

NOVARTIS AG  
Form 6-K  
April 02, 2012

# 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 April 2, 2012**

**(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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Yes:  No:

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**Novartis QVA149 Phase III COPD studies meet primary endpoints**

- *QVA149 efficacy, safety and exercise endurance primary endpoints all met(1),(2),(3)*
- *Studies are part of IGNITE Phase III clinical trial program intended to form the basis for an NDA filing in COPD*
- *QVA149, a bronchodilator with dual mode of action, is Novartis' third innovation in its Breezhaler® Single Dose Dry Powder Inhaler*
- *COPD is predicted to be the third leading cause of death in the world by 2020(4)*

**Basel, April 2, 2012** The first three Novartis QVA149 Phase III studies in the treatment of chronic obstructive pulmonary disease (COPD) all met their primary endpoints. The SHINE, BRIGHT and ENLIGHTEN studies, which are key components of the IGNITE program, demonstrate the potential of QVA149 in the treatment of COPD.

The results of SHINE, with an enrollment of more than 2,100 patients, met the primary endpoint by demonstrating the superiority in trough FEV1 ( $p < 0.001$ ) of once-daily QVA149 compared to once-daily indacaterol or once-daily NVA237 in patients with moderate to severe COPD(1). In addition, QVA149 showed superiority in trough FEV1 ( $p < 0.001$ ) compared to placebo and open-label tiotropium (18 mcg).

The results of BRIGHT demonstrated that patients experienced significantly better exercise endurance versus placebo ( $p = 0.006$ )(3). ENLIGHTEN demonstrated that QVA149 was well tolerated with a safety and tolerability profile similar to placebo(2).

Meeting the primary endpoints in the IGNITE Phase III clinical trial program signals significant progress in establishing the potential of QVA149, which is expected to be the third innovative medicine in our strong COPD portfolio, said Tim Wright, Head of Development, Novartis Pharmaceuticals. Novartis is committed to addressing the unmet needs of COPD patients and improving their quality of life by providing innovative medicines and devices.

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QVA149 (indacaterol 110 mcg/glycopyrronium bromide 50 mcg) is an investigational inhaled, once-daily, fixed dose combination of the long acting beta2-agonist (LABA) indacaterol, and the long-acting muscarinic antagonist (LAMA) glycopyrronium bromide (NVA237). Data from the IGNITE clinical trial program examining QVA149 in a number of settings will be submitted for presentation to a major medical congress later this year.

IGNITE is one of the largest international patient registration programs in COPD comprising 10 studies in total. The first seven studies (ENLIGHTEN, BRIGHT, SHINE, ILLUMINATE, SPARK, BLAZE, ARISE) are expected to complete in 2012 and include more than 5,700 patients across 42 countries and support planned filings in the EU and Japan. Included in the program is a head-to-head trial vs Seretide®(5) (ILLUMINATE), which is also expected to complete during the second quarter of 2012 and will be incorporated into regulatory filings. These studies are designed to investigate efficacy,

safety and tolerability, lung function, exercise endurance, exacerbations, dyspnea and quality of life.

SHINE is a 26-week, multicenter, randomized, double-blind, parallel-group, placebo and active controlled pivotal trial of 2,144 patients with moderate to severe COPD to assess efficacy in terms of trough FEV<sub>1</sub>. BRIGHT is a three-week, randomized, blinded, double-dummy, multi-center, placebo controlled, three-period crossover pivotal trial of 85 patients with moderate or severe COPD to assess the effect on exercise tolerance of QVA149. ENLIGHTEN is a 52-week, multicenter, randomized, double-blind, parallel-group, placebo controlled pivotal trial of 339 patients with moderate or severe COPD to assess the safety and tolerability of QVA149.

COPD is a progressive disease associated mainly with tobacco smoking, air pollution or occupational exposure, which can cause obstruction of airflow in the lungs resulting in debilitating bouts of breathlessness. It affects an estimated 210 million people worldwide(6) and is predicted to be the third leading cause of death by 2020(4). Although COPD is often thought of as a disease of the elderly, 50% of patients are estimated to be within the ages of 50 and 65, which means that half of the COPD population are likely to be impacted at the peak of their earning power and family responsibilities(7).

QVA149 would be the third innovation in the Novartis COPD portfolio to be delivered using the Breezhaler® Single Dose Dry Powder Inhaler, along with Onbrez® Breezhaler® (indacaterol) and investigational Seebri® Breezhaler® (glycopyrronium bromide/NVA237).

Onbrez® Breezhaler® (indacaterol maleate) is the only COPD treatment to offer clinically relevant 24-hour bronchodilation combined with a rapid onset of action at first dose and has shown significant symptomatic improvement especially on breathlessness(8). In March 2012, Novartis launched the 75 mcg once-daily dose in the US under the brand name Arcapta Neohaler . It is also available as a 150 mcg once-daily dose in Japan under the brand name Onbrez® Inhalation Capsules.

Seebri® Breezhaler® (glycopyrronium bromide/NVA237) is an investigational long-acting muscarinic antagonist (LAMA) developed as a once-daily inhaled maintenance therapy for the treatment of COPD. Phase III data from the GLOW 1, 2 and 3 studies demonstrated that Seebri increased patients' lung function over a 24-hour period compared to placebo with a fast onset of action at first dose, as well as improving exercise endurance. Glycopyrronium bromide (Seebri® Breezhaler®) was licensed to Novartis in April 2005 by Vectura and its co-development partner Sosei, and was submitted for regulatory approval in Europe in Q3 2011 and Japan in Q4 2011.

## Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as intended, predicted, potential, expected, committed, will, planned, designed to, or similar expressions, or by express or implied discussions regarding potential marketing submissions or approvals for QVA149 and Seebri Breezhaler, or regarding the timing of any such submissions or approvals, or regarding potential future revenues from QVA149, Onbrez Breezhaler and Seebri 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 these products to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that QVA149 or Seebri Breezhaler will be submitted or approved for sale in any market, or that any such submissions or approvals will happen at any particular time. Nor can there be any guarantee that QVA149, Onbrez Breezhaler, or Seebri Breezhaler will achieve any particular levels of revenue in the future. In particular, management's expectations regarding these 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; unexpected manufacturing issues; 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 innovative healthcare solutions that address the evolving needs of patients and societies. Headquartered in Basel, Switzerland, Novartis offers a diversified portfolio to best meet these needs: innovative medicines, eye care, cost-saving generic pharmaceuticals, preventive vaccines and diagnostic tools, over-the-counter and animal health products. Novartis is the only global company with leading positions in these areas. In 2011, the Group's continuing operations achieved net sales of USD 58.6 billion, while approximately USD 9.6 billion (USD 9.2 billion excluding impairment and amortization charges) was invested in R&D throughout the Group. Novartis Group companies employ approximately 124,000 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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**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: April 2, 2012

By: /s/ MALCOLM B. CHEETHAM

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