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FORM 6-K

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Novartis AG

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Novartis data at ERS shows efficacy of once-daily COPD portfolio versus comparators, further establishes dual-bronchodilator QVA149

- *QVA149 demonstrated superior bronchodilation compared to indacaterol 150 mcg, glycopyrronium 50 mcg, salmeterol/fluticasone 50/500 mcg BID, OL tiotropium 18 mcg and placebo(1),(2)*

- *Seebri® Breezhaler® (glycopyrronium bromide) demonstrated rapid, sustained bronchodilation and reduced exacerbations similar to OL tiotropium 18 mcg in GLOW pooled data analysis(3),(4)*

- *Onbrez® Breezhaler® (indacaterol maleate) was superior to OL tiotropium 18 mcg in improving severe breathlessness symptoms in pooled INERGIZE data(5)*

Basel, September 3, 2012 Further data from the Novartis once-daily chronic obstructive pulmonary disease (COPD) clinical trial programs were presented today at the European Respiratory Society (ERS) Congress. Overall, Novartis presented 14 abstracts, including data from the investigational QVA149 (fixed-dose combination of indacaterol maleate / glycopyrronium bromide) IGNITE Phase III clinical trial program, the glycopyrronium bromide (Seebri® Breezhaler®) GLOW Phase III clinical trial program and the indacaterol maleate (Onbrez® Breezhaler®) INERGIZE Phase III/IV clinical trial program. The data further demonstrated the potential of the Novartis COPD portfolio to provide once-daily, innovative treatment choices for patients and physicians.

Among the data presented, three new studies from the investigational QVA149 IGNITE Phase III clinical trial program (SHINE, ILLUMINATE and ENLIGHTEN) demonstrated that QVA149 significantly improved lung function compared to other COPD therapies(1),(2),(6). Data from the GLOW program showed that glycopyrronium 50 mcg once daily provided rapid and sustained bronchodilation, and reduced exacerbations and symptoms when compared to placebo, similar to the levels observed with open-label (OL) tiotropium 18 mcg(3),(4). Additionally, a new pooled-analysis from the INERGIZE studies showed that Onbrez® Breezhaler® 300 mcg was superior to OL tiotropium 18 mcg in improving breathlessness in COPD patients who had more severe breathlessness symptoms on entry to the studies ($p<0.05$)(5).

We are very excited that the Novartis data at ERS brings us one step further to delivering on the promise to provide COPD patients and physicians with a range of innovative treatments, said David Epstein, Head of Novartis Pharmaceuticals. These products are all being made available in the Breezhaler device which allows patients to hear, feel and see that they have taken the drug correctly.

IGNITE data demonstrated the efficacy of the dual-bronchodilator QVA149 (indacaterol maleate / glycopyrronium bromide) and showed a superior effect on lung function and patient-reported outcomes versus comparators(1),(2),(6)

SHINE met its primary endpoint by demonstrating that once-daily QVA149 110/50 mcg improved lung function as measured by trough FEV1 compared to once-daily indacaterol

maleate 150 mcg (+70mL above indacaterol alone; p<0.001) and once-daily glycopyrronium 50 mcg (+90mL above glycopyrronium alone; p<0.001)(1). QVA149 110/50 mcg is an investigational inhaled dry-powder fixed-dose combination medication that provides the equivalent amount of indacaterol as Onbrez (indacaterol maleate) 150 mcg along with glycopyrronium 50 mcg(7). QVA149 was also more effective at improving lung function compared to OL tiotropium 18 mcg (+80mL above tiotropium; p<0.001) and placebo (+200mL; p<0.001)(1). Mean peak FEV1 at Week 26 was also significantly higher with QVA149 compared to placebo (+330mL, p<0.001), indacaterol 150 mcg (+120mL; p<0.001), glycopyrronium 50 mcg (+130mL; p<0.001) and OL tiotropium 18 mcg (+130mL; p<0.001)(1). Mean FEV1 area under the curve (AUC) for 0 24hr at Week 26 was significantly higher with QVA149 compared to placebo (+320mL, p<0.001), indacaterol 150 mcg (+110mL; p<0.001), glycopyrronium 50 mcg (+110mL; p<0.001) and OL tiotropium 18 mcg (+110mL; p<0.001)(1).

The results also showed that QVA149 improved breathlessness measured by the transition dyspnea index or TDI (p<0.001 versus placebo; p<0.05 versus OL tiotropium 18 mcg), increased health-related quality of life (HRQoL) measured by the St George s Respiratory Questionnaire or SGRQ (p<0.01 versus placebo; p<0.05 versus OL tiotropium 18 mcg) and reduced rescue medication use (p<0.001 versus both placebo and OL tiotropium 18 mcg)(1). QVA149 was superior to indacaterol 150 mcg and glycopyrronium 50 mcg at reducing use of rescue medication (p<0.05 and p<0.001 respectively) and also provided numerically higher improvements in breathlessness and HRQoL compared to indacaterol 150 mcg and glycopyrronium 50 mcg(1).

ILLUMINATE compared QVA149 110/50 mcg to the twice-daily LABA/ICS salmeterol/fluticasone 50/500 mcg head-to-head over 26 weeks in patients with COPD (2). The study met its primary endpoint by demonstrating that the mean FEV1 area under the curve (AUC) for 0 12hr at Week 26 was significantly higher with QVA149 compared to salmeterol/fluticasone 50/500 mcg (+140mL; p<0.001)(2). Mean FEV_1 AUC_{0-12h} was also significantly higher with QVA149 versus salmeterol/fluticasone 50/500 mcg at Day 1 (+70mL; p<0.001)(2) and Week 12 (+120mL; p<0.001)(2). The ILLUMINATE trial also demonstrated that QVA149, in comparison to salmeterol/fluticasone 50/500 mcg, significantly improved breathlessness measured by TDI (p=0.003) and reduced rescue medication use (p=0.019) over 26 weeks(2).

ENLIGHTEN demonstrated the efficacy of QVA149 at improving lung function over a 52-week period by showing that QVA149 increased FEV1 and forced vital capacity (FVC) versus placebo at Day 1 and Weeks 3, 6, 12, 26, 39 and 52 (p<0.001)(6). At Week 52, the mean difference in FEV1 compared to placebo at 60 minutes post-dose was +257mL (p<0.001)(6).

QVA149 was generally well tolerated in the SHINE, ILLUMINATE and ENLIGHTEN trials with an incidence of adverse events that was similar between respective groups(1),(2),(6).

GLOW pooled analyses demonstrated that investigational glycopyrronium increased lung function, improved patient outcomes compared to placebo(3),(4)

Results of the first pooled analysis of GLOW1 and GLOW2 data demonstrated that patients on glycopyrronium 50 mcg experienced rapid, sustained and clinically meaningful bronchodilation over 52 weeks(3). The improvement in FEV1 was seen within five minutes after the first dose on Day 1 (+90mL at 5 minutes and +144mL at 15 minutes versus placebo; p<0.001) and was sustained throughout the 52-week period (p<0.001 vs. placebo)(3). FEV1 AUC for 0-4h, 0-12h, 0-24h and 12-24h for glycopyrronium 50 mcg was statistically significantly greater than placebo (p<0.05) and numerically greater than OL tiotropium 18 mcg (an exploratory arm in GLOW2) when compared to placebo on Day 1 and Weeks 12, 26 and 52(3). When compared to placebo, glycopyrronium 50 mcg was also numerically higher than OL tiotropium 18 mcg versus placebo at all-time points for trough FEV1 (Day 1 and Weeks 12, 26 and 52)(3).

The second pooled analysis of GLOW1 and GLOW2 data found that for patients taking glycopyrronium 50 mcg, the time to first moderate/severe exacerbation was significantly prolonged compared to placebo at both Week 26 (hazard ratio [HR] 0.64; p<0.001) and Week 52 (HR 0.67; p<0.001)(4). The results were comparable in patients treated with OL tiotropium 18 mcg. Glycopyrronium 50 mcg also significantly lowered the rate of moderate/severe exacerbations versus placebo at Weeks 26 and 52 (both rate ratio [RR] 0.66; p<0.005)(4).

Glycopyrronium 50 mcg improved breathlessness measured by TDI (p<0.05) and health-related quality of life measured by SGRQ (p<0.001) at Weeks 26 and 52(4). The results were similar to OL tiotropium 18 mcg compared to placebo(4).

INERGIZE pooled analysis showed indacaterol 300 mcg superior to OL tiotropium 18 mcg in improving breathlessness(5)

New results from a pooled post-hoc sub-group analysis from three studies (INVOLVE, INHANCE and INLIGHT2) showed that indacaterol maleate 300 mcg was statistically significantly more effective than OL tiotropium 18 mcg at improving breathlessness in patients who were more breathless on entry to the studies(5).

In patients with less severe breathlessness at the start of the study (mMRC score <2.0), both indacaterol maleate 150 mcg and 300 mcg were similarly effective at increasing trough FEV1, reducing breathlessness and improving health-related quality of life (measured by SGRQ) and were both superior to placebo (all p<0.05)(5). The results for the two indacaterol doses were similar to OL tiotropium 18 mcg compared to placebo(5). In patients with more severe breathlessness at the start of the studies (mMRC score ≥2.0), treatment with indacaterol maleate 150 mcg was more effective than placebo (p<0.05) at improving breathlessness (measured by TDI). Indacaterol maleate 300 mcg was also more effective than OL tiotropium 18 mcg at increasing trough FEV1 and improving breathlessness (both p<0.05)(5).

About the study designs

SHINE was 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 FEV1(1). Patients were randomized to receive QVA149, indacaterol maleate 150 mcg, glycopyrronium 50 mcg, OL tiotropium 18 mcg or placebo.

ILLUMINATE was a 26 week, multi-center, randomized, double-blind, double dummy, parallel-group study to assess the efficacy, safety and tolerability of once-daily QVA149 compared to twice-daily fixed dose combination of salmeterol/fluticasone 50/500 mcg in patients with moderate-to-severe stable COPD(2).

ENLIGHTEN was a 52 week, multicenter, randomized, double-blind, parallel-group, placebo controlled pivotal trial of 339 patients with moderate-to-severe COPD to assess the safety and tolerability of QVA149(6).

GLOW1 and **GLOW2** were multicenter, randomized, double-blind, placebo controlled, parallel group studies in patients with moderate-to-severe COPD. GLOW1 was a 26 week study with patients randomized to receive once-daily glycopyrronium 50 mcg or placebo. GLOW2 was a 52 week study with patients randomized to receive once-daily glycopyrronium 50 mcg or placebo, and included an exploratory arm to compare the effects of once-daily OL tiotropium 18 mcg versus placebo(3),(4).

The first pooled analysis assessed the efficacy of once-daily glycopyrronium 50 mcg versus placebo and once-daily OL tiotropium 18 mcg over 26 to 52 weeks in 1,888 patients with moderate-to-severe COPD from clinical trials (GLOW1 and GLOW2)(3). The second pooled analysis assessed the efficacy of once-daily glycopyrronium 50 mcg versus placebo and once-daily OL tiotropium 18 mcg at reducing COPD exacerbations,

symptoms and improving health status over 26 to 52 weeks in 1,854 patients from clinical trials (GLOW1 and GLOW2)(4).

INERGIZE data analysis compared data from three randomized studies (INVOLVE, INHANCE and INLIGHT2) in the clinical trial program which included 3,176 patients with moderate-to-severe COPD(5). The analysis assessed patients randomized to receive once-daily indacaterol maleate 150 mcg, once-daily indacaterol maleate 300 mcg, placebo or once-daily OL tiotropium 18 mcg for six months(5).

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 beta2-adrenergic agonist (LABA) that is currently the only COPD 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(8)-(11). 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).

Glycopyrronium bromide is an investigational 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 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(12)-(14). Glycopyrronium bromide was licensed to Novartis in April 2005 by Vectura and its co-development partner Sosei. In June 2012, the European Medicines Agency s Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion for the approval of glycopyrronium bromidein Europe under the brand name Seebri® Breezhaler®.

QVA149 is an investigational inhaled, once-daily, fixed-dose combination of indacaterol maleate and glycopyrronium bromide. QVA149 is being investigated for the 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(1),(2),(6),(15)-(21). 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 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(19).

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(22) and is predicted to be the third leading cause of death by 2020(23). 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(24).

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as potential, promise, committed, positive opinion, expected, being developed, or similar expressions, or by express or implied discussions regarding potential marketing submissions or approvals, or new indications or labeling for products in the Novartis COPD portfolio, 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 products in the Novartis COPD portfolio will be submitted or approved for sale in any market, or for any additional indications or labeling in any market. Nor can there be any guarantee that any of these products will achieve any particular levels of revenue in the future. In particular, management s expectations regarding the COPD portfolio 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; 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 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 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.

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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 3, 2012	By:	/s/ MALCOLM B. CHEETHAM
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