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 July 26, 2013

(Commission File No. 1-15024)

Novartis AG

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MEDIA RELEASE • COMMUNIQUE AUX MEDIAS • MEDIENMITTEILUNG

Novartis first in class once-daily dual bronchodilator Ultibro® Breezhaler® (QVA149) gains positive CHMP opinion for the treatment of COPD

- *QVA149 (indacaterol/glycopyrronium) is the first once-daily fixed-dose combination of both a LABA and a LAMA bronchodilator to gain positive CHMP opinion*

- *Pivotal Phase III IGNITE data showed QVA149 significantly improved lung function and patient-reported outcomes including breathlessness and rescue medication use, compared to current standard of care(1)*

- *QVA149 demonstrated significantly reduced rates of COPD exacerbations and improved health-related quality of life compared to open-label tiotropium 18 mcg and glycopyrronium 50 mcg*(2),(3)

Basel, July 26, 2013 Novartis announced today that the European Medicines Agency s Committee for Medicinal Products for Human Use (CHMP) has adopted a positive opinion for approval of once-daily Ultibro® Breezhaler® (indacaterol 85 mcg/glycopyrronium 43 mcg delivered dose, equivalent to 110 mcg/50 mcg metered dose per capsule), as a maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease (COPD). Ultibro Breezhaler was developed under the name of QVA149.

The CHMP s positive opinion supports a major breakthrough in the treatment of COPD, where many patients do not have adequate treatment options, commented David Epstein, Division Head, Novartis Pharmaceuticals. QVA149 has shown significant improvements compared with some of the most commonly used treatment options for COPD, which is projected to be the third leading cause of death by 2020.

QVA149 is an investigational fixed dose combination of two bronchodilators, indacaterol, a long-acting beta2-adrenergic agonist (LABA) and glycopyrronium, a long-acting muscarinic antagonist (LAMA).

QVA149 significantly improved the rate of all exacerbations compared to open-label (OL) tiotropium 18 mcg, glycopyrronium 50 mcg and was comparable to salmeterol/fluticasone (SFC) 50 mcg/500 mcg(3). The rate of moderate or severe exacerbations was significantly lower compared to glycopyrronium 50 mcg and numerically lower compared to OL tiotropium 18 mcg(2),(3).

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(2),(4),(5).

The European Commission generally follows the recommendations of the CHMP and normally grants a marketing authorization within three months of the opinion. Worldwide

submissions and reviews of QVA149 are ongoing with US filing expected at the end of 2014.

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, fixed-dose combination 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(3),(6-9),(10-17). The first eight studies (ILLUMINATE, SHINE, BRIGHT, ENLIGHTEN, SPARK, BLAZE, ARISE, BEACON) completed in 2012. The studies were 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 five of the Phase III IGNITE trials(3), (6-9) supported the CHMP s positive opinion for QVA149 which demonstrated statistically significant improvements in bronchodilation versus treatments widely used as current standards of care(1). 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, along with symptomatic improvements(1),(3),(7),(8). These symptomatic improvements included breathlessness, exercise tolerance, rescue medication use and health-related quality of life(3),(4),(5),(6).

**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-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(18-32). 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(28). Onbrez Breezhaler was first approved and launched in the EU (150 mcg and 300 mcg once-daily doses) for maintenance bronchodilator treatment of airflow obstruction in adult patients with COPD(33). It has now received approvals in approximately 100 countries around the world including Japan (as Onbrez® Inhalation Capsules 150 mcg once-daily) and USA (as 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(34). Glycopyrronium bromide was exclusively licensed to Novartis in April 2005 by Vectura and its co-development partner Sosei. In Phase III studies (GLOW 1, 2 and 3) Seebri Breezhaler (glycopyrronium 50 mcg) once-daily demonstrated rapid improvements in lung function after first dose on Day 1 which was sustained for 24 hours and maintained over the 52 week study period compared with placebo. Glycopyrronium 50 mcg

also significantly improved shortness of breath, health-related quality of life, exacerbation risk, and exercise endurance versus placebo(35),(36),(37). Seebri Breezhaler is approved in the EU, 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 airflow limitation(38). The Breezhaler® device allows patients to hear, feel and see that they have taken the full dose correctly(34).

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(39),(40). It affects an estimated 210 million people worldwide and is projected to be the third leading cause of death by 2020(40),(41). 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(42).

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as positive CHMP opinion, projected, investigational, generally follows, normally grants, ongoing, expected, is being investigated, designed to, committed, continues de similar expressions, or by express or implied discussions regarding potential marketing approvals for Ultibro Breezhaler or regarding potential future revenues from Ultibro 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 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 Ultibro Breezhaler will achieve any particular levels of revenue in the future. In particular, management s expectations regarding Ultibro Breezhaler 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.

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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: July 26, 2013

By: /s/ MALCOLM B. CHEETHAM

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