NOVARTIS AG
Form 6-K
May 17, 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 May 15, 2011

(Commission File No. 1-15024)

Novartis AG

(Name of Registrant)

Lichtstrasse 35

4056 Basel

Switzerland

(Address of Principal Executive Offices)

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

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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**

Novartis International AG

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- Investor Relations Release -

Novartis studies show Onbrez® Breezhaler® plus tiotropium is more effective than tiotropium alone in treatment of COPD

- *Phase III studies show once-daily Onbrez Breezhaler plus tiotropium improved lung function (measured by trough FEV1) by up to 230 mL from baseline(1)*

- *Reported incidence of side effects was similar in both treatment groups(1)*

- *Results add to comprehensive data supporting Onbrez Breezhaler as an effective treatment for COPD with good safety profile*

Basel, May 15, 2011 Results of two Phase III studies show that once-daily Onbrez® Breezhaler® (indacaterol) plus tiotropium produced a significantly greater improvement in lung function than tiotropium alone in patients with chronic obstructive pulmonary disease (COPD)(1), supporting current treatment guidelines which recommend use of one or more bronchodilators for treating moderate-to-severe disease(2). The reported incidence of adverse events and serious adverse events was similar in both treatment groups(1).

The internationally recognized GOLD guidelines state that combining bronchodilators with different modes of action may provide improved efficacy with no increase in side effects(2) , said the principal investigator Donald A. Mahler, MD, of the Dartmouth-Hitchcock Medical Center in Lebanon, New Hampshire, USA. These are the first 12-week studies to report on the efficacy of two once-daily bronchodilators given concurrently, and the results confirm that the GOLD recommendation holds true for the use of indacaterol plus tiotropium.

The findings were presented today at the American Thoracic Society (ATS) congress in Denver, Colorado.

Onbrez Breezhaler is the only once-daily long-acting beta-2 agonist (LABA) approved in more than 50 countries, while tiotropium (Spiriva® HandiHaler®∗) is a long-acting anti-muscarinic (LAMA), both indicated for the treatment of COPD. The two classes of medicines have different modes of action but both therapies are inhaled to provide bronchodilation, i.e. increased airflow into the patient s lungs.

The INTRUST 1 and 2 studies met their primary endpoints by demonstrating significant improvements in lung function of 130 and 120 mL respectively for Onbrez Breezhaler (150 mcg) plus tiotropium (18 mcg) compared to tiotropium alone after 12 weeks (both p<0.001)(1). Both therapies were given once-daily. Lung function was assessed by measuring patients forced expiratory volume of breath in one second (FEV_1) averaged over eight hours (i.e. FEV_1 $AUC_{5\ min-8h}$)(1).

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

Onbrez Breezhaler plus tiotropium also performed significantly better than tiotropium in improving trough FEV1 (i.e. mean of 23 hrs 10 mins and 23 hrs 45 mins post-dose) at week 12, with the two studies showing differences of 80 and 70 mL compared to tiotropium alone (both p<0.001)(1). The changes in trough FEV1 from baseline at week 12 were 230 mL and 190 mL for indacaterol plus tiotropium, and 150 mL and 110 mL for tiotropium alone. In both studies the reduction in use of rescue medication (albuterol) was numerically greater with Onbrez Breezhaler plus tiotropium than with tiotropium alone(1).

Previous studies have demonstrated the safety and efficacy profile of Onbrez Breezhaler as monotherapy in COPD, and the latest results indicate that it may have even greater therapeutic potential when combined with another leading class of treatment, said Trevor Mundel, MD, Global Head of Development at Novartis Pharma AG. These studies add to the comprehensive data supporting Onbrez Breezhaler as an effective treatment for COPD with a good overall safety profile.

INTRUST 1 and 2 were matching 12-week randomized, double-blind Phase III studies involving 1,134 and 1,142 patients respectively with moderate-to-severe COPD (as defined by the GOLD 2007 criteria). One group of patients received Onbrez Breezhaler 150 mcg once-daily, while the other group received placebo. All patients concurrently received open-label tiotropium 18 mcg once-daily.

Indacaterol, formerly known as QAB149, is approved at 150 and 300 mcg once-daily doses for the treatment of COPD under the brand name Onbrez Breezhaler. It was first approved in November 2009 in the European Union, and is now available in more than 15 European countries with additional launches planned during 2011.

QAB149 is not approved in the US, where the Food and Drug Administration (FDA) is due to complete its regulatory review by July 2011. If approved in the US, the proposed trade name will be Arcapta Neohaler .

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(3) and is projected to be the third leading cause of death by 2020(2). Although often considered a disease of the elderly, research has shown that a majority of COPD patients are under the age of 65(4) when they are likely to be at the peak of their earning power and family responsibilities.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as may, potential, due, will, or similar expressions, or by express or implied discussions regarding potential new indications or labeling for indacaterol, or regarding potential future approvals for indacaterol, or regarding the timing of any such approvals, or regarding potential future revenues from indacaterol. 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 indacaterol to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that indacaterol will be approved for any additional indications or labeling in any market. Nor can there be any guarantee that indacaterol will be approved for sale in any additional markets or at any particular time. Neither can there be any guarantee that indacaterol will achieve any particular levels of revenue in the future. In particular, management s expectations regarding indacaterol 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; 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) Mahler DA, D Urzo A, Peckitt C, Lassen C, Kramer B. Combining once-daily bronchodilators in COPD: Indacaterol plus tiotropium versus tiotropium alone. Presented at American Thoracic Society (ATS) International Conference, Denver Colorado, May 2011.

(2) 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 11 May 2011.

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(4) Data on file, Novartis Pharma AG.

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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 15, 2011

By: /s/ MALCOLM B. CHEETHAM

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