucentis received an average of 13.9 injections over three years. 19-25% of patients across all study arms did not require any Lucentis injections during years two and three. An average of 3.7 injections in the second year and 2.7 in the third year were sufficient to fully maintain the mean of seven letters of visual acuity gained in the RESTORE core study. The safety profile was consistent with previous studies conducted in other indications. There were no cases of endophthalmitis reported within the RESTORE core and extension studies.

The results of this study show that individualized treatment with Lucentis can lead to a significant improvement in vision and that these improvements are sustained in the long term said Professor Francesco Bandello, Department of Ophthalmology, Hospital San Raffaele, University Vita Salute San Raffaele, Milan, Italy and president elect of EURETINA. It is important that we explore how these insights apply to real-world clinical practice to ensure that we are providing the best possible care for our patients .

## **LUMINOUS**

The Luminous program is one of the largest observational studies in ophthalmology and consists of two parts launched in 2011. The retrospective part comprises pooled data from four European registries of nearly 4,500 patients with wet AMD treated with Lucentis. These data showed no new safety signals for Lucentis and reinforces its well-characterized safety profile. The registries revealed low incidences of key adverse events at 12-months. Additionally, a low number of Lucentis injections were observed during the first year. The mean number of Lucentis injections over twelve months ranged from 4.3 to 5.0 (based on all patients) and 4.7 to 5.5 (based on patients completing one year).

The prospective part of Luminous is expected to provide important long-term evidence on the real-world effectiveness and safety profile of Lucentis in its licensed indications. This 5-year study is ongoing and currently has more than 5,500 patients enrolled. It is expected to recruit more than 30,000 patients from clinics across Asia, Australia, Europe, North and South America.

## **About Lucentis® (ranibizumab)**

Lucentis is a humanized therapeutic antibody fragment designed to block all biologically active forms of vascular endothelial cell growth factor-A (VEGF-A). Increased levels of VEGF-A are seen in wet AMD and other ocular diseases such as diabetic macular edema (DME) and retinal vein occlusion (RVO). Lucentis has been designed, developed and formulated specifically for use in ocular disease with the aim of stabilizing and improving visual acuity in these patients, while minimizing the risk of systemic side effects.

Lucentis is licensed for the treatment of wet AMD in more than 100 countries, in more than 80 countries for the treatment of visual impairment due to DME and in 80 countries for visual impairment due to macular edema secondary to RVO, including both branch- and central-RVO. In many countries, including those in Europe, Lucentis has an individualized treatment regimen with the goal of maximizing visual outcomes while minimizing under- or over-treating patients.

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Novartis and Alcon sponsor the eXcellence in Ophthalmology Vision Award (XOVA). XOVA is an annual award launched in 2010 that provides funding to non-profit initiatives

and projects that will have a positive impact on improving the quality of eye care and make a significant impact in addressing unmet needs in the fields of ophthalmology and optometry.

Lucentis has a well-characterized safety profile and Novartis systematically monitors the safety and tolerability of Lucentis for licensed indications on an ongoing basis. Its safety profile has been well established in a clinical development program that enrolled more than 10,000 patients across indications. Since its launch in the United States in 2006, there are more than one million patient-treatment years of exposure for Lucentis.

Serious adverse events related to the injection procedure include endophthalmitis, retinal detachment, retinal tear and traumatic cataract. Other serious ocular events observed among Lucentis-treated patients included intraocular inflammation and increased intraocular pressure. Non-eye related serious side effects, although not common, include heart attacks, strokes and death.

Lucentis was developed by Genentech and Novartis. Genentech has the commercial rights to Lucentis in the United States. Novartis has exclusive rights in the rest of the world. Lucentis is a registered trademark of Genentech Inc.

#### **Disclaimer**

The foregoing release contains forward-looking statements that can be identified by terminology such as can, ensuring, will, dedicated, expected, goal, 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, or at any particular time. 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 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; unexpected regulatory actions or delays or government regulation generally; the company's ability to obtain or maintain patent or other proprietary intellectual property protection; 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 2011, the Group achieved net sales of USD 58.6 billion, while approximately USD 9.6 billion (USD 9.2 billion excluding impairment and amortization charges) was invested in R&D throughout the Group. Novartis Group companies employ approximately





126,000 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>.

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## References

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- (2) Tufail A on behalf of the REPAIR study group. The REPAIR study: 12 Month, prospective, multi-center trial of ranibizumab in choroidal neovascularization (CNV) due to pathological myopia (PM). EURETINA 2012.
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- (4) Bandello F on behalf of the LUMINOUS group. Outcomes of the retrospective pooled safety analysis of ranibizumab therapy for neovascular age-related macular degeneration from four european registries and update on the ongoing prospective analysis for the LUMINOUS study. EURETINA 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: September 5, 2012

By: /s/ MALCOLM B. CHEETHAM

Name: Malcolm B. Cheetham  
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Reporting and Accounting