NOVARTIS AG
Form 6-K
July 05, 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 June 30, 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:

Form 20-F: x Form 40-F: o

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):

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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: o **No**: x

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- Investor Relations Release -

Novartis Phase III study shows once-daily NVA237 is superior to placebo and similar to tiotropium in improving lung function in COPD

- *GLOW2 study shows NVA237 provides superior 24-hour bronchodilation to placebo (p<0.001) with comparable efficacy to open-label tiotropium at 12 weeks(1)*

- *NVA237 shown to be well-tolerated in patients with moderate-to-severe chronic obstructive pulmonary disease (COPD)(1)*

- *Phase III data support first regulatory submission for NVA237 by end of 2011*

Basel, June 30, 2011 Results from the pivotal Phase III GLOW2 clinical trial show that once-daily NVA237 (glycopyrronium bromide) 50 mcg significantly improved lung function in patients with moderate-to-severe chronic obstructive pulmonary disease (COPD) relative to placebo (p<0.001), with similar efficacy to open-label tiotropium(1).

Further efficacy and safety results from GLOW2 will be presented at a scientific congress in 2012, and the data will be used to support an application for regulatory approval to be filed before the end of 2011.

NVA237 has demonstrated its potential benefit for COPD patients in two large pivotal Phase III studies, said Trevor Mundel, MD, Global Head of Development at Novartis Pharmaceuticals. This new study adds to the growing evidence that NVA237 could be an important treatment option for COPD, and supports our plans to develop a fixed-dose combination with our long-acting beta2-agonist Onbrez® Breezhaler® (indacaterol).

In an exploratory arm of the study, NVA237 was compared with open-label tiotropium (Spiriva® HandiHaler®*) 18 mcg, another once-daily long-acting muscarinic antagonist (LAMA) indicated for the treatment of COPD. Results show that NVA237 produced similar improvements in lung function to tiotropium(1).

The study met its primary endpoint by demonstrating superior 24-hour bronchodilation to placebo at 12 weeks measured by trough FEV1 (i.e. forced expiratory volume in one second), a standard measure of lung function(1). NVA237 was delivered using the Concept1® device, a single-dose dry-powder inhaler.

Key secondary endpoints were improvement in breathlessness assessed using the Transition Dyspnea Index (TDI) at 26 weeks, and improved quality of life as measured by the St George s Respiratory Questionnaire (SGRQ) at 52 weeks. Important secondary endpoints were time to first

* Spiriva® and HandiHaler® are registered trademarks of Boehringer Ingelheim Pharma GmbH & Co. KG.

COPD exacerbation and use of rescue medication during 52 weeks of treatment. The study met all of these endpoints.

The GLOW2 study also showed that NVA237 was well-tolerated with a similar incidence of adverse events for patients treated with NVA237, placebo and open-label tiotropium(1).

GLOW2 was a 52-week double-blind, placebo-controlled, parallel-group study involving 1,066 patients to assess the efficacy, safety and tolerability of NVA237 in patients with COPD. Patients were randomized into three treatment arms receiving either once-daily NVA237 50 mcg or placebo (double-blind), or once-daily tiotropium 18 mcg(1) (open label). They were also permitted to use COPD background therapy and rescue medication.

In April 2011 Novartis announced results from the first Phase III clinical trial with NVA237. The pivotal double-blind 26-week GLOW1 study met its primary endpoint by demonstrating superior bronchodilation to placebo at 12 weeks measured by trough FEV1 ($p<0.001$)(1). The incidence of adverse events was similar in NVA237-treated patients and in those receiving placebo(1). Further data from GLOW1 will be presented at the European Respiratory Society congress in Amsterdam in September 2011.

COPD is a progressive, life-threatening disease associated with tobacco smoking, air pollution or occupational exposure, which causes obstruction of airflow in the lungs resulting in debilitating bouts of breathlessness. COPD affects 210 million people worldwide(2) and is projected to be the third leading cause of death by 2020(3). Although often considered a disease of the elderly, research has shown that a majority of COPD patients are under the age of 65(1) when they are likely to be at the peak of their earning power and family responsibilities.

NVA237 was licensed to Novartis in April 2005 by Vectura and its co-development partner Sosei.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as will, to be filed, potential, could, pla projected, or similar expressions, or by express or implied discussions regarding potential marketing submissions or approvals for NVA237 or a potential combination respiratory product, or regarding potential future revenues from such products. 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 such products to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that NVA237 or a potential combination respiratory product will be submitted approved for sale in any market, or at any particular time. Nor can there be any guarantee that such products will achieve any particular levels of revenue in the future. In particular, management s expectations regarding such products could be affected by, among other things, unexpected regulatory actions or delays or government regulation generally, including uncertainties as to FDA dosing requirements; 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, eye care, cost-saving generic pharmaceuticals, consumer health products, preventive vaccines and diagnostic tools. Novartis is the only 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. Headquartered in Basel, Switzerland, Novartis Group companies employ approximately 119,000 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.

References

(1) Data on file, Novartis Pharma AG.

(2) Global Alliance against Chronic Respiratory Diseases (GARD). Global surveillance, prevention and control of chronic respiratory diseases: a comprehensive approach. Available at: http://www.who.int/gard/publications/GARD%20Book%202007.pdf Last accessed 24 May 2011.

(3) Global Initiative for Chronic Obstructive Lung Disease (GOLD). Global Strategy for the Diagnosis, Management, and Prevention of Chronic Obstructive Pulmonary Disease. Updated 2010. Available at: http://www.goldcopd.org/Guidelineitem.asp?l1=2&l2=1&intId=989. Last accessed 24 May 2011.

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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: June 30, 2011

By: /s/ MALCOLM B. CHEETHAM

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