

NOVARTIS AG  
Form 6-K  
December 02, 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 December 02, 2011

(Commission File No. 1-15024)

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**Novartis AG**

(Name of Registrant)

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**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:

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**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:

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**- Investor Relations Release -**

**Novartis highlights advances for patients with breast cancer and hematological diseases with over 160 SABCS and ASH abstracts**

- *Updated Phase III data from BOLERO-2 trial studying everolimus in women with ER+HER2- advanced breast cancer*
- *Tasigna® Phase III trials in Ph+ CML including 36-month follow-up data in newly diagnosed patients*
- *Exjade® pivotal study results investigating iron chelation in patients with non-transfusion-dependent thalassemia*
- *Phase III trial further exploring benefit of INC424 (ruxolitinib) in patients with myelofibrosis, a debilitating blood cancer with limited treatment options*

**Basel, December 2, 2011** Novartis will showcase more than one hundred and sixty presentations on data from its robust oncology portfolio at two key medical congresses this month, demonstrating significant advances for patients with cancers and hematological diseases.

The CTRC-AACR San Antonio Breast Cancer Symposium (SABCS), held from December 6-10, will feature data presentations from Phase III studies of Afinitor® (everolimus) tablets for investigational uses and Zometa® (zoledronic acid) 4mg/5mL Injection, as well as early-stage studies of the investigational drug BKM120, an inhibitor of PI3K, a key cancer pathway(1).

The American Society of Hematology (ASH) annual meeting in San Diego, held from December 10-13, will showcase key data for Tasigna® (nilotinib), Exjade® (deferasirox) and the investigational drug INC424 (ruxolitinib)(1). Several early-stage studies will also be presented, including everolimus in Hodgkin lymphoma and Waldenström's macroglobulinemia and LBH589 (panobinostat) in relapsed and bortezomib (BTZ)-refractory multiple myeloma(2).

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(1) Novartis and Incyte Corporation have a worldwide collaboration and licensing agreement for INC424.



These important data are examples of our research and development strategy to focus on significant unmet medical needs by targeting the fundamental mechanisms of disease, said Hervé Hoppenot, President, Novartis Oncology. Through our collaborations with the scientific and patient communities, we continue to advance our goal of transforming patients' lives.

Highlights at SABCS include:

- **Everolimus** Updated data from the BOLERO-2 (Breast cancer trials of OraL EveROlimus) Phase III trial of everolimus in combination with exemestane for postmenopausal women with ER+HER2- advanced breast cancer who recurred or progressed while on or following previous treatment with the hormonal therapies letrozole or anastrozole (SABCS abstract #S3-7; December 8, 9:30 – 11:15AM).
- **Zometa** ABCSG-12 (Austrian Breast & Colorectal Cancer Study Group Trial) long-term data will examine possible carry-over anticancer benefits of zoledronic acid three years after treatment completion in premenopausal women with endocrine-responsive early breast cancer receiving adjuvant goserelin and endocrine therapy (SABCS abstract #S1-2; December 7, 9:15 – 11:30AM) and five-year ZO-FAST (ZOmeta-Femara Adjuvant Synergy Trial) follow-up data on long-term overall survival outcomes among postmenopausal women with hormone receptor-positive early breast cancer receiving adjuvant zoledronic acid and letrozole (SABCS abstract #S1-3; December 7, 9:15 – 11:30AM).
- **BKM120** Two studies investigating the activity of BKM120, a pan-PI3K inhibitor, in advanced breast cancer: data from a trial evaluating the safety profile and clinical activity of BKM120 as a single agent for the treatment of patients with metastatic breast cancer (SABCS abstract #P3-16-01; December 8, 5:00 – 7:00PM) and data from a Phase I/II study evaluating BKM120 in combination with trastuzumab in patients with HER2 overexpressing metastatic breast cancer resistant to trastuzumab-containing therapy (SABCS abstract #PD09-03; December 9, 5:00 – 7:00PM).

Highlights at ASH include:

- **Tasigna** ENESTnd (Evaluating Nilotinib Efficacy and Safety in Clinical Trials) 36-month update of the ENESTnd study comparing Tasigna to Glivec in patients with newly diagnosed chronic phase Ph+ chronic myeloid leukemia (ASH abstract #452; December 12, 10:30AM – 12:00PM) and results from ENESTcmr trial assessing the efficacy and safety of switching patients with residual molecular disease on Glivec® (imatinib)(2) treatment to Tasigna (ASH abstract #606; December 12, 2:45 – 4:15PM).
- **Exjade** Data from the first randomized, placebo-controlled study evaluating the reduction of liver iron concentration and serum ferritin in patients with non-transfusion-dependent thalassemia after one year of treatment with Exjade oral iron chelation therapy (ASH abstract #902; December 13, 7:30 – 9:00AM) and data from a retrospective analysis of hematological response during iron chelation therapy in patients with myelodysplastic syndrome (MDS) and aplastic anemia with transfusional iron overload (ASH abstract #611; December 12, 2:45 – 4:15PM).
- **INC424** Data from multiple research programs will be presented, including two pivotal Phase III studies evaluating INC424 benefit versus placebo (COMFORT-I [COntrolled MyeloFibrosis study with ORal JAK inhibitor Therapy]) (ASH abstract #278; December 12, 7:00 – 8:30AM) and versus best available therapy (COMFORT-II) (ASH abstract #795; December 12, 4:30 – 6:00PM). These data will assess measures of spleen reduction, symptom improvement, health-related quality of life and overall survival.

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

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- **Everolimus** Results from a Phase II study evaluating everolimus as a monotherapy in relapsed/refractory Hodgkin lymphoma (ASH abstract #2717; December 11, 6:00 – 8:00PM) and data from a Phase I trial of everolimus in combination with rituximab or in combination with BTZ and rituximab in relapsed/refractory Waldenström's macroglobulinemia (ASH abstract #2705; December 11, 6:00 – 8:00PM).
- **LBH589** Results from PANORAMA-2 (PANobinostat ORAL in Multiple myeloma), a Phase II study of LBH589 in combination with BTZ and dexamethasone in patients with relapsed and BTZ-refractory multiple myeloma (ASH abstract #814; December 12, 4:30 – 6:00PM). Data from two trials in myelofibrosis: final results from a Phase I trial of prolonged low dose therapy with LBH589 in myelofibrosis patients (ASH abstract #794; December 12, 4:30 – 6:00PM) and a preclinical study of LBH589 in combination with INC424 in JAK2V617F-driven disease (ASH abstract #798; December 12, 4:30 – 6:00PM).

### About everolimus tablets

Everolimus is approved as Afinitor® (everolimus) tablets in more than 80 countries including the United States and throughout the European Union in the oncology settings of advanced renal cell carcinoma (RCC) following progression on or after vascular endothelial growth factor (VEGF)-targeted therapy and in the US and EU for locally advanced, metastatic or unresectable progressive neuroendocrine tumors of pancreatic origin (pNET).

Everolimus is also available from Novartis for use in non-oncology patient populations under the brand names Afinitor® or Votubia®, Certican® and Zortress® and is exclusively licensed to Abbott and sublicensed to Boston Scientific for use in drug-eluting stents.

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

### Everolimus tablets Important Safety Information

Everolimus can cause serious side effects including lung or breathing problems, infections, and renal failure which can lead to death. Mouth ulcers and mouth sores are common side effects. Everolimus can affect blood cell counts, kidney and liver function, and blood sugar and cholesterol levels. Everolimus may cause fetal harm in pregnant women. Women taking everolimus should not breast feed.

The most common adverse drug reactions (incidence  $\geq 15\%$ ) are mouth ulcers, diarrhea, feeling weak or tired, skin problems (such as rash or acne), infections, nausea, swelling of extremities or other parts of the body, loss of appetite, headache, inflammation of lung tissue, abnormal taste, nose bleeds, inflammation of the lining of the digestive system, weight decreased and vomiting. The most common Grade 3-4 adverse drug reactions (incidence  $\geq 2\%$ ) are mouth ulcers, feeling tired, low white blood cells (a type of blood cell that fights infection), diarrhea, infections, inflammation of lung tissue, and diabetes. Cases of hepatitis B reactivation and blood clot in the lung and leg have been reported.

### **About Zometa (zoledronic acid)**

Zometa® (zoledronic acid) Injection is indicated for the prevention of skeletal-related events (SREs; pathological fractures, spinal compression, radiation or surgery to bone, or tumor-induced hypercalcemia) in patients with multiple myeloma and advanced malignancies involving bone. The recommended dose is a 4 mg, 15-minute infusion every 3-4 weeks.

### **Zometa Important Safety Information**

Zometa has been associated with reports of renal insufficiency. Adequately rehydrate patients and assess serum creatinine prior to each dose. 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 and dose adjustments are required. Not recommended in patients with severe renal impairment. Monitor serum levels of calcium, phosphate and magnesium and treat as necessary. Severe and occasionally incapacitating bone, joint, and/or muscle pain has been reported. Monitor for thigh, hip or groin pain, evaluate for femur fractures as necessary and discontinue treatment if required. Use caution in aspirin-sensitive patients, and when using aminoglycosides, loop diuretics and other potentially nephrotoxic drugs. Use caution in multiple myeloma patients using thalidomide. Patients being treated with Zometa should not be treated with Aclasta(3) concomitantly. Zometa should not be used in patients who are pregnant, or plan to become pregnant, or who are breast-feeding. Contraindicated in patients with hypersensitivity to zoledronic acid, other bisphosphonates, or any of the excipients in Zometa.

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. 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.

Please see full Prescribing Information. Approved indications vary by country.

### **About BKM120 and LBH589 (panobinostat)**

Because these are investigational compounds, the safety and efficacy profile of BKM120 and LBH589 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 BKM120 and LBH589 will ever be commercially available anywhere in the world.

### **About Tasigna (nilotinib)**

Tasigna® (nilotinib) is approved in more than 90 countries for the treatment of chronic phase and accelerated phase Philadelphia chromosome-positive chronic myelogenous leukemia (Ph+ CML) in adult patients resistant or intolerant to at least one prior therapy, including Glivec, and for the treatment of adult patients with newly diagnosed Ph+ CML in chronic phase. Take twice daily 12 hours apart. Do not take with food. No food to be consumed for 2 hours before or one hour after dosing. Avoid grapefruit juice and CYP3A4 inhibitors.

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(3) Known as Reclast in the US.





### **Tasigna Important Safety Information**

Use with caution in patients with uncontrolled or significant cardiac disease and in patients who have or may develop prolongation of QTc. Low levels of potassium or magnesium must be corrected prior to Tasigna administration. Monitor closely for an effect on the QTc interval. Baseline ECG is recommended prior to initiating therapy 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.

Use with caution in patients with liver impairment, with a history of pancreatitis and with total gastrectomy. Patients with rare hereditary problems of galactose intolerance, severe lactase deficiency or glucose-galactose malabsorption should not use Tasigna. Tasigna may cause fetal harm in pregnant women. Women taking Tasigna should not breastfeed.

The most frequent Grade 3 or 4 adverse events are hematological (neutropenia and thrombocytopenia) which are generally reversible and usually managed by withholding Tasigna temporarily or dose reduction. Monitor blood counts regularly. Pancreatitis has been reported. The most frequent non-hematologic adverse events were rash, pruritus, nausea, fatigue, headache, alopecia, myalgia, constipation and diarrhea. Most of these adverse events were mild to moderate in severity.

Please see full Prescribing Information.

### **About Glivec (imatinib)**

Glivec® (imatinib) is approved in more than 110 countries for the treatment of all phases of Ph+ CML, for the treatment of adult patients with KIT (CD117)-positive gastrointestinal stromal tumors (GIST), which cannot be surgically removed and/or have metastasized and for the treatment of adult patients following complete surgical removal of KIT+ GIST. Take with food and a large glass of water.

### **Glivec Important Safety Information**

Glivec can cause fetal harm in pregnant woman. Glivec has been associated with severe edema (swelling) and serious fluid retention. Cytopenias (anemia, neutropenia, thrombocytopenia) are common, generally reversible and usually managed by withholding Glivec or dose reduction. Monitor blood counts regularly. Severe congestive heart failure and left ventricle dysfunction, severe liver problems including cases of fatal liver failure and severe liver injury requiring liver transplants have been reported. Use caution in patients with cardiac dysfunction and hepatic dysfunction. Monitor carefully.

Bleeding may occur. Severe gastrointestinal (GI) bleeding has been reported in patients with KIT+ GIST. Skin reactions, hypothyroidism in patients taking levothyroxine replacement, GI perforation, in some cases fatal and tumor lysis syndrome, which can be life threatening, have also been reported with Glivec. Correct dehydration and high uric acid levels prior to treatment. Long-term use may result in potential liver, kidney, and/or heart toxicities; immune system suppression may also result from long-term use. In patients with hypereosinophilic syndrome and heart involvement, cases of heart disease have been associated with the initiation of Glivec therapy. Growth retardation has been reported in children taking Glivec. The long-term effects of extended treatment with Glivec on growth in children are unknown.

The most common side effects include fluid retention, muscle cramps or pain and bone pain, abdominal pain, loss of appetite, vomiting, diarrhea, decreased hemoglobin, abnormal bleeding, nausea, fatigue and rash.

Please see full Prescribing Information.

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### **About Exjade (deferasirox)**

Exjade® (deferasirox) is indicated for the treatment of chronic iron overload due to blood transfusions (transfusional hemosiderosis) in adult and pediatric patients (aged 2 years and over). It is approved in over 100 countries including the U.S., Switzerland, Japan, and the countries comprising the European Union. The approved indication may vary depending upon the individual country.

### **Exjade Important Safety Information**

Exjade is contraindicated in patients with an estimated creatinine clearance <60 mL/min, with hypersensitivity to the active substance or any of the excipients, or in combination with other iron chelator therapies. Exjade is not recommended in patients with severe hepatic impairment.

There have been postmarketing reports of acute renal failure, hepatic failure, and cytopenias. Renal failure requiring temporary or permanent dialysis, renal tubulopathy, and interstitial nephritis have been reported. Upper gastrointestinal ulceration and hemorrhage, sometimes fatal, have been reported. Caution should be used in elderly patients due to a higher frequency of adverse reactions. Exjade is not recommended in patients with a short life expectancy (e.g., high-risk myelodysplastic syndromes), especially when co-morbidities could increase the risk of adverse events.

Skin rashes, serious hypersensitivity reactions, decreased hearing, and lens opacities have been reported. The most common adverse reactions are nausea, vomiting, diarrhea, abdominal pain, rash, non-progressive increases in serum creatinine, increased transaminases, abdominal distension, constipation, dyspepsia, proteinuria, and headache.

Please visit [www.exjade.com](http://www.exjade.com) for more information.

### **About INC424 (ruxolitinib)**

INC424 (ruxolitinib) is an oral inhibitor, of the JAK1 and JAK2 tyrosine kinases. INC424 is being investigated in primary myelofibrosis as well as post-polycythemia vera myelofibrosis (PPV-MF) and post-essential thrombocythemia myelofibrosis (PET-MF). INC424 is also being investigated in clinical trials for the treatment of polycythemia vera (PV).

Novartis licensed INC424 from Incyte for development and potential commercialization outside the US. Incyte has retained rights for the development and potential commercialization of INC424 in the US. Both the US Food and Drug Administration and the European Medicines Agency have granted INC424 orphan drug status for myelofibrosis.

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## Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as will, goal, potential, or similar expressions, or by express or implied discussions regarding potential new indications or labeling, or potential marketing approvals for Novartis Oncology products, or regarding potential future revenues from 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 additional indications or labeling will be approved for any existing Novartis Oncology products, or that any new Novartis Oncology products will be approved for sale in any market, or at any particular time. Nor can there be any guarantee that any such products will achieve any particular levels of revenue in the future. 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; unexpected manufacturing issues; 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 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. 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>.

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**References**

1. San Antonio Breast Cancer Symposium. SABCS Annual 11 Meeting Program. Available at <http://www.sabcs.org/ProgramSchedule/index.asp>. Accessed November 2011.
2. American Society of Hematology. ASH Annual 11 Meeting Program. Available at <http://ash.confex.com/ash/2011/webprogram/start.html>. Accessed November 2011.

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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 02, 2011

By: /s/ MALCOLM B. CHEETHAM

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

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