

NOVARTIS AG  
Form 6-K  
January 18, 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 January 18th 2012**

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

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**Novartis AG**

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

**Novartis receives approval for Lucentis® and launches Galvus® in China, two innovative therapies that support public health goals**

- *Lucentis® (ranibizumab) approved in China to treat wet age-related macular degeneration, a major cause of blindness and severe vision loss in people over 50*
- *Oral type 2 diabetes treatment Galvus® (vildagliptin) now available in China, the country with the largest number of adults with diabetes in the world(1),(2)*
- *Demonstrates Novartis commitment to providing access to innovative therapies in emerging markets and supporting public health goals in China*

**Basel, January 18, 2012** Novartis announced today that it received regulatory approval in China from the State Food and Drug Administration (SFDA) for Lucentis® (ranibizumab) to treat wet (neovascular) age-related macular degeneration (AMD), and is launching Galvus® (vildagliptin), an oral treatment for patients with type 2 diabetes approved in China as an add-on to metformin, the standard of care(3),(4) .

Wet AMD is a major cause of blindness and severe vision loss in people over 50(5). In China, there are an estimated 300,000 new wet AMD patients per year, and as many as 75 million people have uncontrolled type 2 diabetes(6),(7),(8),(9). The number of people with diabetes in China has nearly quadrupled in recent years, making it the country with the largest number of adults with diabetes in the world(1),(2),(9).

Today's announcement demonstrates our continued commitment to providing patients in emerging markets access to innovative treatments where there is significant unmet need, said David Epstein, Head of the Pharmaceuticals Division of Novartis. We are proud to bring Lucentis and Galvus to patients and physicians in China and support the achievement of the Chinese government's public health goals.

Lucentis is the first licensed therapy in its class available to patients in China. The approval of Lucentis in China for the wet AMD indication is based on comprehensive clinical data and experience, including global and local Chinese clinical studies. Since its launch, Lucentis has become the standard first line therapy in the treatment of wet AMD and, to date, there are more than 1,000,000 patient-treatment years of exposure for

Lucentis.

There is a huge unmet need for wet AMD patients in China and we have been waiting for the Lucentis approval here since it was first launched in the United States in 2006, said Professor Xiaoxin Li, Chairman of the China Fundus Society. We hope access to Lucentis will improve wet AMD patient treatment outcomes and optimize doctors' experiences.

Wet AMD is a disease that affects the macula, which is the part of the eye that allows one to see fine detail and is responsible for the straight ahead central vision necessary for identifying faces and undertaking everyday activities like reading, driving and telling the time.

Lucentis is a humanized therapeutic antibody fragment designed to block all biologically active forms of vascular endothelial cell growth factor-A (VEGF-A)(10). 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.

In 2011, Novartis launched the Luminous program, one of the largest observational studies in ophthalmology, aiming 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 issues of patients treated with Lucentis.

Lucentis is licensed for the treatment of wet AMD in more than 100 countries. Outside of China, Lucentis is also approved in more than 50 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.

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(10).

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.

### **Galvus Launch**

Galvus (vildagliptin) is now available in China. Vildagliptin is an oral treatment for patients with type 2 diabetes and is approved in China as an add-on to metformin, the standard of care(3),(4).

Rapid economic development has led to dramatic changes in life expectancy, physical activity and diet, increasing the number of people with obesity-related diabetes and placing a significant strain on healthcare resources(9),(11). Diabetes currently accounts for nearly 20 percent of medical expenditure in China and the economic burden is projected to increase from USD 26 billion in 2007 to USD 47 billion by 2030(11).

Uncontrolled diabetes is threatening to overwhelm our healthcare system, said Professor Ning Guang, Endocrinologist, Shanghai Jiatong University affiliated Ruijing Hospital. It is important that new treatments continue to be made available to help physicians address the growing healthcare need.

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Approval was based on a 24-week, double-blind, randomized, parallel-group study which compared the effects of vildagliptin versus placebo in Chinese patients with type 2 diabetes already receiving metformin (n=438)(12). Vildagliptin (50mg twice a day) achieved a statistically significant reduction in blood sugar levels(12). Incidence of serious adverse events, including hypoglycemia was low, and vildagliptin was generally demonstrated to be well-tolerated(12).

Galvus is approved in more than 90 countries across Europe, Asia Pacific, Africa and Latin America. It is indicated for the treatment of type 2 diabetes as a monotherapy and

in combination with metformin, a sulphonylurea, a thiazolidinedione or insulin. Specific indications vary by country.

Since becoming available, Galvus has been shown to be generally well-tolerated in more than 11,500 patients as part of a large clinical development program and the total post-marketing exposure is nearly two and a half million patient-treatment years(12).

In clinical trials the majority of adverse events reported have been mild and transient, not requiring treatment discontinuations(3). No severe hypoglycemic events have been reported in the Galvus arms of clinical studies(3). In rare cases of hepatic dysfunction following treatment with Galvus, patients were generally asymptomatic and liver function returned to normal after discontinuation of treatment(3). Vildagliptin should not be used in patients with hepatic impairment(3). Pancreatitis has been reported in post-marketing experience(3).

#### **Disclaimer**

The foregoing release contains forward-looking statements that can be identified by terminology such as launches, commitment, launching, hope, will, aim, expected, launch, or similar expressions, or by express or implied discussions regarding potential new indications or labeling of Lucentis or Galvus. 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 or Galvus 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 or Galvus will achieve any particular levels of revenue in the future. In particular, management's expectations regarding Lucentis and Galvus 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; unexpected manufacturing issues; 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 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 2010, the Group's continuing operations achieved net sales of USD 50.6 billion, while approximately USD 9.1 billion (USD 8.1 billion excluding impairment and amortization charges) was invested in R&D throughout the Group. Novartis Group companies employ approximately 121,000 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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**References**

- (1) International Diabetes Federation. New diabetes figures in China: IDF press statement 2010. <http://www.idf.org/node/4250>. Accessed January 12, 2012.
- (2) Yang W et al. Prevalence of diabetes among men and women in China. *N Engl J Med* 2010;362:1090-1101.
- (3) Galvus Summary of Product Characteristics. Novartis Pharma AG, China.
- (4) Decision Resources. China's type 2 diabetes market will grow to \$2.5 billion in 2014. <http://decisionresources.com/News-and-Events/Press-Releases/Type2DiabetesinChina-121010>. Accessed January 12, 2012.
- (5) Brown DM et al. Ranibizumab versus verteporfin for neovascular age-related macular degeneration. *N Engl J Med* 2006;355(14):1432-1444.
- (6) Yasuda M et al. Nine-year incidence and risk factors for age-related macular degeneration in a defined Japanese population the Hisayama study. *Ophthalmology* 2009;116:2135-40.
- (7) Zou HD et al. Prevalence study of age-related macular degeneration in Caojiadu blocks, Shanghai. *Zhonghua Yan Ke Za Zhi*. 2005;41:15-19.
- (8) International Diabetes Federation. Types of diabetes. <http://www.idf.org/types-diabetes>. Accessed January 12, 2012.
- (9) Shen J et al. The emerging epidemic of obesity, diabetes, and the metabolic syndrome in China. *Cardiol Res Pract* 2011. doi: 10.1155/2012/178675.
- (10) Ferrara N et al. Development of ranibizumab, an anti-vascular endothelial growth factor antigen binding fragment, as therapy for neovascular age-related macular degeneration. *Retina* 2006;26(8):859-870.
- (11) Wang W et al. Type 2 diabetes mellitus in China: a preventable economic burden. *Am J Manag Care* 2009;15(9):593-601.
- (12) Novartis data on file.

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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 18th 2012

By: /s/ MALCOLM B. CHEETHAM

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