

NOVARTIS AG  
Form 6-K  
May 10, 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 May 10, 2012.**

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

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(Name of Registrant)

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**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 among 200 Lucentis® abstracts at ARVO show low number of injections with Novartis drug required to achieve and maintain vision gains over 3 years in AMD and DME patients**

- *Data from key studies highlight the value of individualized therapy and reinforce Lucentis (ranibizumab) well-characterized long-term efficacy and safety profile*
- *RESTORE extension study in DME patients shows mean of 3.7 and 2.7 Lucentis injections required in years two and three, respectively, to maintain vision gains from core study*
- *Swiss retrospective study shows mean 8 letter VA gain sustained in wet AMD patients using individualized Lucentis dosing with mean of 16 Lucentis injections over 3 years*
- *Nearly 4,500 patients in retrospective part of LUMINOUS observational trial confirm safety profile of Lucentis*

**Basel, May 10, 2012** Research on Lucentis® (ranibizumab) is highlighted in more than 200 abstracts this week at the 2012 Association for Research in Vision and Ophthalmology (ARVO) annual meeting. Lucentis research across multiple retinal disease areas continues to further advance our understanding of the long-term efficacy and safety profile of Lucentis as well as the benefits of an individualized treatment regimen.

The research presented on Lucentis this week at ARVO highlights the benefit of an individualized approach to treating patients rather than a fixed, inflexible regimen, said Tim Wright, Global Head of Development, Novartis Pharma. With an individualized as needed dosing regimen, the goal is for patients to achieve and maintain maximum vision gains without undergoing more injections than necessary, which brings benefit to the patient and economic value to the health system. Several studies presented at ARVO demonstrate how successful an individualized Lucentis treatment approach can be for patients with wet AMD and DME.

Lucentis ARVO highlights include:

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**The RESTORE extension study:** In RESTORE, patients with diabetic macular edema (DME) were treated with Lucentis 0.5 mg (monotherapy or combined with laser) or laser alone for a duration of 12 months. Lucentis-treated patients received a mean of seven injections and, on average, achieved a gain in vision of seven letters at one year(1). Of the 303 patients who completed the core RESTORE, 240 entered the extension study, all of whom were eligible for individualized treatment with Lucentis according to a regimen consistent with the European Union label. Results showed that an average of 3.7 injections in the second year and 2.7 in the third year of treatment were sufficient to fully maintain the mean visual acuity gained in the core study(2),(3). The safety profile was consistent with previous studies across different indications. There were no cases of endophthalmitis reported through the RESTORE core and extension studies. [Paper session 4667]

**Three Year Results of Visual Outcome with Disease-Activity-Guided Ranibizumab Algorithm for the Treatment of Exudative**

**Age-Related Macular Degeneration**(4),(5): There were 316 wet AMD patients in a Swiss clinic evaluated following treatment with Lucentis 0.5 mg administered either monthly or quarterly on a pro re nata (PRN, or as needed ) basis according to a disease-activity-guided monitoring and treatment algorithm. This independent, retrospective, interventional case series showed that at 36 months, patients had achieved a mean gain of approximately eight letters in visual acuity with a mean total of 16 Lucentis injections over the three years. [Poster session 438/D1115]

The vision gains seen at the end of three years of Lucentis treatment in wet AMD patients were favorable and similar when compared to the pivotal Phase III trials MARINA and ANCHOR said Prof. Sebastian Wolf, University of Bern, Switzerland. However the number of injections, a mean of 16 during three years, is significantly less than the monthly regimen used in those studies. This data confirms that an individualized treatment regimen, now standard of care in Europe, is best for patients.

**LUMINOUS**(6): Data on nearly 4,500 patients with wet age related macular degeneration (AMD) treated with Lucentis were pooled for the retrospective part of Luminous, one of the largest observational studies in ophthalmology that is expected to provide additional long-term evidence on the effectiveness and safety profile of Lucentis in its licensed indications and real-world settings. The retrospective pooled analysis of European registries shows no new safety risks with Lucentis and confirmed its well characterized safety profile. The prospective arm of Luminous is ongoing and currently has more than 3,000 patients. It is expected to recruit more than 30,000 patients in all licensed indications from clinics across Asia, Australia, Europe, North and South America. [Poster session 2031/D1049]

**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.

Lucentis is licensed for the treatment of wet AMD in more than 100 countries, and in more than 60 countries for the treatment of visual impairment due to DME, and visual impairment due to macular edema secondary to RVO, including both branch- and central-RVO. In many countries, including in Europe, Lucentis has an individualized treatment regimen with the goal of maximizing visual outcomes while minimizing under- or over-treating patients.

In 2011, Novartis launched the Luminous(TM) program, one of the largest observational studies in ophthalmology, expected to recruit over 30,000 patients from clinics across Asia, Australia, Europe, North and South America to further broaden the understanding of ocular disease and the use of Lucentis in its approved indications. Luminous is a five-year observational, international, multicenter program that is expected to provide long-term effectiveness and safety data for Lucentis as well as assess the treatment patterns and health-related quality of life inpatients treated with Lucentis.

Novartis works closely with reimbursement authorities to ensure that Lucentis is cost effective for appropriate patients and has an excellent track record of working with healthcare systems to secure access to medicines for patients. In fact, Lucentis has been shown to be cost effective and is reimbursed for the treatment of wet AMD in most countries, including a recommendation by the National Institute for Health and Clinical Excellence (NICE) in the UK.



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.

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 "expected," "to further broaden," or similar expressions, or by express or implied discussions regarding potential new 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 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; unexpected regulatory actions or delays or government regulation generally; 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; 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's continuing operations 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 124,000 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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**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 10, 2012

By: /s/ MALCOLM B. CHEETHAM

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