

NOVARTIS AG
Form 6-K
January 22, 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 January 20, 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:

Edgar Filing: NOVARTIS AG - Form 6-K

Form 20-F: ☒ **Form 40-F:** ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):

Yes: ☐ **No:** ☒

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7):

Yes: ☐ **No:** ☒

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:** ☒

Novartis International AG

Novartis Global Communications

CH-4002 Basel

Switzerland

<http://www.novartis.com>

- Investor Relations Release -

Three new Novartis medicines approved in Japan for patients with type 2 diabetes, high blood pressure and advanced kidney cancer

- *Equa®, Exforge® and Afinitor® provide new treatment options for unmet medical needs*
- *Three major approvals for innovative medicines to treat serious and life-threatening diseases affecting millions of Japanese patients*
- *Approvals follow six product launches in 2009, reinforcing the strong presence of Novartis in Japan, the company's second-largest pharmaceutical market*

Basel, January 20, 2010 Patients in Japan will benefit from the approval of three new Novartis medicines – Equa® (vildagliptin), marketed as Galvus® in the European Union, for the treatment of type 2 diabetes, Exforge® (valsartan/amlodipine) for high blood pressure, and Afinitor® (everolimus) for advanced kidney cancer. These approvals reinforce the strong commitment of Novartis to helping patients in Japan, the company's second-largest pharmaceutical market.

It is a significant achievement to secure the approval of three such important new medicines for the benefit of Japanese patients, said Joe Jimenez, CEO of the Novartis Pharmaceuticals Division. These approvals, which follow six launches last year, mean we continue to quickly introduce innovative medicines to treat serious and life-threatening diseases affecting millions of Japanese patients and their families.

Equa has been approved in Japan for the treatment of type 2 diabetes, as monotherapy or in combination with a sulfonylurea. As a DPP-4 inhibitor, Equa works by targeting the dysfunction in the pancreatic islets that causes high blood sugar levels in people with type 2 diabetes.

Equa has been approved for doses of 50 mg twice daily, or 50 mg once daily, depending on the needs of the individual patient(1). Patients treated with Equa 50 mg twice daily demonstrated an average reduction in HbA1c – a marker of blood glucose level – of 1.2% compared to placebo(2), which would bring half of them within the maximum HbA1c value of 6.5% recommended by the Japan Diabetes Society(2). Equa was shown to be well-tolerated with a favorable profile in terms of hypoglycemia and bodyweight(2).

Edgar Filing: NOVARTIS AG - Form 6-K

An estimated 7 million people in Japan have type 2 diabetes(3) and approximately 70% of patients are still not meeting their HbA1c goals on their current medications(4). When left untreated or inadequately controlled, type 2 diabetes can lead to heart and kidney disease, blindness, and vascular or neurologic problems(5).

Exforge has been approved in Japan as a single-pill combination of two treatments for high blood pressure: Diovan® (valsartan), the number one selling hypertension medication worldwide(6), and amlodipine, the world's most prescribed calcium channel

blocker(6). Exforge has been shown to be effective across all grades of high blood pressure(7),(8), with placebo-like tolerability(9). As many as nine out of 10 Exforge patients reach their blood pressure goal(10), with drops of up to 43 mmHg reported in patients with particularly elevated blood pressure(8).

High blood pressure affects an estimated 40 million people in Japan; nearly a third of the population(11). With approximately 70% of patients not reaching their blood pressure treatment goal(12), there is a growing need for effective and convenient single-pill combination therapies. High blood pressure is one of the most important treatable risk factors for cardiovascular disease – the number one cause of death worldwide(13).

Afinitor (everolimus) in tablet form has been approved in Japan for the treatment of patients with non-resectable, metastatic renal cell carcinoma (advanced kidney cancer). Each year, more than 10,000 people in Japan are diagnosed with kidney cancer(14).

A once-daily therapy, Afinitor provides continuous inhibition of the mTOR protein, a central regulator of tumor cell division and blood vessel growth in cancer cells. Afinitor is the first mTOR inhibitor approved to treat advanced kidney cancer patients in Japan.

Japan took part in the pivotal, international, Phase III trial for Afinitor on which the approval was based. The trial, RECORD-1 (REnal Cell cancer treatment with Oral RAD001 given Daily), included patients from 14 trial sites across Japan. RECORD-1 showed that Afinitor, when compared with placebo, more than doubled the median time without tumor growth or death in patients with advanced kidney cancer whose disease progressed following earlier VEGF-targeted therapy (4.9 vs. 1.9 months, $p < 0.0001$)(15). Prior to Afinitor, no other therapy had been studied in a Phase III trial in this patient population where there is an important unmet medical need.

This regulatory decision marks the third major approval for Afinitor in less than a year, following approvals in the European Union and United States(15),(16). Afinitor is also being studied worldwide in multiple tumor types, including in Japanese patients with pancreatic neuroendocrine tumors, gastric cancer, lymphoma and breast cancer.

As an investigational compound, the safety and efficacy profile of everolimus has not yet been established in these cancer and tumor types. Because of the uncertainty of clinical trials, there is no guarantee that everolimus will ever become commercially available for these cancer and tumor types anywhere in the world. In Japan, everolimus is available in different dosage strengths under the trade name Certican® for the prevention of organ rejection in heart transplant recipients.

Novartis Pharma K.K. is a Japanese affiliate of Novartis AG, Switzerland. For more information on NPKK, please visit <http://www.novartis.co.jp/>.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as commitment, can, will, or similar expressions, or by express or implied discussions regarding potential new indications or labeling for Afinitor, potential future approvals of Novartis products in Japan, or regarding potential future revenues from the products referred to in this release or from Novartis products sold in Japan. 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 to be materially

Edgar Filing: NOVARTIS AG - Form 6-K

different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Afinitor will be approved for any additional indications or labeling in any market. Nor can there be any guarantee that these products, or any other Novartis products sold in Japan, will achieve any particular levels of revenue in the future. In particular, management's expectations 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 each of these areas. In 2008, the Group's continuing operations achieved net sales of USD 41.5 billion and net income of USD 8.2 billion. Approximately USD 7.2 billion was invested in R&D activities throughout the Group. Headquartered in Basel, Switzerland, Novartis Group companies employ approximately 99,000 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) Equa package insert in Japan.
- (2) Kikuchi M, et al. Vildagliptin dose-dependently improves glycemic control in Japanese patients with type 2 diabetes mellitus. *Diabetes Research and Clinical Practice* 83 (2009) 233-240. Published online 31 December 2008. Doi:10.1016/j.diabres.2008.10.006.
- (3) International Diabetes Federation. *Diabetes Atlas*, fourth edition. 2009. Online version of the *Diabetes Atlas* is available at www.eatlas.idf.org
- (4) Azuma K, et al. Research on Antihyperglycemic Drug Therapies in Patients with Type 2 Diabetes Mellitus in Japan (II): the Effectiveness on Glycemic Control. *Diabetes* 49(12):919-927,2006 (JDDM). Online ISSN : 1881-588X. Print ISSN : 0021-437X.
- (5) International Diabetes Federation. *Complications of Diabetes*. 2008: <http://www.idf.org/home/index.cfm?node=13>
- (6) IMS Health MIDAS sales data. September 2009.
- (7) Smith TR, et al. Amlodipine and valsartan combined and as monotherapy in stage 2, elderly, and black hypertensive patients: subgroup analyses of 2 randomized, placebo-controlled studies. *J Clin Hypertens* 2007;9:355-64.
- (8) Poldermans D, et al. Tolerability and blood pressure-lowering efficacy of the combination of amlodipine plus valsartan compared with lisinopril plus hydrochlorothiazide in adult patients with stage 2 hypertension. *Clin Ther* 2007;29:279-89.
- (9) Philipp T, et al. Two multicenter, 8-week, randomized, double-blind, placebo-controlled, parallel-group studies evaluating the efficacy and tolerability of amlodipine and valsartan in combination and as monotherapy in adult patients with mild to moderate essential hypertension. *Clin Ther* 2007;29:563-80.
- (10) Allemann Y, et al. Efficacy of the combination of amlodipine and valsartan in patients with hypertension uncontrolled with previous monotherapy: the Exforge in Failure After Single Therapy (EX-FAST) Study. *J Clin Hypertens* 2008;10:185-94.
- (11) Japanese Ministry of Health, Labour and Welfare. National Health and Nutrition Survey Japan, 2006. Available at: http://www.nih.go.jp/eiken/english/research/project_nhns.html
- (12) Fujita T, Teramoto T, *Progress in Medicine* Vol. 26 No.9, 2006.
- (13) World Health Organization. Cardiovascular diseases factsheet. Available at: <http://www.who.int/mediacentre/factsheets/fs317/en/index.html>.
- (14) Ferlay J, et al., GLOBOCAN 2002. Cancer Incidence, Mortality and Prevalence Worldwide. IARC CancerBase No.5, Version 2.0. IARC Press, Lyon, 2004. Available at: <http://www-dep.iarc.fr>. Accessed December 2009.
- (15) Afinitor® (everolimus) tablets Summary of Product Characteristics. August 2009.
- (16) Afinitor® (everolimus) tablets US Prescribing Information. March 2009.

#

Novartis Media Relations

Central media line : +41 61 324 2200

Eric Althoff

Novartis Global Media Relations
+41 61 324 7999 (direct)
+41 79 593 4202 (mobile)
eric.althoff@novartis.com

Gail Corbett-Smith

Novartis Pharma Communications
+41 61 324 6720 (direct)
+41 79 367 4763 (mobile)
gail.corbett-smith@novartis.com

e-mail: media.relations@novartis.com

Novartis Investor Relations

Central phone:

	+41 61 324 7944
Ruth Metzler-Arnold	+41 61 324 9980
Pierre-Michel Bringer	+41 61 324 1065
John Gilardi	+41 61 324 3018
Thomas Hungerbuehler	+41 61 324 8425
Isabella Zinck	+41 61 324 7188

North America:

Richard Jarvis	+1 212 830 2433
Jill Pozarek	+1 212 830 2445
Edwin Valeriano	+1 212 830 2456

e-mail: investor.relations@novartis.com

e-mail: investor.relations@novartis.com

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 20, 2010

By: /s/ MALCOLM B. CHEETHAM

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