

NOVARTIS AG  
Form 6-K  
September 29, 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 September 27, 2011**

**(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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**- Investor Relations Release -**

**New Novartis data show potential of respiratory portfolio to help COPD patients maintain active and productive lives**

- *Studies show investigational once-daily NVA237 provides superior 24-hour bronchodilation and increases exercise endurance relative to placebo(1),(2)*
- *Additional data show NVA237 significantly prolonged time to first moderate/ severe COPD exacerbation and reduced associated hospitalizations(3)*
- *NVA237 submitted for EU approval under brand-name Seebri® Breezhaler® for treatment of chronic obstructive pulmonary disease (COPD)*

**Basel, September 27, 2011** Novartis has presented new Phase III data at the European Respiratory Society (ERS) congress demonstrating the potential for its portfolio of once-daily inhaled therapies to help patients with chronic obstructive pulmonary disease (COPD) to maintain more active and productive lives.

The GLOW1 and GLOW3 studies show that investigational NVA237 (glycopyrronium bromide) significantly increased patients' lung function compared to placebo with a fast onset of action at first dose, as well as improving exercise endurance. NVA237 is a new drug in the long-acting anti-muscarinic (LAMA) class which has recently been submitted for approval in the European Union under the brand-name Seebri® Breezhaler®.

These results illustrate the potential benefits of NVA237 for COPD patients and are especially encouraging as we move ahead with plans to develop a fixed-dose combination with Onbrez® Breezhaler®, our once-daily therapy in the LABA class, said David Epstein, Division Head of Novartis Pharmaceuticals. This investigational combination of two bronchodilators with complementary modes of action is designed to give COPD patients access to the two leading classes of therapy in a single inhaler for the first time.

The studies, presented at the ERS congress in Amsterdam, The Netherlands, underscore the company's commitment to developing innovative medicines to treat this life-threatening disease. Although COPD is often thought of as a disease of the elderly, 50% of patients are estimated to

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be below the age of 65, and are likely to be at the peak of their earning power and family responsibilities(4),(5),(6).

The GLOW1 study met its primary endpoint by showing that NVA237 50 mcg once-daily produced a significant improvement in lung function of 108 mL in trough FEV<sub>1</sub>(1) after 12 weeks in patients with moderate-to-severe COPD compared to placebo ( $p < 0.001$ )(1). Moreover, NVA237 had a rapid onset of action, with a 93 mL improvement in FEV<sub>1</sub> compared to placebo at five minutes post-dose following the first dose on the first day of treatment ( $p < 0.001$ )(1).

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(1) Forced expiratory volume of breath in one second

NVA237 also significantly prolonged the time to first moderate/severe COPD exacerbation compared to placebo, and reduced the percentage of associated hospitalizations(3). Significant improvement in breathlessness was seen at 26 weeks compared to placebo, accompanied by a significant improvement in health-related quality of life and reduction in the use of rescue medication(7).

The GLOW3 study investigated the effects of NVA237 50 mcg once-daily on exercise endurance in moderate-to-severe COPD patients. The study met its primary endpoint by showing a significant 21% improvement in exercise endurance versus placebo at the end of the study (i.e. day 21), with a significant 10% increase from day one (both  $p < 0.001$ )(2).

Both studies showed that NVA237 was well-tolerated, with a similar incidence of adverse events for patients treated with NVA237 and placebo(1),(2),(3),(7).

These results provide important new insights into the potential effects of NVA237 in improving lung function and relieving symptoms such as breathlessness, said Dr Kai-Michael Beeh of the insaf Respiratory Research Institute in Wiesbaden, Germany, the principal investigator of the GLOW3 study. The improvements in exercise endurance are significant as exercise limitation is a considerable burden for COPD patients, affecting everyday activities such as climbing the stairs. These trials show that NVA237 may provide a future option that could positively impact the way COPD is treated.

#### **New analyses of Onbrez Breezhaler data at ERS**

New pooled analyses of data were also presented confirming the efficacy of Onbrez Breezhaler (indacaterol), a long-acting beta2-agonist (LABA) approved in more than 70 countries for the maintenance treatment of COPD.

One pooled analysis examined the efficacy of Onbrez Breezhaler in patients with moderate or less, and severe or worse COPD (defined as stages I-II and III-IV respectively in the GOLD guidelines(8)). This showed that Onbrez Breezhaler 150 and 300 mcg once-daily significantly improved lung function in both subgroups at six months compared to placebo ( $p < 0.001$ )(9). The analysis also showed that in the more severe subgroup, Onbrez Breezhaler 300 mcg was significantly more effective than 150 mcg in improving breathlessness compared to baseline, as assessed using the Transition Dyspnea Index (TDI) ( $p < 0.05$ )(9).

A second pooled analysis showed that Onbrez Breezhaler 150 and 300 mcg improved lung function regardless of patients' background use of ICS. In patients not using ICS, the improvements in lung function were 180 and 170 mL with Onbrez Breezhaler 150 and 300 mcg respectively compared to placebo ( $p < 0.001$ )(10).

Onbrez Breezhaler is the only COPD treatment to offer clinically relevant 24-hour bronchodilation combined with a rapid onset of action within five minutes of the first dose. In July 2011, Novartis announced approval of the 75 mcg once-daily dose in the US under the brand name Arcapta Neohaler, and of the 150 mcg once-daily dose in Japan under the brand name Onbrez® Inhalation Capsules.

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COPD is a progressive disease associated with tobacco smoking, air pollution or occupational exposure, which causes obstruction of airflow in the lungs resulting in debilitating bouts of breathlessness. It affects an estimated 210 million people worldwide(11) and is predicted to be the third leading cause of death by 2020(8).

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 potential, encouraging, plans, designed, commitment, could, or similar expressions, or by express or implied discussions regarding potential new indications or labeling for Onbrez Breezhaler, potential marketing approvals for NVA237 or a potential fixed-dose combination 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 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 NVA237 or a potential fixed-dose combination product will be submitted or approved in any market, or at any particular time. Neither can there be any guarantee that any of the products referred to in this release 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 clinical trial results, including unexpected new clinical data and unexpected additional analysis of existing clinical data; unexpected regulatory actions or delays or government regulation generally; 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 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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**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: September 27, 2011

By: /s/ MALCOLM B. CHEETHAM

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