

NOVARTIS AG  
Form 6-K  
June 22, 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 June 22, 2012

(Commission File No. 1-15024)

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(Name of Registrant)

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(Address of Principal Executive Offices)

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Yes:       **No:**

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**MEDIA RELEASE • COMMUNIQUE AUX MEDIAS • MEDIENMITTEILUNG**

**Novartis receives positive CHMP opinion for once-daily Seebri® Breezhaler® to treat COPD patients in the EU**

- *COPD patients in Phase III GLOW trials experienced improved lung function, reduced shortness of breath, reduced exacerbations, and improved quality of life(1),(2),(3),(4)*
- *GLOW2 study showed Seebri Breezhaler provided 24-hour bronchodilation and was superior to placebo and similar to open-label tiotropium in improving lung function(2)*
- *Seebri Breezhaler is the latest innovation in the Novartis COPD portfolio and when approved will offer patients an alternative once-daily choice of LAMA therapy*

**Basel, June 22, 2012** Novartis announced today that the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has adopted a positive opinion for Seebri® Breezhaler® (glycopyrronium/NVA237) 44 mcg delivered dose (50 mcg glycopyrronium per capsule), as a once-daily inhaled maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease (COPD). Seebri Breezhaler is a long-acting muscarinic antagonist (LAMA), a type of bronchodilator that is recommended in COPD global treatment strategies as maintenance therapy administered either alone or in combination with other treatments(5).

This positive opinion for Seebri Breezhaler is a major milestone in our efforts to offer COPD patients and health care professionals an alternative once-daily therapy in the LAMA class that has the potential to reduce breathlessness, increase the capacity to exercise and help improve quality of life, said David Epstein, Division Head of Novartis Pharmaceuticals. When approved, Seebri Breezhaler will be the second innovative once-daily inhaled treatment in the growing Novartis COPD portfolio delivered using the low-resistance Breezhaler device that allows patients to hear, feel and see that they have taken the drug correctly.

Data from three of the Novartis Phase III GLOW trials informed the CHMP's positive opinion for Seebri Breezhaler and included 1,996 COPD patients from around the world with many in EU countries(1),(2),(3),(4),(6).

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GLOW1 demonstrated the clinically significant superiority of Seebri versus placebo for lung function improvements at 12 weeks measured by trough FEV1 ( $p < 0.01$ )(1). GLOW2 demonstrated a similar magnitude of effect and also showed that Seebri was similar to open-label (OL) tiotropium over 52 weeks measured by improvements in trough FEV1 compared to placebo(2). In addition to demonstrating benefits in terms of lung function, Seebri Breezhaler exhibited a rapid onset of action within five minutes at first dose(2) and reduced exacerbations(4). Significant benefits in both breathlessness and health-related quality of life, as measured by the Transition Dyspnea Index (TDI) and St. George's Respiratory Questionnaire (SGRQ) compared to placebo, were also demonstrated(3).

The GLOW3 study showed that after Seebri Breezhaler was administered in the morning, patients experienced improved exercise tolerance from the first dose onward(6). Overall, patients treated with Seebri Breezhaler experienced a significant 21% improvement in exercise endurance versus placebo at the end of the study (day 21), with a significant 10% increase from day one (both  $p < 0.001$ )(6).

In all studies, Seebri Breezhaler was well tolerated with an incidence of adverse events similar to placebo(1),(2),(3),(4),(6).

The European Commission generally follows the recommendations of the CHMP and usually delivers its final decision within three months of the CHMP recommendation. Worldwide submissions and reviews of Seebri® Breezhaler® (glycopyrronium bromide/NVA237) are ongoing. The US filing for Seebri Breezhaler is expected in 2014.

### **About Seebri Breezhaler**

Seebri® Breezhaler® (glycopyrronium bromide/NVA237) is an investigational LAMA developed as a once-daily inhaled maintenance therapy for the treatment of COPD. Glycopyrronium bromide was licensed to Novartis in April 2005 by Vectura and its co-development partner Sosei. It was submitted for regulatory approval in Europe in Q3 2011 and Japan in Q4 2011.

### **About the Novartis COPD portfolio**

Novartis is committed to addressing the unmet medical needs of COPD patients and improving their quality of life by providing innovative medicines and devices.

Onbrez® Breezhaler® (indacaterol maleate) is a long-acting beta-agonist (LABA) that is the only COPD treatment to offer clinically relevant 24-hour bronchodilation combined with a rapid onset of action at first dose(7),(8),(9),(10). Onbrez Breezhaler has also shown significant improvement in breathlessness scores compared to placebo and tiotropium(7). It was first launched in the EU in 150 mcg and 300 mcg once-daily doses. Most recently, 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.

In addition to Seebri Breezhaler, also under development is QVA149 (indacaterol maleate 110 mcg/glycopyrronium bromide 50 mcg), an investigational inhaled, once-daily, fixed dose combination of the LABA indacaterol maleate, and the LAMA glycopyrronium bromide.

The first four Novartis QVA149 Phase III studies in the treatment of COPD all met their primary endpoints(11),(12),(13),(14). The results of the SHINE, BRIGHT, ENLIGHTEN and ILLUMINATE studies, which are key components of the IGNITE program, demonstrate the potential of QVA149 in the treatment of COPD(11),(12),(13),(14).

### **About COPD**

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(15) and is predicted to

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be the third leading cause of death by 2020(5). 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(16).

### **Disclaimer**

The foregoing release contains forward-looking statements that can be identified by terminology such as will, milestone, potential, generally follows, usually delivers, expected, committed, or similar expressions, or by express or implied discussions

regarding potential marketing submissions or approvals for Seebri or the timing of such submissions or approvals, or regarding potential future revenues from Seebri. 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 Seebri to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Seebri will be approved for sale in any market, or submitted for approval in any additional markets, or that such submissions or approvals will occur at any particular time. Nor can there be any guarantee that Seebri will achieve any particular levels of revenue in the future. In particular, management's expectations regarding Seebri 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; 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: June 22, 2012

By: /s/ MALCOLM B. CHEETHAM

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

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