Novartis data presented at ERS showcases once-daily COPD portfolio and further demonstrates efficacy of Ultibro® Breezhaler® (QVA149)

- New analyses in the IGNITE clinical trial program showed that QVA149 provided superior, rapid and sustained improvements in lung function and significantly reduced shortness of breath versus comparator therapies1,2

- BLAZE study also demonstrated significant improvements in shortness of breath with QVA149 compared to tiotropium 18 mcg in patients with moderate-to-severe COPD3

- SPARK study showed similar rates of reduction in exacerbations with once-daily Seebri® Breezhaler® (glycopyrronium bromide) and open-label tiotropium 18 mcg in patients with severe-to-very severe COPD4,5

Basel, September 8, 2013 – Novartis announced today new analyses of data for once-daily Ultibro® Breezhaler® (investigational QVA149 - indacaterol 85 mcg/glycopyrronium 43 mcg delivered dose, equivalent to 110 mcg/50 mcg metered dose per capsule), which showed significant improvements in lung function, shortness of breath and health-related quality of life for chronic obstructive pulmonary disease (COPD) patients versus all comparators1,2. These data were part of 39 respiratory abstracts presented at the European Respiratory Society (ERS) Annual Congress in Barcelona, Spain.

First results from a pooled analysis of 4,891 COPD patients in the IGNITE clinical trial program (SHINE, ILLUMINATE and SPARK studies) showed that QVA149 provided superior, rapid and sustained improvements in lung function, and significantly reduced shortness of breath, compared to placebo, once-daily indacaterol maleate 150 mcg, glycopyrronium 50 mcg, open-label (OL) tiotropium 18 mcg and twice-daily salmeterol/fluticasone fixed dose combination (FDC SFC) 50 mcg/500 mcg1,2. These improvements were maintained throughout the duration of the trials1,2.

"COPD is known to affect an estimated 210 million people worldwide6 and is projected to be the third leading cause of death by 20207. Many patients find COPD symptoms really tough to cope with – even if they're already taking treatment," said Tim Wright, Head of Development, Novartis Pharmaceuticals. "Novartis is pleased that these new analyses further support that the efficacy of dual therapy, which has the potential to make a real difference to peoples' lives."

Currently being assessed in a clinical trial program involving over 10,000 patients8-18, investigational QVA149 is a Fixed-Dose Combination (FDC) of two bronchodilators, Onbrez® Breezhaler® (indacaterol maleate), a long-acting beta2-adrenergic agonist (LABA) and Seebri® Breezhaler® (glycopyrronium bromide), a long-acting muscarinic antagonist (LAMA). Both are currently used by healthcare professionals as individual therapies to treat COPD.

QVA149 recently received a positive opinion for approval from the European Medicine Agency's (EMA) Committee for the Human use of Medicinal Products (CHMP) in July
2013 as a maintenance bronchodilator treatment to relieve symptoms in adult patients with COPD.

About additional data presented at ERS
A new evaluation of patients with moderate-to-severe COPD from the BLAZE study showed that QVA149 provided significant improvements in patient-reported shortness of breath compared to tiotropium 18 mcg.

Clinical data for Seebri® Breezhaler® (glycopyrronium bromide) presented at ERS included efficacy and safety results from the SPARK study. At Week 64, once-daily glycopyrronium 50 mcg showed similar efficacy to OL tiotropium 18 mcg in reducing the rate of exacerbations, improving lung function and health-related quality of life, and reducing rescue medication use in patients with severe-to-very severe COPD.

In analyses from the SPARK study, glycopyrronium 50 mcg (via Breezhaler®) showed a safety profile in patients with severe-to-very severe COPD that was similar to OL tiotropium 18 mcg (via HandiHaler®).

These results build upon the data previously presented from the glycopyrronium bromide Phase III GLOW trials and provide further evidence for Seebri® Breezhaler® as a once-daily LAMA option for COPD patients.

About the IGNITE clinical trial program
In the Phase III IGNITE clinical trial program, QVA149 is being investigated for the treatment of COPD patients as an inhaled, once-daily, FDC of indacaterol maleate and glycopyrronium bromide. IGNITE is one of the largest international clinical trial programs in COPD comprising 11 studies in total (ILLUMINATE, SHINE, BRIGHT, ENLIGHTEN, SPARK, BLAZE, ARISE, BEACON, RADIATE, LANTERN, FLAME) with more than 10,000 patients across 52 countries. The first eight studies (ILLUMINATE, SHINE, BRIGHT, ENLIGHTEN, SPARK, BLAZE, ARISE, BEACON) completed in 2012. The studies are designed to investigate the efficacy, safety and tolerability, lung function, exercise endurance, exacerbations, shortness of breath and quality of life in patients treated with QVA149.

Results from the Phase III IGNITE trials demonstrated statistically significant improvements in bronchodilation with QVA149 versus comparator treatments widely used as current standards of care. Data showed that QVA149 significantly improved bronchodilation compared to OL tiotropium 18 mcg, SFC 50 mcg/500 mcg, indacaterol maleate 150 mcg, glycopyrronium 50 mcg and placebo providing a rapid onset within five minutes, and sustained bronchodilation during a 24 hour period which was maintained for up to 26 weeks. In the IGNITE Phase III trial program, QVA149 also showed symptomatic improvements versus placebo in COPD patients. These symptomatic improvements included shortness of breath, exercise tolerance, rescue medication use and health-related quality of life.

In clinical studies, QVA149 demonstrated an acceptable safety profile with no meaningful differences between the treatment groups (placebo, indacaterol 150 mcg, glycopyrronium 50 mcg, OL tiotropium 18 mcg, SFC 50 mcg/500 mcg) in the incidence of adverse and serious adverse events.

*Total refers to all 11 IGNITE studies.*

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 offers clinically relevant 24 hour bronchodilation combined with a rapid onset
of action within five minutes at first dose, as demonstrated in the INERGIZE Phase III trial program. Onbrez® Breezhaler® 150 mcg once-daily provided greater clinical benefit in terms of reduced shortness of breath, lower use of rescue medication and improved health status, compared with blinded tiotropium bromide 18 mcg in patients with moderate-to-severe COPD. Onbrez® Breezhaler® is approved in approximately 100 countries around the world for maintenance bronchodilator treatment of airflow obstruction in adult patients with COPD. 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).

Once-daily Seebri® Breezhaler® (glycopyrronium bromide) is a novel inhaled long-acting muscarinic antagonist (LAMA; also referred to as a long-acting anticholinergic) indicated as a maintenance bronchodilator treatment to relieve symptoms in adult patients with 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 50 mcg delivered rapid and significant sustained improvements in lung function (measured by mean FEV₁) from Day 1 compared with placebo and sustained this for 24 hours over 52 weeks, and significantly improved exercise endurance versus placebo. Seebri® Breezhaler® is approved in the EU/EEA, Japan, Switzerland, Canada, Australia and a number of other countries.

Novartis continues development of respiratory products for delivery via a single-dose dry powder inhaler (SDDPI) called the Breezhaler® device which has low air flow resistance, making it suitable for patients with different severity of airflow limitation. The Breezhaler® device allows patients to hear, feel and see that they have taken the full dose correctly.

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

About COPD
COPD is a progressive life-threatening disease that makes it hard to breathe, with symptoms that have a destructive impact on patients’ function and quality of life. It affects an estimated 210 million people worldwide and is projected to be the third leading cause of death by 2020. COPD is often considered to be a disease of later years, but estimates suggest that 50% of those with COPD are now less than 65 years old, resulting in increases in absenteeism, premature retirement and reductions in workforce participation.

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The foregoing release contains forward-looking statements that can be identified by terminology such as “investigational,” “projected,” “potential,” “currently being assessed,” “positive opinion,” “committed,” “continues development,” or similar expressions, or by express or implied discussions regarding marketing approvals for Ultibro Breezhaler or other investigational 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 Ultibro Breezhaler will be approved for sale in any market or at any particular time. Nor can there be any guarantee that any other investigational products will be submitted or approved for sale in any market or at any particular time. Neither can there be any guarantee that Ultibro Breezhaler or any other investigational products will achieve any particular levels of revenue in the future. In particular, management’s expectations regarding such 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 2012, the Group achieved net sales of USD 56.7 billion, while R&D throughout the 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 2012, the Group achieved net sales of USD 56.7 billion, while R&D throughout the Group amounted to approximately USD 9.3 billion (USD 9.1 billion excluding impairment and amortization charges). Novartis Group companies employ approximately 131,000 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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