

NOVARTIS AG  
Form 6-K  
June 04, 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 May 31, 2012**

**(Commission File No. 1-15024)**

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(Name of Registrant)

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**Switzerland**

(Address of Principal Executive Offices)

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**MEDIA RELEASE • COMMUNIQUE AUX MEDIAS • MEDIENMITTEILUNG**

**Novartis showcases ongoing research at ASCO to help patients fight various cancers, including updated data in advanced breast cancer**

- *18-month BOLERO-2 data confirm Afinitor® combined with exemestane delays time without tumor growth for women with HR+ advanced breast cancer(1)*
- *Data highlighted by ASCO show twice as many Ph+ CML-CP patients achieved deeper levels of response with Tasigna® compared to imatinib(2),(3)*
- *Early data on pipeline compounds demonstrate potential in breast cancer, non-small cell lung cancer, NRAS-mutated melanoma and other solid tumors(4)*

**Basel, May 31, 2012** Novartis will showcase the clinical progress of multiple marketed and pipeline compounds with 160 abstracts at the 48th Annual Meeting of the American Society of Clinical Oncology (ASCO; June 1-5, Chicago)(4). These studies demonstrate key findings for Novartis compounds to address unmet treatment needs of patients with cancer and rare diseases.

Among the data we will share at this year's ASCO are results from our key products, Afinitor and Tasigna, which demonstrate the magnitude of benefit these treatments may provide for patients with some types of advanced breast cancer and chronic myeloid leukemia, said Hervé Hoppenot, President, Novartis Oncology. In addition, we are seeing promising data from our early pipeline across multiple disease areas, including non-small cell lung cancer, multiple myeloma, NRAS-mutated melanoma and other solid tumors.

**Updated data from BOLERO-2**

An 18-month analysis from the Phase III BOLERO-2 study (Breast cancer trials of Qral Everolimus) (abstract #559; June 2, 8:00AM 12:00PM) confirm that Afinitor® (everolimus) plus exemestane, an aromatase inhibitor, more than doubled the time postmenopausal women

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with hormone receptor-positive (HR+) advanced breast cancer lived without tumor growth (progression-free survival; PFS).

The updated results show median PFS for everolimus plus exemestane was 7.8 months compared to 3.2 months with hormonal therapy alone (hazard ratio=0.45 [95% confidence interval (CI): 0.36 to 0.54];  $p<0.0001$ ) by local investigator assessment and significantly reduced the risk of cancer progression by 55% versus exemestane alone(1). In addition, 32.2% of patients in the exemestane-only arm and 25.4% in the everolimus plus exemestane arm died(1). The overall survival data is not yet mature.

The most common adverse events in the everolimus arm (incidence  $\geq 30\%$ ) were stomatitis, rash, fatigue, nausea, diarrhea and decreased appetite. The most common grade 3/4 adverse reactions (incidence  $\geq 2\%$ ) were stomatitis, hyperglycemia, non-infectious pneumonitis, fatigue and diarrhea(1).

These results are supportive of previously presented data from BOLERO-2. Regulatory submissions for Afinitor in HR+ advanced breast cancer are currently under

consideration with the US Food and Drug Administration and other health authorities worldwide.

#### **Tasigna in Philadelphia chromosome-positive CML in chronic phase**

Also featured at ASCO will be two Phase III studies from the ENEST (Evaluating Nilotinib Efficacy and Safety in Clinical Trials) clinical research program, which demonstrate that twice as many adult patients with Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic phase treated with Tasigna® (nilotinib) achieved deeper levels of response compared to those treated with imatinib(2),(3). These findings were first presented at the 2011 American Society of Hematology Annual Meeting and include:

- ENESTnd 36-month update showed the superiority of Tasigna vs. imatinib for the treatment of patients with newly diagnosed chronic phase Ph+ CML, with 32% of patients reaching the deepest levels of response on Tasigna compared to 15% on imatinib (*abstract #6509; June 1, 1:00PM - 5:00PM*)(2).
- ENESTcmr 12-month analysis demonstrated that switching patients with detectable Bcr-Abl transcripts from imatinib to Tasigna resulted in deeper molecular responses compared to those patients who remained on imatinib, with 23% of patients switched to Tasigna achieving undetectable levels of Bcr-Abl compared to 11% who continued on imatinib (*abstract #6505; June 4, 9:30AM - 9:45AM*)(3).

These data will also be presented at 17th Congress of the European Hematology Association (EHA), June 14-17 in Amsterdam.

#### **Notable data on Novartis pipeline compounds**

Early data on several Novartis pipeline compounds show promise for further research and development in areas of unmet medical needs and for targeted treatment approaches(5).

Our strong pipeline data demonstrate the progress we are making to target new signaling pathways, including MEK, ALK, Hh and PI3K, that play a critical role in many types of cancers where there remain significant unmet medical needs, said Alessandro Riva, Global Head, Oncology Development & Medical Affairs, Novartis Oncology. This is representative of our ongoing research using multiple strategies across a broad range of cancers and rare diseases.

- **BEZ235** Phase I/Ib dose-escalation study of BEZ235 plus trastuzumab in patients with trastuzumab-resistant HER2+ metastatic breast cancer demonstrated an acceptable safety profile and established maximum tolerated dose (*abstract #508; June 2, 1:30PM - 1:45PM*)(5).

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- **BKM120** Phase Ib study of BKM120 with letrozole in patients with metastatic ER+/HER2- breast cancer (*abstract #510; June 2, 2:15PM – 2:30PM*)(6) and a Phase Ib study of BKM120 in combination with the MEK inhibitor GSK1120212 in patients with advanced solid tumors showed positive safety results for these combinations. Signs of clinical activity were seen in patients with RAS/RAF-mutated tumors treated with BKM120 and GSK1120212 (*abstract #3003; June 3, 10:45AM – 11:00AM*)(7).
- **LBH589** Updated data from the Phase II PANORAMA-2 (PANobinostat ORAl in Multiple myelomA) study showed promise of LBH589 in combination with bortezomib and dexamethasone to achieve overall responses and clinical benefit in patients with relapsed and bortezomib-refractory multiple myeloma (*abstract #8012; June 3, 9:00AM – 9:15AM*)(8).
- **LDE225** A Phase I/II study demonstrated promising efficacy of LDE225 in pediatric patients with recurrent medulloblastoma and correlative analysis supports the use of the 5-gene hedgehog (Hh) assay as a pre-selection tool in future trials (*abstract #9519; June 4, 12:00PM – 12:15PM*)(9).

- **LDK378** First-in-human Phase I study of LDK378 showed preliminary clinical response in patients with ALK-positive advanced non-small cell lung cancer (*abstract #3007; June 3, 12:00PM – 12:15PM*)(10).
- **MEK162** Phase II study of MEK162 showed clinical activity in patients with BRAF and NRAS-mutated advanced melanoma. This is the first targeted therapy to show activity in patients with NRAS-mutated melanoma (*abstract #8511; June 4, 3:45PM – 4:00PM*)(11).

#### About Afinitor (everolimus)

Afinitor (everolimus) tablets is approved in more than 80 countries, including the United States and throughout the European Union, in the adult 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. 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.

#### Afinitor Important Safety Information

Afinitor 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 decreases 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, diabetes and amenorrhea. Cases of hepatitis B reactivation and blood clot in the lung and leg have been reported.

Please see full Prescribing Information.

#### About Tasigna (nilotinib)

Tasigna (nilotinib) is approved in more than 100 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 imatinib, and/or 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.

**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.

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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.

### **About LBH589, MEK162, BEZ235, BKM120, LDK378, LDE225**

Because these are investigational compounds, the safety and efficacy profile of LBH589, MEK162, BEZ235, BKM120, LDK378 and LDE225 have not yet been established. Access to these investigational compounds is available only through carefully controlled

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

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, MEK162, BEZ235, BKM120, LDK378 and LDE225 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 ongoing, pipeline, potential, will, may, promising, under consideration, promise, expected, or similar expressions, or by express or implied discussions regarding potential new submissions or marketing approvals for the Novartis Oncology products referred to in this release, potential new indications or labeling for such Novartis Oncology products, or regarding potential future revenues from such Novartis Oncology 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 with to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that the Novartis Oncology products referred to in this release will be submitted or approved for sale, or for any additional indications or labeling in any market, or at any particular time. Nor can there be any guarantee that Novartis Oncology products will achieve any particular levels of revenue in the future. In particular, management's expectations regarding Novartis Oncology products 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; unexpected manufacturing issues; 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 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 2011, the Group's continuing operations achieved net sales of USD 58.6 billion, while approximately USD 9.6 billion (USD 9.2 billion excluding impairment and amortization charges) was invested in R&D throughout the Group. Novartis Group companies employ approximately 124,000 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

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- (1) Piccart M et al. Everolimus for Postmenopausal Women with Advanced Breast Cancer: Updated Results of the BOLERO-2 Phase III Trial. Abstract #559. American Society of Clinical Oncology 2012 Annual Meeting, Chicago, IL.

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- (2) Kantarjian H et al. Nilotinib vs. imatinib in patients with newly diagnosed CML in chronic phase: ENESTnd 3-year follow-up. Abstract #6509. American Society of Clinical Oncology 2012 Annual Meeting, Chicago, IL.

- (3) Lipton J et al. Switch to nilotinib vs. continued imatinib in patients with CML in chronic phase with detectable Bcr-Abl after  $\geq 2$  years on imatinib; ENESTcmr 12-month follow-up. Abstract #6505. American Society of Clinical Oncology 2012 Annual Meeting, Chicago, IL.
- (4) American Society of Clinical Oncology. ASCO Annual 2012 Meeting Program. Available at: <http://chicago2012.asco.org/MeetingProgram.aspx>. Accessed May 2012.
- (5) Krop I et al. A phase I/Ib dose-escalation study of BEZ235 in combination with trastuzumab in patients with PI3-kinase or PTEN altered HER+ metastatic breast cancer. Abstract #508. American Society of Clinical Oncology 2012 Annual Meeting, Chicago, IL.
- (6) Mayer et al. SU2C phase Ib study of pan-PI3K inhibitor BKM120 with letrozole in ER+/HER2- metastatic breast cancer. Abstract #510. American Society of Clinical Oncology 2012 Annual Meeting, Chicago, IL.
- (7) Bedard P et al. A phase Ib, open-label, multi-center, dose-escalation study of the oral pan-PI3K inhibitor BKM120 in combination with the oral MEK1/2 inhibitor GSK1120212 in patients with selected advanced solid tumors. Abstract #3003. American Society of Clinical Oncology 2012 Annual Meeting, Chicago, IL.
- (8) Alsina M et al. PANORAMA 2: A phase II study of panobinostat in combination with bortezomib and dexamethasone in patients with relapsed and bortezomib-refractory multiple myeloma. Abstract #8012. American Society of Clinical Oncology 2012 Annual Meeting, Chicago, IL.
- (9) Geoerger B et al. A Phase I/II study of LDE225, a Smoothened (Smo) antagonist, in pediatric patients with recurrent medulloblastoma (MB) or other solid tumors. Abstract #9519. American Society of Clinical Oncology 2012 Annual Meeting, Chicago, IL.
- (10) Mehra R et al. First-in-human Phase I study of the ALK inhibitor LDK378 in advanced solid tumors. Abstract #3007. American Society of Clinical Oncology 2012 Annual Meeting, Chicago, IL.
- (11) Ascierto P et al. Efficacy and safety of oral MEK162 in patients with locally advanced and unresectable or metastatic cutaneous melanoma harboring BRAFV600 or NRAS mutations. Abstract #8511. American Society of Clinical Oncology 2012 Annual Meeting, Chicago, IL.

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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: May 31, 2012

By: /s/ MALCOLM B. CHEETHAM

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