NOVARTIS AG
Form 6-K
December 07, 2010

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 December 6, 2010

(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

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: o **No**: x

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: o **No**: x

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

- Investor Relations Release -

Novartis Phase II LBH589 data show substantial disease control and tumor reduction in extensively pretreated Hodgkin lymphoma patients

- *LBH589 (panobinostat) shows sustained anticancer activity in Hodgkin lymphoma patients who relapse or are refractory after autologous stem cell transplant*

- *High unmet treatment need exists for patients who relapse or become refractory after initial treatment; patients are often in their mid-thirties or younger*

- *Worldwide regulatory filings are planned based on study findings*

Basel, December 6, 2010 The Novartis oral investigational drug LBH589 (panobinostat) demonstrated substantial disease control and tumor reduction in extensively pretreated Hodgkin lymphoma patients who had relapsed or had become refractory after an autologous stem cell transplant, according to new data from a Phase II clinical trial presented today(1).

In this pivotal single-arm study, one of the largest ever conducted in this patient population, 82% (n=106) of patients, most in their fifth line of therapy or beyond, achieved disease control (defined as stable disease or better) and 74% (n=96) achieved tumor reduction at a median follow-up of 9.6 months, demonstrating the sustained anticancer activity of LBH589. Partial and complete responses to treatment, the primary endpoint, were observed in 27% of patients (n=35), with a median duration of response of 6.9 months and a median progression-free survival measured at 10.5 months among those 35 patients(1).

These data were presented today at the 52nd Annual Meeting and Exposition of the American Society of Hematology (ASH) in Orlando, Florida. Worldwide regulatory filings are planned based on the study results.

Currently, up to 35% of patients with Hodgkin lymphoma relapse or become refractory after initial treatment, which typically involves at least two regimens of combination chemotherapy along with high-dose chemotherapy and stem cell transplant(2). Most patients enrolled in this study had received nearly all of the chemotherapy drugs known to be active in this disease, and 79% had failed an additional round of chemotherapy after a stem cell transplant. In addition, 10% of patients had also received prior allogeneic stem cell transplantations (stem cells from another person) in addition to an autologous transplant (stem cells from the patient). Palliative care is currently the only option remaining for these patients(3),(4).

It s impressive to see this response to LBH589 in patients, many of whom have received multiple courses of chemotherapy, said Anna Sureda, MD, Clinical Hematology Division, Hospital de la Santa Creu i Sant Pau, Barcelona, Spain. The responses suggest LBH589, which has a very different mechanism of action than chemotherapy, has the potential to become a valuable treatment option for these patients.

LBH589 is an oral pan-deacetylase (DAC) inhibitor, which targets changes in gene function (also known as epigenetic regulation) that regulate processes in the development of cancer, including proliferation and survival of Hodgkin lymphoma cells in laboratory studies(5). A Phase III clinical trial (PATH: PAnobinostat Trial in Hodgkin s lymphoma) has begun enrollment, investigating the drug as a maintenance therapy following autologous stem cell transplant in patients with Hodgkin lymphoma who have an increased risk for relapse(6). The clinical development program for LBH589 also includes an ongoing Phase III clinical trial in multiple myeloma and early-stage trials in acute myeloid leukemia and myelodysplastic syndromes.

These positive findings for LBH589 are encouraging for many Hodgkin lymphoma patients who currently lack effective treatments, said Alessandro Riva, Global Head, Oncology Development & Medical Affairs, Novartis Oncology. Patients who are not cured by autologous stem cell transplant and have stopped responding to chemotherapy have an urgent unmet medical need for novel therapeutic options. We are committed to the rapid development of this promising compound for these patients.

Hodgkin lymphoma is most commonly diagnosed in teenagers and adults between the ages of 15 and 35 and in adults over 50(7). It is the third most common cancer in people under the age of 20(8). Treatment options for Hodgkin lymphoma typically involve an initial round of combination chemotherapy, but standard frontline treatments do not lead to long-term disease-free survival in all patients(3),(4). When a patient relapses or becomes refractory, treatment options include high-dose chemotherapy, usually followed by stem cell transplantation(3),(4). The use of transplantation has resulted in improved outcomes in patients with relapsed disease, but still 40% to 50% of these patients subsequently relapse(2). There is currently no standard of care for patients who relapse or are refractory following these treatments(3),(4).

Study details

This Phase II clinical trial evaluated the efficacy and safety of oral LBH589 in patients with refractory/relapsed classical Hodgkin lymphoma who had received prior treatment with high dose chemotherapy and autologous stem cell transplant(9).

The primary outcome measure was objective response rate to therapy. Secondary outcome measures included response rate based on central review of CT scan/MRI, time to response, duration of response, progression-free survival rate and safety and tolerability of treatment(9).

As of the data analysis, 129 patients had been enrolled and treated. Patients had received a median number of four (range 2-7) prior systemic regimens, including combination regimens involving drugs such as gemcitabine, vinca-alkaloids or platinum-based chemotherapies. At a median follow-up of 9.6 months, a reduction in measurable tumor size was observed in 96 (74%) patients; responses were observed in 35 patients (5 complete responses, 30 partial responses; overall response rate 27%). Median progression-free survival was 6.1 months (10.5 months among responders)(1).

Common adverse events (mostly grade 1 or 2) included diarrhea, nausea, fatigue, vomiting, anorexia, dysguesia, asthenia, constipation, leucopenia and muscle spasms. Common related grade 3/4 adverse events included thrombocytopenia, anemia and neutropenia. Thrombocytopenia was reversible with dose hold or modification and was manageable long term, with only 5% treatment discontinuation for this reason. The overall rate of discontinuation due to adverse events was 16%(1).

About LBH589

Because it is an investigational compound, the safety and efficacy profile of LBH589 has not yet been established. Access to this investigational compound is available only through carefully controlled and monitored clinical trials. These trials are designed to better understand the

potential benefits and risks of the compound. Because of uncertainty of clinical trials, there is no guarantee that LBH589 will ever be commercially available anywhere in the world.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as planned, investigational, potential, investigating, ongoing, encouraging, committed, promising, or similar expressions, or by express or implied discussions regarding potential future approvals to market LBH589, or regarding potential future revenues from LBH589. 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 LBH589 will be submitted or approved for sale in any market, or that LBH589 will achieve any particular revenue levels. In particular, management s expectations could be affected by, among other things, unexpected clinical trial results, including unexpected new clinical data and unexpected additional analysis of existing clinical data; unexpected regulatory actions or delays or government regulation generally; competition in general; government, industry and general public pricing pressures; 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 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, cost-saving generic pharmaceuticals, preventive vaccines, diagnostic tools and consumer health products. Novartis is the only company with leading positions in these areas. In 2009, the Group s continuing operations achieved net sales of USD 44.3 billion, while approximately USD 7.5 billion was invested in R&D activities throughout the Group. Headquartered in Basel, Switzerland, Novartis Group companies employ approximately 100,000 full-time-equivalent associates and operate in more than 140 countries around the world. For more information, please visit http://www.novartis.com.

References

(1) Sureda A, Younes A, Ben-Yehuda D, et al. Final analysis: Phase II study of oral panobinostat in relapsed/refractory Hodgkin lymphoma patients following autologous hematopoietic stem cell transplant. 52nd ASH Annual Meeting and Exposition. 2010. Abstract #169. Available at http://ash.confex.com/ash/2010/webprogram/Paper34050.html. Accessed November 2010.

(2) McBride NC, Cavenagh JD, Ward MC, et al. Liposomal daunorubicin (DaunoXome) in combination with cyclophosphamide, vincristine and prednisolone (COP-X) as salvage therapy in poor-prognosis non-Hodgkins lymphoma. Leuk Lymphoma. 2001Jun;42(1-2):89-98.

(3) NCCN Clinical Practice Guidelines in Oncology Hodgkin Lymphoma. V.2.2010. Available at http://www.nccn.org/professionals/physician_gls/PDF/hodgkins.pdf. Accessed November 2010.

(4) Engert A, Eichenauer DA, Dreyling M; on behalf of the ESMO Guidelines Working Group. Hodgkin s lymphoma: ESMO Clinical Recommendations for diagnosis, treatment and follow-up. Ann Oncol. 2009;20 suppl 4: iv108-iv109.

(5) Younes A, Ong, T-C, Ribrag V, et al. Efficacy of panobinostat in Phase II study in patients with relapsed/refractory Hodgkin lymphoma (HL) after high-dose chemotherapy with autologous stem cell transplant. Blood (ASH Annual Meeting Abstracts), 2009;114:923.

(6) A Phase III randomized, double blind, placebo controlled multi-center study of panobinostat for maintenance of response in patients with Hodgkin s lymphoma. Available at http://www.clinicaltrials.gov/ct2/show/NCT01034163 Accessed November 2010.

(7) Straus D. Relapsed and refractory Hodgkin lymphoma. Lymphoma Research Foundation. Available at http://www.lymphoma.org/atf/cf/%7B0363cdd6-51b5-427b-be48-e6af871acec9%7D/HL09RELREF.PDF. Accessed November 2010.

(8) The Leukemia & Lymphoma Society. Hodgkin lymphoma facts & statistics. Available at http://www.leukemia-lymphoma.org/all_page.adp?item_id=8312 Accessed November 2010.

(9) Phase II study of oral panobinostat in adult patients with relapsed/refractory classical Hodgkin s lymphoma. Available at http://www.clinicaltrials.gov/ct2/show/NCT00742027. Accessed November 2010.

# # #

Novartis Media Relations

Central media line : +41 61 324 2200

Eric Althoff	**Denise Brashear**
Novartis Global Media Relations	Novartis Oncology
+41 61 324 7999 (direct)	+1 862 778 7336 (direct)
+41 79 593 4202 (mobile)	+1-862-324-5772 (mobile)
eric.althoff@novartis.com	denise.brashear@novartis.com

e-mail: media.relations@novartis.com

Novartis Investor Relations

Central phone:	+41 61 324 7944	**North America:**	
Susanne Schaffert	+41 61 324 3769	Richard Jarvis	+1 212 830 2433
Pierre-Michel Bringer	+41 61 324 1065	Jill Pozarek	+1 212 830 2445
Thomas Hungerbuehler	+41 61 324 8425	Edwin Valeriano	+1 212 830 2456
Isabella Zinck	+41 61 324 7188		

e-mail: investor.relations@novartis.com

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: December 6, 2010	By:	/s/ MALCOLM B. CHEETHAM
	Name:	Malcolm B. Cheetham
	Title:	Head Group Financial Reporting and Accounting