

NOVARTIS AG
Form 6-K
April 20, 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 April 20, 2012

(Commission File No. 1-15024)

Novartis AG

(Name of Registrant)

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Switzerland

(Address of Principal Executive Offices)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F:

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Yes: No:

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MEDIA RELEASE • COMMUNIQUE AUX MEDIAS • MEDIENMITTEILUNG

Novartis drug Jakavi recommended by CHMP for EU approval to treat patients with the life-threatening blood cancer myelofibrosis

- *Upon approval, Jakavi (INC424, ruxolitinib) will be the first EU approved JAK inhibitor developed to treat patients with myelofibrosis, a rare blood cancer*
- *Patients with myelofibrosis experience severe symptoms due to overactive signaling in the JAK pathway, resulting in reduced quality of life and survival*
- *Phase III trials show Jakavi produces a rapid, durable and significant clinical benefit by alleviating the progressive, debilitating disease burden of myelofibrosis*

Basel, April 20, 2012 - The Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) adopted a positive opinion for Jakavi (INC424, ruxolitinib) for the treatment of disease-related splenomegaly or symptoms in adult patients with primary myelofibrosis (also known as chronic idiopathic myelofibrosis), post-polycythemia vera myelofibrosis or post-essential thrombocythemia myelofibrosis. Globally, there are few available treatments for myelofibrosis, an uncommon, life-threatening blood cancer characterized by multiple severe complications such as bone marrow failure, enlarged spleen (splenomegaly) and shortened survival(1).

The Committee's positive opinion today validates the strong data in support of Jakavi and the very high unmet need in treating myelofibrosis, said Hervé Hoppenot, President, Novartis Oncology. The recommendation for European Commission approval of Jakavi also marks a significant step forward in bringing the first and only JAK 1 and JAK 2 inhibitor to patients with very limited options. Novartis is committed to advancing novel, targeted treatments for rare diseases, and we are invested in continuing research to determine other hematological diseases where Jakavi may address unmet patient needs.

In the European Union (EU), the European Commission generally follows the recommendations of the CHMP and usually delivers its final decision within three months of the CHMP recommendation. The decision will be applicable to all 27 EU member states. The European Commission granted Jakavi orphan drug designation for myelofibrosis.

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The CHMP opinion was based on positive findings from the COMFORT (COnrolled MyeloFibrosis Study with ORal JAK Inhibitor Therapy) program, which represents the largest myelofibrosis clinical development program to date. Jakavi directly targets the underlying mechanism of disease, significantly reducing splenomegaly and improving symptoms regardless of JAK mutational status, disease subtype or any prior treatment, including hydroxyurea(2),(3).

In the COMFORT-I trial, 41.9% of Jakavi treated patients achieved at least a 35% reduction in spleen volume at 24 weeks from baseline compared to 0.7% of patients in the placebo group ($p < 0.001$). An early analysis of COMFORT-I shows Jakavi treatment resulted in an overall survival benefit as compared to placebo (hazard ratio=0.50 [95%

confidence interval: 0.25, 0.98]). The most frequently reported grade 3 or higher adverse events were hematologic. One patient in each group discontinued treatment for thrombocytopenia or for anemia, respectively. The most common non-hematologic adverse events of any grade reported for patients receiving Jakavi or placebo respectively were fatigue (25% vs 34%), diarrhea (23% vs 21%), peripheral edema (19% vs 22%) and ecchymosis (19% vs 9%)(3). COMFORT-I was conducted in the US by Incyte under the worldwide collaboration and license agreement for INC424 (ruxolitinib).

In COMFORT-II, Jakavi produced a volumetric spleen size reduction of 35% or greater (roughly equivalent to a reduction in palpable spleen size by 50%) in 28.5% of patients compared to 0% of patients in the best available therapy (BAT) group at 48 weeks ($p < 0.001$). The BAT is any commercially available agent (such as monotherapy or in combination) or no therapy at all. At week 24, 32% of Jakavi patients demonstrated a 35% or greater volumetric spleen size reduction compared to 0% of patients treated with the BAT ($p < 0.001$) for the key secondary endpoint. Jakavi was associated with improvements in myelofibrosis symptoms at each evaluation as compared to the BAT(2).

Continuous Jakavi therapy also provided a marked and durable improvement in overall quality of life measures, functioning and symptoms, including loss of appetite, dyspnea (shortness of breath), fatigue, insomnia and pain, at week 48 compared to a worsening of symptoms in BAT-treated patients. For Jakavi, the most frequently reported adverse event was increased frequency of anemia and thrombocytopenia. The most frequently reported serious adverse event for Jakavi was anemia (5%). Pneumonia was reported in 1% of patients taking Jakavi(2).

About Myelofibrosis

In the EU, the disease affects about 0.75 out of every 100,000 people annually(5),(6). Myelofibrosis has a poor prognosis and limited treatment options. Symptoms include extreme fatigue, fever, night sweats, itchy skin, bone or muscle pain, abdominal pain or discomfort and weight loss(1),(4).

Studies show that patients with myelofibrosis have a decreased life expectancy, with a median survival of 5.7 years(7). Although allogeneic stem cell transplantation may cure myelofibrosis, the procedure is associated with significant morbidity and transplant-related mortality and is available to less than 5% of patients who are young and fit enough to undergo the procedure(8).

About Jakavi

Jakavi (INC424, ruxolitinib) is an oral inhibitor of the JAK 1 and JAK 2 tyrosine kinases(4). As part of the Novartis clinical development program, Jakavi is being investigated in primary myelofibrosis, post-polycythemia vera myelofibrosis and post-essential thrombocythemia myelofibrosis. Jakavi is also being investigated in clinical trials for the treatment of polycythemia vera(9).

Novartis licensed INC424 (ruxolitinib) from Incyte for development and potential commercialization outside the US. Incyte has retained rights for the development and commercialization of INC424 (ruxolitinib) in the US. Both the European Commission and the US Food and Drug Administration (FDA) granted INC424 (ruxolitinib) orphan drug status for myelofibrosis. Incyte received FDA approval for INC424 (ruxolitinib) in November 2011 under the name Jakafi for the treatment of patients with intermediate or high-risk myelofibrosis.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as recommended, will, recommendation, committed, invested in continuing research, generally follows, being investigated, potential, or similar expressions, or by express or implied discussions regarding potential marketing approvals for Jakavi and the timing of any such approvals, or regarding potential future

revenues from Jakavi. 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 Jakavi to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Jakavi will be approved for sale in any market, or at any particular time. Neither can there be any guarantee that Jakavi will achieve any particular levels of revenue in the future. In particular, management's expectations regarding Jakavi could be affected by, among other things, unexpected regulatory actions or delays or government regulation generally; unexpected clinical trial results, including unexpected new clinical data and unexpected additional analysis of existing clinical data; government, industry and general public pricing pressures; unexpected manufacturing issues; competition in general; 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

- (1) Mesa RA, Schwagera S, Radia D, et al. The Myelofibrosis Symptom Assessment Form (MFSAF): an evidence-based brief inventory to measure quality of life and symptomatic response to treatment in myelofibrosis. *Leuk Res.* 2009;33:1199-1203.
- (2) Harrison C, Kiladjian JJ, Al-Ali HK, et al. JAK Inhibition with Ruxolitinib versus Best Available Therapy for Myelofibrosis. *New Eng J Med.* 2012; March 1;366:787-98.
- (3) Verstovsek S, Mesa RA, Gotlib J, et al. A Double-Blind, Placebo-Controlled Trial of Ruxolitinib for Myelofibrosis. *New Eng J Med.* 2012; March 1;366:799-807.
- (4) Verstovsek S, Kantarjian H, Mesa RA, et al. Safety and Efficacy of JAK1 & JAK2 Inhibitor, INCB018424, in Myelofibrosis. *New Eng J Med.* 2010 September 16;363:1117-1127.
- (5) Girodon F, Bonicelli G, Schaeffer C, et al. Significant increase in the apparent incidence of essential thrombocythemia related to new WHO diagnostic criteria: a population-based study. *Haematologica.* 2009; 94(6):865-869.

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- (6) McNally RJQ, Rowland D, Roman E, Cartwright RA. Age and sex distributions of hematological malignancies in the U.K. *Hematol Oncol.* 1997;15:173-189.
- (7) Cervantes F, Dupriez B, Pereira A, et al. New prognostic scoring system for primary myelofibrosis based on a study of the International Working Group for Myelofibrosis Research and Treatment. *Blood.* 2009;113:2895-2901.
- (8) Patriarca F, Bacigalupo A, Sperotto A, et al. Allogeneic hematopoietic stem cell transplantation in myelofibrosis: the 20-year experience of the Gruppo Italiano Trapianto di Midollo Osseo (GITMO). *Haematologica.* 2008;93(10):1514-1522.
- (9) National Institutes of Health. Study of Efficacy and Safety in Polycythemia Vera Subjects Who Are Resistant to or Intolerant of Hydroxyurea: JAK Inhibitor INC424 (INCB018424) Tablets Versus Best Available Care: The RESPONSE Trial. Available at <http://www.clinicaltrials.gov/ct2/show/NCT01243944?term=ruxolitinib&rank=14>. Accessed January 31, 2012.

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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: April 20, 2012

By: /s/ MALCOLM B. CHEETHAM

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