NOVARTIS AG
Form 6-K
May 15, 2009

# 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 13, 2009**

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

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# Novartis AG

**(Name of Registrant)**

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**- Investor Relations Release -**

**Scientists who developed Novartis Coartem® and Glivec® receive 2009 European Inventor of the Year awards**

- *Glivec, a therapy that has revolutionized the treatment of several life-threatening cancers, invented by Juerg Zimmermann, PhD, Novartis Institutes for Biomedical Research and Brian Druker, MD, Oregon Health & Science University Cancer Institute, is honored in the industry category*

- *Coartem, a highly-effective drug that carries a low risk of resistance when used in combination with other antimalarials, developed by Professor Yiqing Zhou and team at the Institute of Microbiology and Epidemiology in Beijing, wins in the non-European category*

- *Awards affirm Novartis commitment to developing innovative, life-saving medicines to address unmet patient needs, with two wins out of the four award categories*

**Basel, May 13, 2009** Scientists who created life-saving Novartis drugs were recognized as 2009 European Inventors of the Year by the European Commission and the European Patent Office. The Inventor of the Year award honors individuals who have made a defining and lasting contribution to technical progress in Europe and helped strengthen the European economy.

The dedication, determination and expertise of our scientists and our collaboration with academic centers make the discovery and development of such innovative life-saving medicines possible. They have changed the practice of medicine and are improving the lives of patients around the world, said Daniel Vasella, MD, Chairman and CEO, Novartis AG. This also demonstrates that the consistent and sustained investment and focus on research and development at Novartis is making a difference.

Juerg Zimmermann, PhD, Global Head of Novartis Global Discovery Chemistry - Oncology & Exploratory Chemistry, together with Brian Druker, MD, Oregon Health & Science University Cancer Institute, received the inventor award in the industry category for the development of Glivec® (imatinib),* for treating Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) and Kit-positive malignant gastrointestinal stromal tumors (GIST).

Professor Yiqing Zhou and his team of researchers at the Microbiology and Epidemiology Institute in Beijing were awarded the non-European inventor category for developing Coartem®, the leading Artemisinin-based Combination Treatment (ACT) for treating malaria.

**Glivec**

Juerg Zimmermann and his team overcame significant technical challenges to develop a novel class of protein kinase inhibitors to help fight certain types of cancer. The result was Glivec, a treatment that targets the protein Bcr-Abl, the key cause and driver of Ph+ CML. Glivec revolutionized the treatment of this life-threatening disease(2),(3), resulting in the longest overall survival ever observed for people with the Ph+ CML. Nearly nine out of ten (86%) patients taking

Glivec were alive seven years after the start of the landmark International Randomized Interferon versus STI571 (IRIS) trial(4). Prior to Glivec, about half of patients with Ph+ CML progressed from the initial phase to more advanced stages after only three to five years. Once patients reached the final blast crisis phase, survival was generally three to six months(5).

Glivec has also been approved for the treatment of advanced metastatic or unresectable (inoperable) Kit-positive GIST(1), a rare and deadly cancer that has historically been very difficult to treat(1),(6). In addition, Novartis recently received both US and European approval of Glivec as the first and only post-surgery treatment following complete surgical removal of Kit-positive GIST in adult patients(7).

When we started the journey to develop Glivec, we could only hope to produce a drug that might someday become the standard of care for life-threatening cancers, said Dr. Zimmermann. Knowing that our efforts have directly helped the lives of so many patients is extremely rewarding.

**Coartem**

Malaria is a devastating disease that infects nearly 250 million people and causes an estimated 880,000 deaths annually. Its toll is heaviest among young children in sub-Saharan Africa, where it is estimated that a child dies of malaria every 30 seconds(8).

Novartis worked closely with their Chinese partners to develop Coartem, and the invention of this life-saving treatment has delivered more than 235 million treatments of Coartem without profit, helping save an estimated 600,000 lives. Coartem is now the most widely distributed Novartis medicine.

In search of an effective and inexpensive treatment for malaria, Professor Zhou and his team became interested in an old herbal remedy, Artemisia annua, or Sweet Wormwood, used in China beginning around 168 BC and rediscovered in 1967 to treat malaria-stricken soldiers during the Vietnam War. Professor Zhou mixed the active ingredient, artemisinin with a proven anti-malarial agent, benflumetol, and developed a highly effective antimalarial. To get this medicine to patients, Novartis and its Chinese partners completed one of the largest and fastest scale-ups in the industry.

My hope was very simple. We had a great drug for treating malaria in China, and my hope was to make it available to all the people who were suffering from malaria, said Professor Zhou Yiqing of the Academy of Military Medical Sciences in China. We wanted to ease their suffering and give them new opportunity.

Data shows that Coartem is generally well tolerated, controls malaria-related fever in as little as 24 to 36 hours, and delivers cure rates of over 96% after only three to four days of treatment.

**About Glivec**

Glivec is approved in more than 90 countries including the US, EU and Japan for the treatment of all phases of Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML). Glivec is also approved in the US, EU and other countries for the treatment of patients with Kit (CD117)-positive GIST which cannot be surgically removed and/or have already spread to other parts of the body (metastasized). In the US and the EU, Glivec was recently 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.

**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 Coartem**

In a unique collaboration with international organizations, Novartis has provided more than 235 million Coartem treatment courses to the public sector in Africa without profit since 2001. These treatments have helped to save approximately 600,000 lives.

Artemisinin is a compound derived from the sweet wormwood plant and has been used for centuries in traditional Chinese medicine to treat fever. An ACT is a combination of two or more drugs (one of which is an artemisinin derivative) that have different modes of action. Studies have shown that using two or more drugs in combination has the potential to delay the development of resistance. ACTs in particular have been found to be highly effective in treating malaria and their potential to delay resistance in areas of intense transmission is under investigation.

**About Novartis**

Novartis AG 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 2008, the Group s continuing operations achieved net sales of USD 41.5 billion and net income of USD 8.2 billion. Approximately USD 7.2 billion was invested in R&D activities throughout the Group. Headquartered in Basel, Switzerland, Novartis Group companies employ approximately 98,000 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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**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**

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| Date: May 13, 2009 | By: | /s/ MALCOLM B. CHEETHAM |
| | Name: | Malcolm B. Cheetham |
| | Title: | Head Group Financial Reporting and Accounting |