NOVARTIS AG
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SECURITIES AND EXCHANGE COMMISSION

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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 May 17, 2012

(Commission File No. 1-15024)

Novartis AG

(Name of Registrant)

Lichtstrasse 35

4056 Basel

Switzerland

(Address of Principal Executive Offices)

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Novartis International AG
Novartis Global Communications
CH-4002 Basel
Switzerland
http://www.novartis.com

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Novartis NVA237 Phase III data showed rapid, sustained improvement in lung function and symptom relief over one year in COPD patients

- *GLOW2 study showed NVA237 superior to placebo and similar to open-label tiotropium in increasing lung function, improving COPD symptoms and reducing exacerbations (1),(2),(3)*

- *Results demonstrated that once-daily NVA237 had rapid onset of action at first dose, sustained 24-hour bronchodilation, and was well tolerated over 52 weeks(1)*

- *NVA237 submitted for EU approval under proposed brand name Seebri® Breezhaler®; expect US filing in 2014*

- *COPD is predicted to be the third leading cause of death by 2020(4); NVA237 has the potential to provide patients an alternative choice of LAMA therapy*

Basel, May 17, 2012 Results from the pivotal Phase III GLOW2 study demonstrated that once-daily (QD) 50 mcg NVA237 (glycopyrronium bromide) was superior to placebo in improving lung function, symptom relief and quality of life, and reducing exacerbations over a one-year period(1),(2),(3). The data will be presented at the 2012 American Thoracic Society (ATS) International Conference May 18-23, 2012 in San Francisco, CA, USA.

The GLOW2 results affirm the potential for once-daily NVA237 to help patients manage their COPD symptoms and improve their quality of life, said Tim Wright, Head of Development, Novartis Pharmaceuticals. Novartis is committed to addressing the unmet needs of COPD patients by providing innovative medicines and devices, and the results of GLOW2 demonstrate that NVA237 could be the second innovative product in our COPD portfolio.

GLOW2 met its primary endpoint by demonstrating NVA237 provided superior 24-hour bronchodilation compared to placebo at 12 weeks measured by mean trough FEV_1 (97 mL; $p<0.001$)(1). At this same time point, trough FEV_1 for open-label (OL) tiotropium was 83 mL versus placebo ($p<0.001$)(1). In addition, NVA237 showed similar efficacy to OL tiotropium (Spiriva® HandiHaler®*/18 mcg) in patients with moderate-to-severe chronic obstructive pulmonary disease (COPD)(1). NVA237 also demonstrated rapid onset of action (within five minutes at

first dose) and sustained 24-hour bronchodilation over 52 weeks(1).

At Day 1, Week 26 and Week 52 of the GLOW2 study, NVA237 showed significantly improved lung function (measured by mean trough FEV1) compared to placebo (all $p<0.001$)(1) and results were similar to those seen with OL tiotropium(1). At Day 1 and Week 12, 26 and 52, the FEV1 area under the curve (AUC) for 0 4 hr, 0 12 hr, 12 24 hr, and 0 24 hr for NVA237 was superior to placebo ($p<0.05$) and numerically greater than OL tiotropium(1).

* Spiriva® HandiHaler® is a registered trademark by Boehringer Ingelheim Pharma Gmbh & Co. KG.

The study also demonstrated that NVA237 improved COPD symptoms and quality of life and reduced exacerbations(2),(3) compared to placebo. NVA237 significantly reduced breathlessness (measured by the transition dyspnea index or TDI, p=0.002), improved health-related quality of life (measured by the St George s Respiratory Questionnaire or SGRQ, p<0.001), reduced use of rescue medication (p=0.039), and increased the percentage of days with no daytime symptoms (p<0.05) compared to placebo over 52 weeks(2).

For these symptomatic and quality of life indicators, results were numerically similar to those observed with OL tiotropium over the same time period(2). NVA237 also significantly prolonged the time to first exacerbation and significantly reduced the rate of moderate/severe exacerbations versus placebo over 52 weeks (p=0.001); these effects were similar to OL tiotropium (p=0.001)(3).

Throughout the GLOW2 study, NVA237 was well-tolerated with a similar incidence of adverse events to placebo and OL tiotropium(3). Serious adverse events were reported less frequently with NVA237 (12.6%) than with either placebo (15.4%) or OL tiotropium (15.0%)(3).

GLOW2 was a 52-week double-blind, placebo-controlled, parallel-group study involving 1,066 patients to assess the efficacy, safety and tolerability of NVA237 in patients with COPD. Patients were randomized into three treatment arms receiving either once-daily NVA237 50 mcg or placebo (double-blind), or once-daily OL tiotropium 18 mcg. They were also permitted to use COPD background therapy and rescue medication(1),(2),(3).

Phase II clinical trial update

Results have recently been submitted for publication from the NVA237 Phase II A2208 study. This study comparing once-daily and twice-daily dosing regimens of NVA237 met its primary endpoint by demonstrating that all treatments (12.5 mcg, 25 mcg and 50 mcg given once or twice daily and 100 mcg once daily) provided statistically significant bronchodilation over the course of the day (measured by mean trough FEV_1 at Day 28) in patients with moderate-to-severe COPD compared to placebo(5).

Differences in lung function (measured by FEV_1 $AUC_{0\text{-}24h}$) between a single daily dose of NVA237 and the same total amount given twice daily were small and not clinically relevant(5). However once-daily dosing is known to offer the potential to improve patient adherence(6), an important consideration when selecting the optimum dosing regimen for a novel bronchodilator. Throughout the study, NVA237 showed an overall good safety profile and was well tolerated compared to placebo(5). The results of A2208 are consistent with previous NVA237 studies and support once-daily dosing of 50 mcg NVA237 in patients with moderate-to-severe COPD(1),(2),(3),(7),(8).

About NVA237

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. NVA237 is expected to be one of three innovative medicines in the Novartis COPD portfolio to be delivered using the Breezhaler® Single Dose Dry Powder Inhaler, along with Onbrez® Breezhaler® (indacaterol) and investigational QVA149 (indacaterol 110 mcg/glycopyrronium bromide 50 mcg).

Phase III data from the GLOW 1, 2 and 3 studies demonstrated that NVA237 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(1),(2),(3),(7),(8). 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, and expected US filing is the beginning of 2014.

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 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(9). 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.

The first four Novartis QVA149 Phase III studies in the treatment of COPD all met their primary endpoints(10),(11),(12),(13). 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(10),(11),(12),(13).

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(14) 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(15).

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as expect, predicted, potential, will, committed, expected, or similar expressions, or by express or implied discussions regarding potential marketing submissions or approvals for NVA237 and QVA149, or regarding the timing of any such submissions or approvals, or regarding potential future revenues from NVA237, QVA149 and 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 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 NVA237 or QVA149 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 NVA237, QVA149 or Onbrez 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 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.

References

(1) Kerwin E, et al. NVA237 once daily provides rapid and sustained bronchodilation in COPD patients, with efficacy similar to tiotropium: The GLOW2 trial. [Abstract A2920: Thematic poster session B41: Monday, 21 May, 2012; 08:15 16:30].

(2) Korenblat P, et al. NVA237 once daily improves dyspnea and health-related quality of life in patients with COPD: The GLOW2 trial. [Abstract A2254: Poster discussion session A101: Sunday, 20 May, 2012; 14:00 16:30].

(3) Kerwin E, et al. NVA237 once daily reduces COPD exacerbations with similar rates to tiotropium: The GLOW2 trial. [Abstract A2255: Poster discussion session A101: Sunday, 20 May, 2012; 14:00 16:30].

(4) Global Initiative for Chronic Obstructive Lung Disease (GOLD). Global Strategy for the Diagnosis, Management, and Prevention of Chronic Obstructive Pulmonary Disease. Updated December 2011. http://www.goldcopd.org/uploads/users/files/GOLD_Report_2011_Feb21.pdf Last accessed 9 May 2012.

(5) Arievich H, Overend T, Renard D, Gibbs M, Alagappan V, Banerji D. NVA237, an inhaled long-acting muscarinic antagonist: a dose-ranging study in patients with COPD. [Respir Res 2012. *manuscript in preparation*].

(6) Bourbeau J, Bartlett SJ. Patient adherence in COPD. Thorax 2008 Sep;**63**(9):831-8.

(7) D Urzo A, et al., Efficacy and safety of once-daily NVA237 in patients with moderate-to-severe COPD: the GLOW1 trial. Respiratory Research 2011, 12:156 (7 December 2011)

(8) Beeh K, Drollmann A, Di Scala L, Smith R. Once-daily NVA237 improves exercise endurance from first dose in patients with COPD: the GLOW3 trial. Eur Respir J 2011;**38**(Suppl. 55):P4497.

(9) Onbrez® Breezhaler® (indacaterol) EU Summary of Product Characteristics May 31, 2011 http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/001114/human_med_001219.jsp&mid=WC0b01ac058001d124.

(10) QVA149 2313 (ILLUMINATE). Data on file, Novartis Pharma AG. ClinicalTrials.gov identifier: NCT01315249.

(11) QVA149 A2303 (SHINE). Data on file, Novartis Pharma AG. ClinicalTrials.gov identifier: NCT01202188.

(12) QVA149 2305 (BRIGHT). Data on file, Novartis Pharma AG. ClinicalTrials.gov identifier: NCT01294787.

(13) QVA149 A2307 (ENLIGHTEN). Data on file, Novartis Pharma AG. ClinicalTrials.gov identifier: NCT01120717.

(14) Global Alliance Against Chronic Respiratory Diseases (GARD). Global surveillance, prevention and control of chronic respiratory diseases: a comprehensive approach. Available at: http://www.who.int/gard/publications/GARD%20Book%202007.pdf Last accessed 02 May 2012.

(15) Fletcher MJ *et al.,* COPD Uncovered: An International survey on the impact of chronic obstructive pulmonary disease (COPD) on a working age population. *BMC Public Health* 2011, 11:612.

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Novartis Media Relations

Central media line : +41 61 324 2200

Eric Althoff

Novartis Global Media Relations

+41 61 324 7999 (direct)

+41 79 593 4202 (mobile)

eric.althoff@novartis.com

Christina Clinton

Novartis Pharma Communications

+41 61 324 8682 (direct)

+41 79 483 4819 (mobile)

christina.clinton@novartis.com

e-mail: media.relations@novartis.com

For Novartis multimedia content, please visit www.thenewsmarket.com/Novartis For questions about the site or required registration, please contact: journalisthelp@thenewsmarket.com.

Novartis Investor Relations

Central phone:	+41 61 324 7944		
Susanne Schaffert	+41 61 324 7944	**North America:**	
Pierre-Michel Bringer	+41 61 324 1065	Helen Boudreau	+1 212 830 2404
Thomas Hungerbuehler	+41 61 324 8425	Jill Pozarek	+1 212 830 2445
Isabella Zinck	+41 61 324 7188	Edwin Valeriano	+1 212 830 2456

e-mail: investor.relations@novartis.com

e-mail: investor.relations@novartis.com

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:	May 17, 2012	By:	/s/ MALCOLM B. CHEETHAM
		Name:	Malcolm B. Cheetham
		Title:	Head Group Financial Reporting and Accounting