

NOVARTIS AG  
Form 6-K  
December 02, 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 1, 2010**

(Commission File No. 1-15024)

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**Novartis AG**

(Name of Registrant)

**Lichtstrasse 35**

**4056 Basel**

**Switzerland**

(Address of Principal Executive Offices)

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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:**  **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:

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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:

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**Novartis International AG**

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**- Investor Relations Release -**

**Data at ASH, SABCS demonstrate commitment of Novartis R&D in advancing treatments for patients with cancer and rare diseases**

- *24-month update on Phase III data comparing Tasigna® to Glivec® in patients with newly diagnosed Ph+ chronic myeloid leukemia in chronic phase*
- *Afinitor® plus hormonal therapy studied in patients with ER+/HER2- metastatic breast cancer with prior exposure to aromatase inhibitors*
- *Zometa® studies continue to explore anticancer effect in multiple myeloma and breast cancer*
- *Pipeline advances with presentations on multiple investigational compounds, including pivotal results for LBH589 in relapsed/refractory Hodgkin lymphoma*

**Basel, December 1, 2010** With more than 170 presentations focused on its marketed and pipeline compounds at key oncology medical congresses in December, Novartis continues to demonstrate progress of its innovative research and development efforts, collaboration with the scientific community and commitment to patients with cancer and rare diseases(1),(2).

The American Society of Hematology (ASH) annual meeting in Orlando, FL (December 4-7) will feature 30 oral presentations on Novartis Oncology compounds including Tasigna® (nilotinib), Glivec® (imatinib)(1), Afinitor® (everolimus), Exjade® (deferasirox), Zometa® (zoledronic acid) and LBH589 (panobinostat)(1). The San Antonio Breast Cancer Symposium (SABCS), beginning December 8, will feature presentations on everolimus and Zometa(2).

These data highlight progress of our hematology and oncology research with a focus on developing new treatment approaches based on an understanding of the molecular pathways involved in diseases, said Hervé Hoppenot, President of Novartis Oncology. Our goal is to bring the

right treatment to the right patient across a broad range of cancers and rare diseases.

Key presentations at ASH include:

- **Tasigna** ENESTnd 24-month update comparing Tasigna to Glivec in patients with newly diagnosed Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia in chronic phase (ASH Abstract #207; Dec. 6; 7:30 AM EST) (3).
- **Afinitor** Two studies showing activity of everolimus in mantle cell lymphoma (ASH Abstract #2803; Dec. 5; 6:00-8:00 PM EST)(4); (ASH Abstract #3963; Dec. 6; 6:00-8:00 PM EST)(5).

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(1) Known as Gleevec® (imatinib mesylate) tablets in the US, Canada and Israel.

- **Exjade** EPIC sub-studies presenting three-year, end-of-study data on cardiac iron removal (ASH Abstract #4276; Dec. 6; 6:00-8:00 PM EST)(6) and post-hoc analysis from a large study reporting hematologic response in a cohort of MDS patients (ASH Abstract #2912; Dec. 5; 6:00-8:00 PM EST)(7); the first study (109E) to report on long-term safety and efficacy in sickle-cell disease patients up to five years (ASH Abstract #845; Dec. 6; 7:15 PM EST)(8); and the first large study (107E/108E) to assess effect of iron chelation therapy on liver pathology in large cohort of beta-thalassemia patients (ASH Abstract #4274; Dec. 6; 6:00-8:00 PM EST)(9).
- **Zometa** Phase III data evaluating Zometa in the treatment of patients with newly diagnosed multiple myeloma (ASH Abstract #311; Dec. 6; 8:00 AM EST)(10).
- **LBH589 (panobinostat)** Pivotal Phase II data for LBH589 in the treatment of Hodgkin lymphoma patients who relapse or are refractory after autologous stem cell transplant (ASH Abstract #419; Dec. 6; 11:30 AM EST)(11).
- **INC424(2)** Phase II data showing response rates to INC424 in patients with polycythemia vera (ASH Abstract #313; Dec. 6; 7:00 AM EST)(12); Phase II data of INC424 in patients with refractory leukemias including post-myeloproliferative disorder and acute myeloid leukemia (ASH Abstract #509; Dec. 6; 3:45 PM EST)(13).
- **PKC412 (midostaurin)** Phase II data evaluating midostaurin in the treatment of aggressive systemic mastocytosis (ASH Abstract #316; Dec. 6; 7:45 AM EST)(14).
- **HCD122 (lucatumumab)** Clinical activity evaluated in patients with relapsed/refractory Hodgkin or non-Hodgkin lymphoma treated in a Phase Ia/II trial (ASH Abstract #284; Dec. 6; 7:15 AM EST)(15).

Key presentations at SABCS include:

- **Afinitor** TAMRAD Phase II data on everolimus in the treatment of ER+/HER2- metastatic breast cancer after failure of aromatase inhibitors (SABCS Abstract #S1-6; Dec. 9; 10:30 AM CST)(16).
- **Zometa** Phase III data from the AZURE trial (BIG 01/04) of adjuvant treatment with Zometa in stage II/III breast cancer (SABCS Abstract #S4-5; Dec. 10; 4:15 PM CST)(17); Phase III data analyses from the ABCSG-12 trial evaluating the carry-over effect of Zometa in premenopausal women with early breast cancer after completion of therapy (SABCS Abstract #P5-11-02; Dec. 11; 5:30-7:30 PM CST)(18).
- **BEZ235** Clinical data from a dose-escalation study with a special drug delivery system of BEZ235 in patients with metastatic/advanced solid tumors (SABCS Abstract #P6-15-07; Dec. 12, 7:00-8:30 PM CST)(19).

**About Tasigna**

Tasigna has also been approved in more than 80 countries for the treatment of chronic phase (CP) and accelerated phase Ph+ CML in adult patients resistant or intolerant to at least one prior therapy, including Glivec. The effectiveness of Tasigna for this indication is based on confirmed hematologic and unconfirmed cytogenetic response rates. There are no controlled trials demonstrating a clinical benefit, such as improvement in disease-related symptoms or increased survival.

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(2) INC424, also known as INCB018424, is being developed collaboratively by Incyte and Novartis. Novartis has licensed the rights to INC424 outside the United States. Incyte maintains the rights within the United States.

Tasigna is not approved in the EU for the treatment of newly diagnosed Ph+ CML-CP.

### **Tasigna important safety information**

Tasigna should be taken twice daily at an interval of approximately 12 hours apart and must not be taken with food. No food should be consumed for two hours before the dose and for at least one hour after the dose. Avoid grapefruit juice and other foods that are known to inhibit CYP3A4.

Tasigna should not be used in patients who are hypersensitive to nilotinib or any of the excipients.

Treatment with Tasigna has been associated with hematological side effects such as thrombocytopenia, neutropenia and anemia which was generally reversible and usually managed by withholding Tasigna temporarily or dose reduction. Complete blood counts should be performed every two weeks for the first two months and then monthly thereafter as clinically indicated.

Tasigna should be used with caution in patients with uncontrolled or significant cardiac disease (e.g., recent heart attack, congestive heart failure, unstable angina or clinically significant bradycardia), as well as in patients who have or may develop prolongation of QTc. These include patients with abnormally low potassium or magnesium levels, patients with congenital long QT syndrome, patients taking anti-arrhythmic medicines or other drugs that may lead to QT prolongation. Low levels of potassium or magnesium must be corrected prior to Tasigna administration. Close monitoring for an effect on the QTc interval is advisable and a baseline electrocardiography is recommended prior to initiating therapy with Tasigna and as clinically indicated. Uncommon cases (0.1 to 1%) of sudden death have been reported in clinical studies in patients with significant risk factors.

Tasigna should be used with caution in patients with liver impairment, in patients with a history of pancreatitis and in patients with total gastrectomy. Patients with rare hereditary problems of galactose intolerance, severe lactase deficiency or glucose-galactose malabsorption should not use Tasigna. Tasigna should not be used during pregnancy unless clearly necessary and breast feeding is not recommended during treatment.

The most frequent Grade 3 or 4 adverse events for Tasigna were primarily hematological in nature and included neutropenia and thrombocytopenia. Elevations seen in bilirubin, liver function tests, lipase enzymes and blood sugar were mostly transient and resolved over time. These cases were easily managed and rarely led to discontinuation of treatment. Pancreatitis was reported in less than 1% of cases. The most frequent non-hematologic drug-related adverse events were rash, pruritus, nausea, fatigue, headache, alopecia, myalgia, constipation and diarrhea. Most of these adverse events were mild to moderate in severity.

### **About Glivec**

Glivec is approved in more than 90 countries, including the US, EU and Japan, for the treatment of all phases of Ph+ CML. Glivec is also approved in the US, EU and other countries for the treatment of patients with Kit (CD117)-positive gastrointestinal tumors (GIST), which cannot

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be surgically removed and/or have already spread to other parts of the body (metastasized). In the US and EU, Glivec is now approved for the post-surgery treatment of adult patients following complete surgical removal of Kit (CD117)-positive GIST. In the EU, Glivec is also approved for the treatment of adult patients with newly diagnosed Ph+ acute lymphoblastic leukemia (Ph+ ALL) in combination with chemotherapy and as a single agent for patients with relapsed or refractory Ph+ ALL. Glivec is also approved for the treatment of adult patients with unresectable, recurrent and/or metastatic dermatofibrosarcoma protuberans (DFSP) who are not eligible for surgery. Glivec is also approved for the treatment of patients with myelodysplastic/myeloproliferative diseases (MDS/MPD). Glivec is also approved for hypereosinophilic syndrome and/or chronic eosinophilic leukemia (HES/CEL).



The effectiveness of Glivec is based on overall hematological and cytogenetic response rates and progression-free survival in CML, on hematological and cytogenetic response rates in Ph+ ALL, MDS/MPD, on hematological response rates in systemic mastocytosis (SM), HES/CEL, on objective response rates and progression-free survival in unresectable and/or metastatic GIST, on recurrence free survival in adjuvant GIST and on objective response rates in DFSP. Increased survival in controlled trials has been demonstrated only in newly diagnosed chronic phase CML and GIST.

Not all indications are available in every country.

### **Glivec important safety information**

The majority of patients treated with Glivec in clinical trials experienced adverse events at some time. Most events were of mild to moderate grade and treatment discontinuation was not necessary in the majority of cases.

The safety profile of Glivec was similar in all indications. The most common side effects included nausea, superficial edema, muscle cramps, skin rash, vomiting, diarrhea, abdominal pain, myalgia, arthralgia, hemorrhage, fatigue, headache, joint pain, cough, dizziness, dyspepsia and dyspnea, dermatitis, eczema and fluid retention, as well as neutropenia, thrombocytopenia and anemia. Glivec was generally well tolerated in all of the studies that were performed, either as monotherapy or in combination with chemotherapy, with the exception of a transient liver toxicity in the form of transaminase elevation and hyperbilirubinemia observed when Glivec was combined with high dose chemotherapy.

Rare/serious adverse reactions include: sepsis, pneumonia, depression, convulsions, cardiac failure, thrombosis/embolism, ileus, pancreatitis, hepatic failure, exfoliative dermatitis, angioedema, Stevens-Johnson syndrome, renal failure, fluid retention, edema (including brain, eye, pericardium, abdomen and lung), hemorrhage (including brain, eye, kidney and gastrointestinal tract), diverticulitis, gastrointestinal perforation, tumor hemorrhage/necrosis and hip osteonecrosis/avascular necrosis.

Patients with cardiac disease or risk factors for cardiac failure should be monitored carefully and any patient with signs or symptoms consistent with cardiac failure should be evaluated and treated. Cardiac screening should be considered in patients with HES/CEL, and patients with MDS/MPD with high level of eosinophils (echocardiogram, serum troponin level).

Glivec is contraindicated in patients with known hypersensitivity to imatinib or any of its excipients. Women of childbearing potential should be advised to avoid becoming pregnant while taking Glivec.

### **About Afinitor (everolimus)**

Afinitor tablets is approved in the European Union (EU) for the treatment of patients with advanced renal cell carcinoma (RCC) whose disease has progressed on or after treatment with vascular endothelial growth factor (VEGF)-targeted therapy and also in the US for the treatment of patients with advanced RCC after failure of treatment with sunitinib or sorafenib.

Afinitor is also approved in the US to treat patients with subependymal giant cell astrocytomas (SEGA) associated with tuberous sclerosis who require therapeutic intervention but are not candidates for curative surgical resection. The effectiveness of Afinitor is based on an analysis of change in SEGA volume. Improvement in disease-related symptoms or increase in survival has not been shown. Novartis has submitted marketing applications for everolimus to the European Medicines Agency (EMA) and the Swiss Agency for Therapeutic Products (Swissmedic), and additional regulatory submissions are underway worldwide.

In the EU, everolimus is available in different dosage strengths under the trade name Certican® for the prevention of organ rejection in heart and kidney transplant recipients. In the US, everolimus is available in different dosage strengths under the trade name Zortress® for the prophylaxis of organ rejection in adult patients at low-moderate immunologic risk receiving a kidney transplant.

Everolimus is exclusively licensed for use in drug-eluting stents to Abbott for the XIENCE V® and XIENCE PRIME (3) Everolimus Eluting Coronary Stent System, and sublicensed to Boston Scientific for the PROMUS and PROMUS Element (\*\*). Everolimus Eluting Coronary Stent System.

Not all indications are available in every country. As an investigational compound the safety and efficacy profile of everolimus has not yet been established in additional indications or disease areas. Access to everolimus outside of the approved indications has been carefully controlled and monitored in clinical trials designed to better understand the potential benefits and risks of the compound. Because of the uncertainty of clinical trials, there is no guarantee that everolimus will become commercially available for additional indications anywhere in the world.

#### **Afinitor important safety information**

Afinitor is contraindicated in patients with hypersensitivity to everolimus, to other rapamycin derivatives or to any of the excipients.

Cases of non-infectious pneumonitis have been described; some of these have been severe and occasionally fatal. Management of pneumonitis may require dose adjustment and/or interruption, or discontinuation of treatment and/or addition of corticosteroid therapy.

Afinitor is immunosuppressive. Localized and systemic bacterial, fungal, viral or protozoal infections (e.g., pneumonia, aspergillosis, candidiasis, hepatitis B reactivation) have been described; some of these have been severe and occasionally fatal. Pre-existing infections should be treated prior to starting treatment. Patients and physicians should be vigilant for symptoms and signs of infection; in case of emergent infections, appropriate treatment should be promptly instituted and interruption or discontinuation of Afinitor should be considered. Patients with systemic invasive fungal infections should not receive Afinitor.

Hypersensitivity reactions have been observed.

Mouth ulcers, stomatitis and oral mucositis have been seen. Topical treatments are recommended; alcohol- or peroxide-containing mouthwashes should be avoided.

Monitoring of renal function, blood glucose and complete blood counts is recommended prior to initiation and periodically during treatment. Cases of renal failure, some fatal, have been observed.

Afinitor is not recommended in patients with severe hepatic impairment.

Use of live vaccines should be avoided.

Afinitor is not recommended during pregnancy or for women of childbearing potential not using contraception. Afinitor may cause fetal harm in pregnant women. Women taking Afinitor should not breast feed. Male fertility may be compromised by Afinitor.

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(3) XIENCE V® AND XIENCE PRIME are registered trademarks of Abbott.

\*\* PROMUS AND PROMUS ELEMENT are registered trademarks of Boston Scientific.

Avoid concurrent treatment with strong CYP3A4 and PgP inhibitors and use caution with moderate inhibitors. Avoid concurrent treatment with strong CYP3A4 or PgP inducers.

In advanced RCC, the most common adverse reactions ( $\geq 10\%$ ) include stomatitis, rash, fatigue, asthenia, diarrhea, anorexia, nausea, mucosal inflammation, vomiting, cough, infections, peripheral edema, dry skin, epistaxis, pneumonitis, pruritus and dyspnea. Common adverse reactions ( $\geq 1$  to  $< 10\%$ ) include headache, dysgeusia, dry mouth, pyrexia, weight loss, hand-foot syndrome, abdominal pain, erythema, insomnia, dyspepsia, dysphagia, hypertension, increased daytime urination, dehydration, chest pain, renal failure, hemoptysis and exacerbation of diabetes mellitus. Uncommon adverse reactions ( $< 1\%$ ) include ageusia, congestive cardiac failure, new-onset diabetes mellitus, impaired wound healing, and grade 1 hemorrhage.

Cases of hepatitis B reactivation and pulmonary embolism have been reported

In patients with SEGA, the most common adverse reactions ( $\geq 10\%$ ) include infections, hypertriglyceridaemia, cough, stomatitis, diarrhea, acneiform dermatitis, acne, pyrexia, and decreased white blood cell count. Common adverse reactions ( $\geq 1$  to  $< 10\%$ ) include pharyngeal inflammation, gastritis, vomiting, mucosal inflammation, increased blood triglycerides, anxiety, somnolence, hypertension, respiratory disorders, dry skin, pityriasis rosea, proteinuria, fatigue, peripheral oedema, ocular hyperaemia, and decreased blood immunoglobulin G.

## **About Exjade**

Exjade is approved in more than 100 countries, including the US, Switzerland, Japan and the European Union. Exjade is indicated for chronic iron overload due to blood transfusions in patients aged 2 years and older. Exjade is approved for use at doses up to 40 mg/kg in the vast majority of countries.

Disclaimer: The results seen in the EPIC study were achieved with a starting dose of 30 mg/kg, which is approved in most but not all countries and with a dose range of up to 45 mg/kg which is not approved in any country.

## **Exjade important safety information**

Exjade is contraindicated in patients with hypersensitivity to the active substance or to any of the excipients. Exjade is also contraindicated in combination with other iron chelator therapies.

Exjade has not been studied in patients with renal impairment and is contraindicated in patients with moderate/severe renal impairment (estimated creatinine clearance  $< 60$  mL/min).

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In patients with a short life expectancy (e.g. high-risk myelodysplastic syndrome (MDS)), especially when co-morbidities could increase the risk of adverse event, the benefit of Exjade might be limited and may be inferior to risks. Exjade is not recommended in these patients. Caution should be used in elderly patients due to a higher frequency of adverse reactions.

Cases of acute renal failure have been reported following post-marketing use of Exjade, in some cases requiring temporary or permanent dialysis. Serum creatinine, creatinine clearance and/or plasma cystatin C levels should be monitored weekly in the first month after initiation or modification of therapy with Exjade, and monthly thereafter. Renal tubulopathy has been mainly reported in children and adolescents with beta-thalassemia treated with Exjade. Tests for proteinuria should be performed monthly.

Post-marketing cases of hepatic failure, sometimes fatal, have been reported in patients treated with Exjade. Liver function tests should be conducted every 2 weeks during the first month of treatment and monthly thereafter.

Upper gastrointestinal ulceration and hemorrhage have been reported in patients, including children and adolescents, receiving Exjade. There have been reports of fatal GI hemorrhages, especially in elderly patients who had hematological malignancies and/or low platelet counts. Caution should be exercised in patients who are taking Exjade in combination with drugs with known ulcerogenic potential or oral bisphosphonates, in patients receiving anticoagulants and in patients with platelet counts  $<50 \times 1.000.000.000/L$ .

Skin rashes may appear during Exjade treatment. Cases of serious hypersensitivity reactions have been reported. Exjade should be interrupted if a severe rash develops and discontinued if serious hypersensitivity reactions occurs.

Auditory and ocular disturbances have been reported. Auditory and ophthalmic testing should be conducted annually.

There have been post-marketing reports of leukopenia, thrombocytopenia or pancytopenia in patients treated with Exjade. Interruption of treatment should be considered in patients who develop unexplained cytopenias.

Exjade should not be taken with aluminium-containing antacids. Caution should be exercised when Exjade is combined with strong UDP-glucuronosyl transferase (UGT) inducers or CYP2C8 substrates.

The most frequent reactions reported during chronic treatment with Exjade in adult and pediatric patients include gastrointestinal disturbances in about 26% of patients (mainly nausea, vomiting, diarrhea or abdominal pain) and skin rash in about 7% of patients. Increases in serum creatinine of  $>33\%$  on  $\geq 2$  consecutive occasions occurred in about 36% of patients during clinical trials.

### **About Zometa**

Zometa is indicated for the prevention of skeletal related events (pathological fractures, spinal compression, radiation or surgery to bone, or tumor-induced hypercalcemia) in patients with multiple myeloma and advanced malignancies involving bone. An intravenous bisphosphonate, Zometa is the only therapy to demonstrate efficacy in reducing or delaying bone complications across a broad range of tumor types such as breast, prostate, lung and renal cell cancers, in patients with metastatic disease when administered monthly. Zometa offers patients, nurses and clinicians a 4 mg, 15-minute infusion.

Zometa is the number one prescribed treatment for the prevention or delay of skeletal-related events (SREs) in patients with advanced malignancies involving bone across a broad range of tumors.

### **Zometa important safety information**

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Zometa has been associated with reports of renal insufficiency. Patients should be adequately rehydrated and have their serum creatinine assessed prior to receiving each dose of Zometa. Due to the risk of clinically significant deterioration in renal function, single doses of Zometa should not exceed 4 mg and the duration of infusion should be no less than 15 minutes in 100 ml of diluent. The risk of renal adverse events may be greater in patients with renal insufficiency. Zometa is not recommended for treatment of patients with severe renal impairment. Severe and occasionally incapacitating bone, joint, and/or muscle pain has been reported in patients taking bisphosphonates including Zometa. Caution is advised when Zometa is used in aspirin-sensitive patients, or with aminoglycosides, loop diuretics and other potentially nephrotoxic drugs. Zometa contains the same active ingredient (zoledronic acid) as found in Aclasta. Patients being treated with Zometa should not be treated with Aclasta concomitantly. Zometa should not be used in patients who are pregnant, or plan to become pregnant, or who are breast-feeding.



In clinical trials, the most commonly reported adverse events included flu-like syndrome (fever, arthralgias, myalgias, skeletal pain), fatigue, gastrointestinal reactions, anemia, weakness, cough, dyspnea and edema. Zometa should not be used during pregnancy. Zometa is contraindicated in patients with clinically significant hypersensitivity to zoledronic acid or other bisphosphonates, or any of the excipients in the formulation of Zometa.

Osteonecrosis of the Jaw (ONJ): ONJ has been reported in patients with cancer receiving treatment including bisphosphonates, chemotherapy and/or corticosteroids. The majority of reported cases have been associated with dental procedures such as tooth extraction. A dental examination with appropriate preventive dentistry should be considered prior to treatment with bisphosphonates in patients with concomitant risk factors. While on treatment, these patients should avoid invasive dental procedures if possible. No data are available to suggest whether discontinuation of bisphosphonate therapy reduces the risk of ONJ in patients requiring dental procedures. A causal relationship between bisphosphonate use and ONJ has not been established.

#### **About the compounds LBH589, INC424, PKC412, HCD122, BEZ235**

Because these are investigational compounds, the safety and efficacy profile of LBH589, INC424, PKC412, HCD122 and BEZ235 have not yet been established. Access to these investigational compounds 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, INC424, PKC412, HCD122 and BEZ235 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 commitment, continue to explore, pipeline, will, goal, potential, or similar expressions, or by express or implied discussions regarding potential new products, potential new indications for existing products, or regarding potential future revenues from any such products. 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 any new products will be submitted or approved for sale in any market, or that any new indications will be submitted or approved for existing products in any market, or that such products 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; the company's ability to obtain or maintain patent or other proprietary intellectual property protection; 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**

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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>.

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**References**

- (1) American Society of Hematology. 52nd Annual Meeting of the American Society of Hematology Final Program, 2010.
- (2) San Antonio Breast Cancer Symposium. 33rd Annual Meeting of the San Antonio Breast Cancer Symposium Final Program, 2010.
- (3) Hughes T, et al. ENESTnd Update: Continued Superiority of Nilotinib Versus Imatinib In Patients with Newly Diagnosed Chronic Myeloid Leukemia In Chronic Phase (CML-CP). 52nd Annual Meeting of the American Society of Hematology. Abstract #207. December 6, 2010.
- (4) Renner C, et al. A Multi-Center Phase II Study (SAKK 36/06) of Single Agent Everolimus (RAD001) In Patients with Relapsed or Refractory Mantle Cell Lymphoma. 52nd Annual Meeting of the American Society of Hematology. Abstract #2803. December 5, 2010.
- (5) O Connor O, et al. PILLAR-1: Preliminary Results of a Phase II Study of mTOR Inhibitor Everolimus In Patients with Mantle Cell Lymphoma (MCL) Who Are Refractory or Intolerant to Bortezomib. 52nd Annual Meeting of the American Society of Hematology. Abstract #3963. December 6, 2010.
- (6) Pennell D, et al. Continued Improvement and Normalization of Myocardial T2\* In Patients with  $\beta$ -thalassemia Major Treated with Deferasirox (Exjade®) for up to 3 Years. 52nd Annual Meeting of the American Society of Hematology. Abstract #4276. December 6, 2010.
- (7) Gattermann N, et al. Hematologic Responses In Myelodysplastic Syndromes (MDS) Patients Treated with Deferasirox: An EPIC Post-Hoc Analysis Using International Working Group (IWG) 2006 Criteria. 52nd Annual Meeting of the American Society of Hematology. Abstract #2912. December 5, 2010.
- (8) Vichinsky E, et al. Long-Term Safety and Efficacy of Deferasirox (Exjade®) In Transfused Patients with Sickle Cell Disease Treated for up to 5 Years. 52nd Annual Meeting of the American Society of Hematology. Abstract #845. December 6, 2010.

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- (9) Deugnier Y, et al. Deferasirox Improves Liver Pathology In  $\beta$ -Thalassemia Patients with Transfusional Iron Overload. 52nd Annual Meeting of the American Society of Hematology. Abstract #4274. December 6, 2010.
- (10) Morgan G, et al. Optimising Bone Disease In Myeloma; Zoledronic Acid Plus Thalidomide Combinations Improves Survival and Bone Endpoints: Results of the MRC Myeloma IX Trial. 52nd Annual Meeting of the American Society of Hematology. Abstract #311. December 6, 2010.
- (11) Sureda A, et al. Final Analysis: Phase II Study of Oral Panobinostat In Relapsed/Refractory Hodgkin Lymphoma Patients Following Autologous Hematopoietic Stem Cell Transplant. 52nd Annual Meeting of the American Society of Hematology. Abstract #419. December 6, 2010.
- (12) Verstovsek S, et al. Durable Responses with the JAK1/JAK2 Inhibitor, INCB018424, In Patients with Polycythemia Vera (PV) and Essential Thrombocythemia (ET) Refractory or Intolerant to Hydroxyurea (HU). 52nd Annual Meeting of the American Society of Hematology. Abstract #313. December 6, 2010.
- (13) Eghtedar A, et al. Phase II Study of the JAK2 Inhibitor, INCB018424, In Patients with Refractory Leukemias Including Post-Myeloproliferative Disorder (MPD) Acute Myeloid Leukemia (sAML). 52nd Annual Meeting of the American Society of Hematology. Abstract #509. December 6, 2010.
- (14) Gotlib J, et al. KIT Inhibitor Midostaurin Exhibits a High Rate of Clinically Meaningful and Durable Responses in Advanced Systemic Mastocytosis: Report of a Fully Accrued Phase II Trial. 52nd Annual Meeting of the American Society of Hematology. Abstract #316. December 6, 2010.
- (15) Freedman AS, et al. Clinical Activity of Lucatumumab (HCD122) In Patients (pts) with Relapsed/Refractory Hodgkin or Non-Hodgkin Lymphoma Treated In a Phase Ia/II Clinical Trial (NCT00670592). 52nd Annual Meeting of the American Society of Hematology. Abstract #284. December 6, 2010.
- (16) Bachelot T, et al. TAMRAD: A GINECO Randomized Phase II Trial of Everolimus In Combination with Tamoxifen Versus Tamoxifen Alone In Patients (pts) with Hormone-Receptor Positive, HER2 Negative Metastatic Breast Cancer (MBC) with Prior Exposure to Aromatase Inhibitors (AI). 33rd Annual Meeting of the San Antonio Breast Cancer Symposium. Abstract #S1-6. December 9, 2010.
- (17) Coleman R. Adjuvant Treatment with Zoledronic Acid In Stage II/III Breast Cancer. The AZURE Trial (BIG 01/04). 33rd Annual Meeting of the San Antonio Breast Cancer Symposium. Abstract #S4-5. December 10, 2010.
- (18) Gnant, M. The Carry-Over Effect of Adjuvant Zoledronic Acid: Comparison of 48- and 62-Month Analyses of ABCSG-12 Suggests That the Benefits of Combining Zoledronic Acid With Adjuvant Endocrine Therapy Persist Long After Completion of Therapy. 33rd Annual Meeting of the San Antonio Breast Cancer Symposium. Abstract #P5-11-02. December 11, 2010.

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(19) Rodon J. A Dose-Escalation Study with a Special Drug Delivery System (SDS) of BEZ235, a Novel Dual PI3K/mTOR Inhibitor, in Patients with Metastatic/Advanced Solid Tumors. 33rd Annual Meeting of the San Antonio Breast Cancer Symposium. Abstract #P6-15-07. December 12, 2010.

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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: December 1, 2010

By: /s/ MALCOLM B. CHEETHAM

Name: Malcolm B. Cheetham  
Title: Head Group Financial  
Reporting and Accounting