NOVARTIS AG
Form 6-K
October 01, 2012

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

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 October 1, 2012

(Commission File No. 1-15024)

Novartis AG

(Name of Registrant)

Lichtstrasse 35

4056 Basel

Switzerland

(Address of Principal Executive Offices)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F:

Form 20-F: x Form 40-F: o

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Indicate by check mark whether the registrant by furnishing the information contained in this form is also thereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934.

Yes: o **No**: x

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

MEDIA RELEASE • COMMUNIQUE AUX MEDIAS • MEDIENMITTEILUNG

Novartis receives European Commission approval for once-daily Seebri® Breezhaler® as maintenance COPD treatment in the EU

- *Seebri® Breezhaler® 44 mcg delivered dose approved for maintenance treatment of COPD will be available to patients and physicians in some EU markets by year-end*

- *In GLOW trials, Seebri® Breezhaler® improved lung function, reduced shortness of breath, reduced exacerbations, and improved quality of life up to 52 weeks versus placebo(1),(2),(3)*

- *GLOW2 study showed Seebri® Breezhaler® provided 24-hour bronchodilation and is superior to placebo and similar to open-label tiotropium in improving lung function(2)*

Basel, October 1, 2012 Novartis announced today that the European Commission has approved Seebri® Breezhaler® (glycopyrronium bromide) 44 mcg delivered dose (equivalent to 50 mcg glycopyrronium measured dose per capsule), as a once-daily inhaled maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease (COPD). This follows the September 28 approval of once-daily Seebri® (glycopyrronium bromide) Inhalation Capsules 50 mcg in Japan.

The approval of Seebri® Breezhaler® in the European Union is an exciting and critical milestone that provides physicians and patients with a new once-daily COPD therapy so they have the flexibility of having the right treatment for the right patient at the right time, said David Epstein, Division Head of Novartis Pharmaceuticals. We are proud that Novartis can deliver on our commitment to COPD patients and physicians by being the first company to offer two once-daily monotherapy bronchodilators with different modes of action, both delivered using Breezhaler devices.

The European Commission approved Seebri® Breezhaler® based on data from the Novartis Phase III GLOW trials which demonstrated the safety and efficacy of glycopyrronium 44 mcg and involved 1,996 COPD patients who required maintenance treatment from around the world, with many in EU countries(1),(2),(3).

The GLOW trials showed that glycopyrronium, when compared to placebo, significantly improved lung function over the first four hours after morning dosing and that this benefit was sustained for 24 hours over a 52-week period(2). Patients on glycopyrronium demonstrated improved

lung function, reduced shortness of breath, reduced exacerbations, reduced use of rescue medication, improved quality of life and improved exercise tolerance compared to placebo(1),(2),(3).

GLOW1 was a 26-week, randomized, double-blind, placebo-controlled study. The study demonstrated the clinically sig