

NOVARTIS AG
Form 6-K
September 26, 2011

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 September 25, 2011

(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:

Edgar Filing: NOVARTIS AG - Form 6-K

Form 20-F: ☒ **Form 40-F:** ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):

Yes: ☐ **No:** ☒

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7):

Yes: ☐ **No:** ☒

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: ☐ **No:** ☒

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

- Investor Relations Release -

Novartis study shows QTI571 significantly improved walking distance in patients with life-threatening pulmonary arterial hypertension

- *Phase III IMPRES study demonstrates potential benefits of QTI571 in patients who remain symptomatic despite treatment with two or more PAH therapies(1)*
- *Evidence indicates that QTI571 targets an underlying cause of PAH by counteracting uncontrolled growth of arterial smooth muscle cells(2)*
- *PAH is a debilitating disease of the heart and lungs affecting up to 260,000 people worldwide(3) leading to heart failure and death(4),(5)*

Basel, September 25, 2011 Novartis announced new data today from the pivotal Phase III IMPRES clinical trial showing that the investigational therapy QTI571 (imatinib) significantly improved exercise capacity in patients with pulmonary arterial hypertension (PAH) after 24 weeks compared with placebo(1). Evidence indicates that QTI571 targets an underlying cause of PAH by counteracting uncontrolled growth of arterial smooth muscle cells(2).

The IMPRES study met its primary endpoint by demonstrating a significant improvement in the six-minute walk distance (6MWD) test in patients with elevated pulmonary vascular resistance (PVR) despite treatment with two or more specific PAH vasodilator therapies(1). The 6MWD is a predictor of survival in PAH patients(6),(7), and is commonly used to assess exercise capacity in PAH clinical trials(8),(9),(10). In the study, patients treated with QTI571 increased their mean 6MWD by 31.8 meters compared with placebo ($p=0.002$)(1).

The study's secondary endpoints showed that QTI571 produced statistically significant improvements compared to placebo in pulmonary arterial pressure, cardiac output and pulmonary vascular resistance (all $p<0.001$)(1), but not in time to clinical worsening (i.e. death, hospitalization due to PAH, worsening of functional class, or $\geq 15\%$ drop in 6MWD) ($p=0.563$)(1).

These results are impressive as they were achieved in patients who were already receiving two or more established PAH drugs, said Marius Hoepfer MD, Associate Professor, Department of Respiratory Medicine at Hannover Medical School, Germany and principal investigator of the IMPRES study. The data were presented for the first time at the European Respiratory Society (ERS) Annual Congress in Amsterdam, The Netherlands.

PAH is a debilitating disease of the heart and lungs that is characterized by a marked and sustained elevation in pulmonary artery pressure. The disease is chronic and rapidly progressive, and can result in right ventricular heart failure and death(4),(5). An estimated 260,000 people are affected worldwide(3) and approximately half of the people diagnosed with PAH die within five years(5),(11).

If approved, QTI571 has the potential to provide a further treatment option for patients where current therapies are not providing sufficient benefit in the treatment of this life-threatening disease, said Trevor Mundel, Global Head of Development in the Pharmaceuticals Division of Novartis. Novartis has a strong and growing portfolio of respiratory medicines, and we are committed to expanding the support we offer to patients suffering from a number of respiratory and pulmonary disorders.

QTI571 is an oral therapy that works by inhibiting the activity of proliferative factors including platelet-derived growth factor (PDGF) which is thought to be involved, along with its receptor, in the progression of PAH(11),(12). In patients with this disease, PDGF may cause smooth muscle cells in the pulmonary arteries to multiply, restricting blood flow and increasing resistance in these arteries(13).

Safety data showed that the overall incidence of adverse events was similar for QTI571 and for placebo(1). Serious adverse events and discontinuations due to serious adverse events were more frequent with QTI571(1). Adverse events were as expected for this patient population and class of drug, and were similar to those previously reported with QTI571(14).

IMPRES was a 24-week randomized placebo-controlled, double-blind, multi-center clinical trial evaluating the efficacy and safety of oral QTI571 as an add-on therapy in the treatment of patients with PAH(1). The study involved a total of 202 patients with elevated PVR of ≥ 800 dynes.sec.cm⁻⁵ despite treatment with at least two other specific PAH medications (i.e. endothelin receptor antagonists, phosphodiesterase-5 inhibitors and/or prostacyclins)(1).

Treatment was initiated at a dose of 200 mg once-daily, which was increased to 400 mg once-daily after two weeks if well tolerated. The dose could be reduced to 200 mg once-daily if treatment was not well tolerated(1).

QTI571 is currently not approved to treat PAH and is planned to be submitted for regulatory approval later this year for the treatment of this disease. Imatinib, the active ingredient in QTI571, is currently available under the trade names Glivec® and Gleevec® for use in certain oncology indications.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as potential, can, estimated, committed, planned, or similar expressions, or by express or implied discussions regarding potential marketing approvals for QTI571 or regarding potential future revenues from QTI571. 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 with QTI571 to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that QTI571 will be approved for sale in any market. Nor can there be any guarantee that QTI571 will achieve any particular levels of revenue in the future. In particular, management's expectations regarding QTI571 could be affected by, among other things, unexpected clinical trial results, including unexpected new clinical data and unexpected additional analysis of existing clinical data; the company's ability to obtain or maintain patent or other proprietary intellectual property protection; unexpected regulatory actions or delays or government regulation generally; competition in general; government, industry and general public pricing pressures; 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 healthcare solutions that address the evolving needs of patients and societies. Focused solely on healthcare, Novartis offers a diversified portfolio to best meet these needs: innovative medicines, eye care, cost-saving generic pharmaceuticals, consumer health products, preventive vaccines and diagnostic tools. Novartis is the only company with leading positions in these areas. In 2010, the Group's continuing operations achieved net sales of USD 50.6 billion, while approximately USD 9.1 billion (USD 8.1 billion excluding impairment and amortization charges) was invested in R&D throughout the Group. Headquartered in Basel, Switzerland, Novartis Group companies employ approximately 121,000 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) Hoeper M, et al. Imatinib in pulmonary arterial hypertension, a randomized, efficacy study (IMPRES). Data presented at the European Respiratory Society (ERS) Annual Congress. Abstract No. 413. Presented 25th September 2011, 12.15, Room D203-204.
- (2) Schermuly RT, et al. Reversal of experimental pulmonary hypertension by PDGF inhibition. *J Clin Invest* 2005;115:2811-21.
- (3) Novartis data analysis.
- (4) Desai SA, Channick RN. Exercise in patients with pulmonary arterial hypertension. *J Cardiopulm Rehabil Prev* 2008;28:12-16.
- (5) Chin KM, Rubin LJ. Pulmonary arterial hypertension. *J Am Coll Cardiol* 2008;51:1527-38.
- (6) Provencher S, et al. Long-term outcome with first-line bosentan therapy in idiopathic pulmonary arterial hypertension. *Eur Heart J* 2006;27:589-95.
- (7) Miyamoto S, et al. Clinical correlates and prognostic significance of six-minute walk test in patients with primary pulmonary hypertension. Comparison with cardiopulmonary exercise testing. *Am J Respir Crit Care Med* 2000;161:487-492.
- (8) Rubin LJ, et al. Bosentan therapy for pulmonary arterial hypertension. *N Engl J Med* 2002;346:869-903.
- (9) Galiè N, et al. Sildenafil citrate therapy for pulmonary arterial hypertension. *N Engl J Med* 2005;353:2148-2157.
- (10) Barst RJ, et al. A comparison of continuous intravenous epoprostenol (prostacyclin) with conventional therapy for primary pulmonary hypertension. *N Engl J Med* 1996;334:296-301.
- (11) Barst RJ. PDGF signaling in pulmonary arterial hypertension. *J Clin Invest*. 2005;115:2691-2694.
- (12) Grimminger F, Schermuly RT. PDGF receptor and its antagonists: role in treatment of PAH. *Adv Exp Mol Biol* 2010;661:435-446.
- (13) Balasubramaniam V, et al. Role of platelet-derived growth factor in vascular remodeling during pulmonary hypertension in the ovine fetus. *Am J Physiol Lung Cell Mol Physiol* 2003;284:L826-833.
- (14) Ghofrani A, et al. Imatinib in pulmonary arterial hypertension patients with inadequate response to established therapy. *Am J Respir Crit Care Med* 2010;182:1171-1177.

###

Novartis Media Relations

Central media line : +41 61 324 2200

Eric Althoff

Novartis Global Media Relations

John Taylor

Novartis Pharma Communications

Edgar Filing: NOVARTIS AG - Form 6-K

+41 61 324 7999 (direct)
+41 79 593 4202 (mobile)
eric.althoff@novartis.com

+41 61 324 6715 (direct)
+41 79 593 4279 (mobile)
john.taylor@novartis.com

e-mail: media.relations@novartis.com

For Novartis multimedia content, please visit www.thenewsmarket.com/Novartis

For questions about the site or required registration, please contact: journalisthelp@thenewsmarket.com.

Novartis Investor Relations

Central phone: +41 61 324 7944
Susanne Schaffert +41 61 324 7944
Pierre-Michel Bringer +41 61 324 1065
Thomas Hungerbuehler +41 61 324 8425
Isabella Zinck +41 61 324 7188

e-mail: investor.relations@novartis.com

North America:
Richard Jarvis +1 212 830 2433
Jill Pozarek +1 212 830 2445
Edwin Valeriano +1 212 830 2456

e-mail: investor.relations@novartis.com

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 25, 2011

By: /s/ MALCOLM B. CHEETHAM

Name: Malcolm B. Cheetham

Title: Head Group Financial
Reporting and Accounting