Novartis showcases 39 abstracts highlighting robust respiratory portfolio at ERS 2013

- Robust efficacy of once-daily Ultibro® Breezhaler® (QVA149) supported by a pooled analysis of the Phase III IGNITE clinical trial program further strengthens evidence for the Ultibro® LABA+LAMA combination for the treatment of COPD patients1,2,3

- Once-daily Seebri® Breezhaler® (glycopyrronium) efficacy data strengthened by new analyses from the SPARK study on exacerbations and lung function in severe and very severe COPD patients4,5

- First data on investigational QGE031, a new, high-affinity anti-IGE therapy for severe allergic diseases6

Basel, September 4, 2013 – New data to be presented from the Novartis respiratory portfolio at the European Respiratory Society (ERS) Annual Congress 2013 in Barcelona, Spain, further demonstrates Novartis’ commitment to providing treatment options for patients with chronic obstructive pulmonary disease (COPD) or severe allergic asthma (SAA).

“Patients with COPD or severe allergic asthma, and the healthcare professionals that treat them, need effective treatment choices. Novartis is committed to providing a broad range of options to help reduce the significant burden of respiratory disease”, commented Tim Wright, Head of Development, Novartis Pharmaceuticals. “Novartis is very excited to be sharing important new data at ERS to further demonstrate the strength of our expanding respiratory portfolio and continued commitment to this therapeutic area.”

Data presented at ERS include the latest analyses from the Phase III IGNITE clinical trial program on Ultibro® Breezhaler® (QVA149 - indacaterol 85 mcg/glycopyrronium 43 mcg delivered dose, equivalent to 110 mcg/50 mcg metered dose per capsule)1,2,3. QVA149 is a once-daily investigational fixed dose combination of a long-acting beta2-adrenergic agonist (LABA) and a long-acting muscarinic antagonist (LAMA), that 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.

New exacerbation, lung function and safety data will also be presented on Seebri® Breezhaler® (glycopyrronium 44 mcg delivered dose equivalent to 50 mcg metered dose per capsule)4,5, and efficacy data on Onbrez® Breezhaler® (indacaterol maleate 150 mcg)7, which are the monotherapy components of QVA149.

In severe allergic asthma, new data will be presented on Xolair® (omalizumab), an anti-IgE monoclonal antibody indicated as an add-on therapy for patients with uncontrolled severe allergic (IgE–mediated) asthma. It is well recognized that omalizumab can significantly reduce the risk of exacerbations in patients with severe allergic asthma and
new studies are helping to better understand its effects on the processes that underlie the disease.

New clinical data relating to investigational QGE031 will be presented for the first time at ERS. QGE031 is a humanized anti-Immunoglobulin E monoclonal antibody in development for the treatment of IgE-driven diseases where a significant unmet need exists such as severe uncontrolled asthma, atopic dermatitis (AD) and food allergies.

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Alongside abstract presentations, Novartis will also be holding the following three symposia at ERS:

- Rethinking the treatment landscape of COPD: September 8 (17:15-19:15 CET, Room 3.13)
- The omalizumab story: Past, present and future: September 8 (17:15-19:15 CET, Room 3.12)
- Dual bronchodilation: A new treatment option for COPD patients: September 9 (17:15-19:15 CET, Room 3.13)
ERS is the largest respiratory meeting in the world, with delegates attending from more than 100 countries. All abstracts and details on timings can be accessed through the ERS website: http://www.erscongress2013.org.

About the Novartis respiratory portfolio

Novartis is committed to addressing the unmet medical needs of patients with respiratory diseases and improving their quality of life by providing innovative medicines and devices. In addition, the company is currently conducting more than 145 sponsor-led clinical trials involving more than 140,000 patients in support of regulatory submissions for new respiratory medicines. Novartis is consistently rated as having one of the industry’s most respected pharmaceutical development pipelines with more than 140 projects in pharmaceutical clinical development.

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.

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 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 efficacy, safety and tolerability, lung function, exercise endurance, exacerbations, shortness of breath and quality of life of patients treated with QVA149.

Results from the Phase III IGNITE trials demonstrated statistically significant improvements in bronchodilation with QVA149 versus certain treatments widely used as current standards of care. Data showed that QVA149 significantly improved bronchodilation compared to open-label (OL) tiotropium 18 mcg, salmeterol/fluticasone fixed dose combination (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 breathlessness, 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.

Novartis continues development of respiratory products for delivery via a platform called the Breezhaler® device. This is a single-dose dry powder inhaler (SDDPI), 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.

In 2003, the US Food and Drug Administration (FDA) approved Xolair® (omalizumab), an injectable therapy, for the treatment of patients 12 years of age and older with moderate-to-severe persistent allergic asthma that is inadequately controlled with inhaled corticosteroids. In 2005, the Committee for Medicinal Products for Human Use (CHMP) gave a positive opinion on the marketing authorization for Xolair for the treatment of severe persistent allergic asthma in adults and adolescents (≥12 years of age), who have multiple severe asthma exacerbations despite daily high dose inhaled corticosteroids plus a long acting beta agonist. This was followed by the European Commission granting marketing authorization for all 25 EU member states. In 2009, Novartis also received marketing approval for Xolair in the EU as an add on therapy to high dose inhaled corticosteroid (ICS) plus a LABA, to treat children aged 6 to <12 years with severe persistent allergic asthma.

Xolair is a humanized monoclonal antibody that blocks the action of immunoglobulin E (IgE), an antibody involved in the underlying mechanism of allergic asthma. In three pivotal trials involving 482, 525 and 546 patients respectively, by targeting IgE, Xolair was shown to significantly decrease the incidence of asthma exacerbations in severely affected patients when added to an ICS and LABA. Novartis co-promotes Xolair with Genentech/Roche in the US and shares a portion of the operating income, but does not book US sales.

*Total refers to all 11 IGNITE studies.

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.

About severe allergic asthma
Asthma is a chronic, inflammatory lung disease that is often triggered by allergies. Asthma is characterized by airway obstruction, resulting in the symptoms of chest tightness, wheezing and coughing.

Asthma affects around 300 million people globally and is one of the most common chronic diseases among children. For an estimated 5-8% of patients, symptoms are more severe. A proportion of asthmatic patients have their symptoms triggered when...
exposed to everyday allergens such as dust and mould – these patients have allergic asthma.57,59

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The foregoing release contains forward-looking statements that can be identified by terminology such as "showcases," "investigational," "will," "commitment," "to be presented," "committed," "to be sharing," "expanding," "positive opinion," "in development," "continues," "projected," "is being investigated," "designed to," "continues development," or similar expressions, or by express or implied discussions regarding potential marketing approvals for Ultibro Breezhaler or QGE031, or regarding potential future revenues from Ultibro Breezhaler, Seebri Breezhaler, Onbrez Breezhaler, Xolair or QGE031. 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 or QGE031 will be approved for sale in any market, or at any particular time. There can be no guarantee that Seebri Breezhaler, Onbrez Breezhaler or Xolair will be approved for any additional indications or labeling in any market, or at any particular time. Nor can there be any guarantee that Ultibro Breezhaler, Seebri Breezhaler, Onbrez Breezhaler, Xolair or QGE031 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 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.

Novartis is on Twitter. Sign up to follow @Novartis at http://twitter.com/novartis.

References
1. Vogelmeier C et al. Once-daily QVA149 provides clinically meaningful improvements in lung function and clinical outcomes. [ERS abstract 851178; Session 82; Date: September 8, 2013 Time: 12:50-14:40].
2. Banerji D et al. Dual bronchodilation with once-daily QVA149 improves dyspnea and health status and reduces symptoms and rescue medication use in patients with COPD: the IGNITE trials. [ERS abstract 851388; Session 346; Date: September 10 2013 Time: 8:30-10:30]
3. Banerji D et al. Dual bronchodilation with once-daily QVA149 improves lung function and reduces exacerbations in patients with COPD: the IGNITE trials. [ERS abstract 851415; Session 346; Date: September 10 2013 Time: 8:30-10:30].
4. Wedzicha JA et al. Once-daily glycopyrronium improves lung function and reduces exacerbations in severe-to-very severe COPD patients: the SPARK study. [ERS abstract 851270; Session 41; Date: September 8, 2013 Time: 8:30-10:30].
5. Decramer M et al. Safety of once-daily glycopyrronium in patients with severe-to-very severe COPD: the SPARK study. [ERS abstract 851279; Session 346; Date September 10, 2013 Time: 8:30-10:30].
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7. Kerstiens H et al. Once-daily indacaterol 150µg or 300µg and other bronchodilators in COPD patients of GOLD 2011 groups A and B. [ERS abstract 852515; Session 85; Date: August 8 2013 Time: 12:50-14:40].
8. Mahler D et al. Patients with severe COPD show significant improvements in dyspnea and lung function with once-daily QVA149: the BLAZE study. [ERS abstract 851256; Session 346; Date: September 10, 2013 Time: 8:30-10:30].
9. Ficker J et al. QVA149 improves lung function and reduces exacerbations compared to tiotropium in patients with severe-to-very severe COPD: the SPARK study. [ERS abstract 851282; Session 369; Date: September 10, 2013 Time: 10:45-12:45].
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35. Mahler D et al. Superior lung function with once-daily QVA149 translates into improvements in patient reported breathlessness compared with placebo and tiotropium in COPD patients: the BLAZE study. [ATS abstract 45308; Session C20; Date: May 21, 2013 Time: 8:15-10:45].
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