

NOVARTIS AG  
Form 6-K  
October 01, 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 October 1, 2012**

**(Commission File No. 1-15024)**

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

**Novartis receives European Commission approval for once-daily Seebri® Breezhaler® as maintenance COPD treatment in the EU**

- *Seebri® Breezhaler® 44 mcg delivered dose approved for maintenance treatment of COPD will be available to patients and physicians in some EU markets by year-end*
- *In GLOW trials, Seebri® Breezhaler® improved lung function, reduced shortness of breath, reduced exacerbations, and improved quality of life up to 52 weeks versus placebo(1),(2),(3)*
- *GLOW2 study showed Seebri® Breezhaler® provided 24-hour bronchodilation and is superior to placebo and similar to open-label tiotropium in improving lung function(2)*

**Basel, October 1, 2012** Novartis announced today that the European Commission has approved Seebri® Breezhaler® (glycopyrronium bromide) 44 mcg delivered dose (equivalent to 50 mcg glycopyrronium measured dose per capsule), as a once-daily inhaled maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease (COPD). This follows the September 28 approval of once-daily Seebri® (glycopyrronium bromide) Inhalation Capsules 50 mcg in Japan.

The approval of Seebri® Breezhaler® in the European Union is an exciting and critical milestone that provides physicians and patients with a new once-daily COPD therapy so they have the flexibility of having the right treatment for the right patient at the right time, said David Epstein, Division Head of Novartis Pharmaceuticals. We are proud that Novartis can deliver on our commitment to COPD patients and physicians by being the first company to offer two once-daily monotherapy bronchodilators with different modes of action, both delivered using Breezhaler devices.

The European Commission approved Seebri® Breezhaler® based on data from the Novartis Phase III GLOW trials which demonstrated the safety and efficacy of glycopyrronium 44 mcg and involved 1,996 COPD patients who required maintenance treatment from around the world, with many in EU countries(1),(2),(3).

The GLOW trials showed that glycopyrronium, when compared to placebo, significantly improved lung function over the first four hours after morning dosing and that this benefit was sustained for 24 hours over a 52-week period(2). Patients on glycopyrronium demonstrated improved

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lung function, reduced shortness of breath, reduced exacerbations, reduced use of rescue medication, improved quality of life and improved exercise tolerance compared to placebo(1),(2),(3).

GLOW1 was a 26-week, randomized, double-blind, placebo-controlled study. The study demonstrated the clinically significant superiority of glycopyrronium versus placebo for lung function improvements at 12 weeks (primary endpoint) measured by trough FEV1 ( $p < 0.01$ )(1).

GLOW2 demonstrated a similar magnitude of effect and also showed that glycopyrronium was similar to open-label (OL) tiotropium over 52 weeks measured by improvements in trough FEV1 compared to placebo. In addition to demonstrating benefits in terms of lung function, glycopyrronium exhibited a rapid onset of action within five minutes at first dose and reduced exacerbations. Significant benefits in both breathlessness and health-related quality of life (HRQL), as measured by the Transition Dyspnea Index (TDI) and St. George's Respiratory Questionnaire (SGRQ) compared to placebo, were also demonstrated. GLOW2 was a 52-week, randomized, double-blind, placebo-controlled study with OL tiotropium 18 mcg as an active exploratory arm.(2)

The GLOW3 study showed that after glycopyrronium was administered in the morning, patients experienced improved exercise tolerance from the first dose onward. Overall, patients treated with glycopyrronium 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  $p < 0.001$ ). In all studies, glycopyrronium was shown to have an overall safety profile similar to placebo(3).

Seebri® Breezhaler® is a long-acting muscarinic antagonist (LAMA), a type of bronchodilator that is recommended in COPD global treatment strategies as maintenance therapy. Also approved in the EU for the maintenance bronchodilator treatment of airflow obstruction in adult patients with COPD is Novartis' product Onbrez® Breezhaler® (indacaterol maleate /150 mcg and 300 mcg once-daily doses), a long-acting beta2-adrenergic agonist (LABA)(4).

Novartis is currently developing a fixed-dose combination of glycopyrronium and indacaterol, QVA149, which is expected to be filed in the EU and Japan by the end of 2012. In addition, Novartis is committed to continue the study of glycopyrronium bromide in further clinical trials following this approval.

#### **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 LABA that is currently the only COPD maintenance treatment on the market to offer clinically relevant 24-hour bronchodilation combined with a rapid onset of action at first dose, as demonstrated in the INERGIZE Phase III/IV trial program(5-8). Onbrez® Breezhaler® is approved in more than 85 countries around the world. It was first launched in the EU (150 mcg and 300 mcg once-daily doses) and has since received approvals in markets worldwide including Japan (Onbrez® Inhalation Capsules 150 mcg once-daily) and US (Arcapta™ Neohaler™ 75 mcg once-daily).

Seebri® Breezhaler® (glycopyrronium bromide) is a LAMA developed as a once-daily inhaled maintenance therapy for the treatment of COPD. Glycopyrronium bromide was exclusively licensed to Novartis in April 2005 by Vectura and its co-development partner Sosei. Phase III data from the GLOW 1, 2 and 3 studies demonstrated that glycopyrronium increased patients' lung function over a 24-hour period compared to placebo with a fast onset of action at first dose, and improved exercise endurance versus placebo(1),(2),(3). The US filing for Seebri® Breezhaler® is expected in 2014.

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QVA149 is an investigational inhaled, once-daily, fixed-dose combination of indacaterol maleate and glycopyrronium bromide. QVA149 is being investigated for the maintenance treatment of COPD in the Phase III IGNITE clinical trial program. IGNITE is one of the largest international clinical trial programs in COPD comprising 10 studies in total with more than 7,000 patients across 42 countries(4),(9-20). The first five studies (ILLUMINATE, SHINE, BRIGHT, ENLIGHTEN, SPARK) have already completed in 2012 with three additional studies (BLAZE, ARISE, BEACON) expected to complete by the end of the year. The studies are designed to investigate efficacy, safety and tolerability, lung

function, exercise endurance, exacerbations, breathlessness and quality of life. Initial filings for regulatory approval are expected in Q4 2012 for Europe and Japan. US filing is expected at the end of 2014.

All Novartis inhaled COPD portfolio products are being developed for delivery via the Breezhaler® device, a single-dose dry powder inhaler (SDDPI), which has low air flow resistance, making it suitable for patients with airflow limitation, such as COPD patients. The Breezhaler® device allows patients to hear, feel and see that they have taken the drug correctly(4).

### **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(21) and is predicted to be the third leading cause of death by 2020(22). 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(23).

### **Disclaimer**

The foregoing release contains forward-looking statements that can be identified by terminology such as will, expected, commitment, developing, committed, being investigated, designed to, being developed, or similar expressions, or by express or implied discussions regarding potential additional marketing approvals for Novartis respiratory products 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 any Novartis respiratory products will obtain any additional marketing approvals. Nor can there be any guarantee that such products will achieve any particular levels of revenue in the future. In particular, management's expectations 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; unexpected manufacturing issues; 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 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



126,000 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: October 1, 2012

By: /s/ MALCOLM B. CHEETHAM

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