

NOVARTIS AG  
Form 6-K  
November 04, 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 November 3, 2010**

(Commission File No. 1-15024)

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**Novartis AG**

(Name of Registrant)

**Lichtstrasse 35**

**4056 Basel**

**Switzerland**

(Address of Principal Executive Offices)

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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: ☐ **No:** ☒

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**- Investor Relations Release -**

**Onbrez® Breezhaler® from Novartis provides greater clinical benefits than tiotropium in new study of COPD patients**

- *Study shows Onbrez Breezhaler superior to tiotropium in reducing breathlessness and use of rescue medication and in improving overall health status(1)*
- *INTENSITY is first blinded head-to-head study with primary goal of comparing once-daily Onbrez Breezhaler with tiotropium, an established COPD therapy*
- *Study shows once-daily Onbrez Breezhaler was as effective as tiotropium in improving patients' lung function(1)*
- *Phase III study adds to comprehensive data supporting Onbrez Breezhaler as effective and well-tolerated treatment for chronic obstructive pulmonary disease*

**Basel, November 3, 2010** Novartis today announced new results from a blinded Phase III head-to-head study showing that once-daily Onbrez® Breezhaler® (indacaterol) was as effective as tiotropium in improving lung function in patients with chronic obstructive pulmonary disease (COPD), while providing greater clinical benefits in terms of reduced breathlessness, lower use of rescue medication and improved health status(1).

The results were presented at the annual CHEST meeting of the American College of Chest Physicians (ACCP) in Vancouver, Canada.

INTENSITY is the first blinded head-to-head study whose primary objective was to compare Onbrez Breezhaler, a novel long-acting beta-2 agonist (LABA), with tiotropium (Spiriva® HandiHaler®\*), a long-acting anti-muscarinic (LAMA) and an established treatment for COPD. The two medicines have different modes of action but are both inhaled once-daily to provide bronchodilation, i.e. increased airflow into the patient's lungs.

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These results add to the growing body of evidence supporting the use of indacaterol in COPD, delivering sustained improvements in lung function that can translate into real patient benefits, said Leonard Dunn, MD, FCCP, Medical Director for Pulmonology at Clinical Research of West Florida, Clearwater, Florida, and lead investigator in the INTENSITY study. The study confirms that indacaterol is an effective and well-tolerated treatment that should be considered, where available, as a maintenance therapy option for COPD patients.

A total of 1,598 patients with moderate-to-severe COPD were enrolled in the blinded, double-dummy study in which they received once-daily treatment with either Onbrez Breezhaler 150 mcg or tiotropium 18 mcg(1). The study met its primary endpoint by demonstrating non-inferiority of Onbrez Breezhaler to tiotropium after 12 weeks in terms of lung function, measured by forced expiratory volume of breath in one second (FEV1)(1). Results showed that baseline-adjusted trough FEV1 at 12 weeks was 1.44 L with Onbrez Breezhaler and 1.43 L with tiotropium (mean of 23 hrs

10 mins and 23 hrs 45 mins post-dose,  $p < 0.001$  for non-inferiority)(1). FEV1 superiority to tiotropium, one of the secondary endpoints, did not reach statistical significance(2).

Onbrez Breezhaler showed superiority to tiotropium on other secondary endpoints relating to key patient outcomes. Breathlessness improved significantly more with Onbrez Breezhaler than tiotropium (total scores of 2.01 vs. 1.43 in transition dyspnea index,  $p < 0.001$ )(1). Onbrez Breezhaler patients used less albuterol rescue medication (change of -1.40 vs. -0.85 puffs/day,  $p < 0.001$ ) and had a higher percentage of days without rescue medication use (46.1 vs. 41.4,  $p = 0.004$ )(1). Patients using Onbrez Breezhaler reported significantly better health status than those on tiotropium (mean change of -5.1 vs. -3.0 in St George's Respiratory Questionnaire,  $p < 0.001$ )(1).

This study provides further evidence of the potential additional benefits that Onbrez Breezhaler can bring to COPD patients compared to medicines that are widely used in current clinical practice, said Trevor Mundel, MD, Global Head of Development at Novartis Pharma AG. Our Phase III program involves 16,000 patients in a series of clinical trials which together provide a comprehensive understanding of the efficacy and safety of Onbrez Breezhaler.

The incidence of adverse events in the INTENSITY study was similar for both treatments, with adverse events reported in 39.7% vs. 37.2% of patients using Onbrez Breezhaler and tiotropium respectively, and serious adverse events in 2.8% vs. 3.8% respectively(1). The most common adverse events were COPD worsening (including exacerbations), cough, and nasopharyngitis(3).

A third-party blinding system was used under which the drug was dispensed to patients by a person at each site who was neither the investigator nor the study coordinator. Both the investigator staff and patient were therefore blinded to treatment assignment(2).

Another study to be presented at the CHEST meeting investigated patients' use of different inhaler devices, an important factor in the success of COPD therapy. The seven-day, open-label, crossover study called INDEED compared patients' handling and preference for the Onbrez Breezhaler and the tiotropium HandiHaler®\* devices(4). Results will be presented on November 3.

Onbrez Breezhaler was first approved in November 2009 in the European Union, where it is indicated for the maintenance bronchodilator treatment of airflow obstruction in adult patients with COPD(5). It is now approved in more than 40 countries and has been launched in 12 of them. Indacaterol is currently under regulatory review in the US. Following a Complete Response Letter received in October 2009, data from additional studies were submitted to the Food and Drug Administration (FDA) in September 2010.

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(6) and is projected to be the third leading cause of death by 2020(7). Although often considered a disease of the elderly, research has shown that a majority of COPD patients are under the age of 65(2) when they are likely to be at the peak of their earning power and family responsibilities.

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

**Disclaimer**

The foregoing release contains forward-looking statements that can be identified by terminology such as can, should, potential, projected, or similar expressions, or by express or implied discussions regarding potential new indications or labeling for Onbrez Breezhaler, regarding potential approvals to sell Onbrez Breezhaler in additional markets or regarding potential future revenues from Onbrez Breezhaler. 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 Onbrez Breezhaler to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Onbrez Breezhaler will be submitted or approved for any additional indications or labeling in any market. Nor can there be any guarantee that Onbrez Breezhaler will be approved for sale in any additional markets. Neither can there be any guarantee that Onbrez Breezhaler will achieve any particular levels of revenue in the future. In particular, management's expectations regarding Onbrez Breezhaler 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, cost-saving generic pharmaceuticals, preventive vaccines, diagnostic tools and consumer health products. Novartis is the only company with leading positions in these areas. In 2009, the Group's continuing operations achieved net sales of USD 44.3 billion, while approximately USD 7.5 billion was invested in R&D activities throughout the Group. Headquartered in Basel, Switzerland, Novartis Group companies employ approximately 100,000 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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### References

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- (2) Data on file, Novartis Pharma AG.
- (3) Dunn LJ, et al. Blinded 12-Week Comparison of Once-daily Indacaterol and Tiotropium in COPD. Presentation at ACCP CHEST Congress, Vancouver, Canada, November 1, 2010.
- (4) Chapman KR, et al. Patient Handling And Preference For The Single-dose Dry-powder Inhalers Used With Indacaterol and Tiotropium. Abstract and poster at ACCP CHEST Congress, Vancouver, Canada. Embargoed until November 3, 2010.
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- (6) WHO. Factsheet No 315: Chronic obstructive pulmonary disease (COPD), Available at: [www.who.int/mediacentre/factsheets/fs315/en/index.html](http://www.who.int/mediacentre/factsheets/fs315/en/index.html). Last accessed 22 October 2010.
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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: November 3, 2010

By: /s/ MALCOLM B. CHEETHAM

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