NOVARTIS AG
Form 6-K
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UNITED STATES
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 March 6, 2015
(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: x Form 40-F: o

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: o No: x

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: o No: x

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: o No: x

Communiqué Aux Médias

Sandoz International
Industriestr. 25
83607 Holzkirchen,Germany
Tel: +49 8024 476 2596
Fax: +49 8024 476 2599
www.sandoz.com

FDA approves first biosimilar ZarxioTM (filgrastim-sndz) from Sandoz

- Sandoz is the first company to receive approval of a biosimilar in the US through the new FDA biosimilars pathway established under BPCIA
- Zarxio is approved for all indications included in the reference product's (NEUPOGEN®) label
- Approval paves way for greater access to high-quality biologics in the US and underscores Sandoz global leadership in biosimilars

Holzkirchen, March 6, 2015 – Sandoz, a Novartis company, announced today that the US Food and Drug Administration (FDA) approved Zarxio™ (filgrastim-sndz) for all indications included in the reference product's label. Sandoz is the first company to receive approval of a biosimilar in the US through the new FDA biosimilars pathway established under the Biologics Price Competition and Innovation Act. The approval was based on a comprehensive package of analytical, nonclinical, and clinical data, which confirmed that Zarxio is highly similar to the US-licensed reference product. The approval of Zarxio follows the unanimous positive vote in January by the Oncologic Drugs Advisory Committee (ODAC).

"The FDA approval of Zarxio marks a significant milestone for the United States healthcare system and for patients who might suffer from neutropenia," said Carol Lynch, Global Head of Biopharmaceuticals & Oncology Injectables at Sandoz. "As the global leader in biosimilars, we are honored to be the first company to successfully work with FDA to navigate the US biosimilar pathway and we look forward to making this high-quality biosimilar available to patients in the US."

"Filgrastim has proven clinical value in treating patients at increased risk of neutropenia, but it is underused in the US for a variety of reasons, including price" said Dr. Louis Weiner, chairman of the department of oncology and director of the Lombardi Comprehensive Cancer Center at Georgetown University. "Biosimilars have the potential to increase access and the approval of Zarxio may reduce costs to the healthcare system. The comprehensive data set supports its use in clinical practice."

The successful Sandoz pivotal head-to-head PIONEER study was the final piece of data contributing to the totality of evidence used by FDA to approve Zarxio as biosimilar to the reference product. Importantly, the data demonstrating high similarity was sufficient to allow extrapolation of use of Zarxio to all indications of the reference product. In the PIONEER study, Zarxio and the reference product both produced the expected reduction in the duration of severe neutropenia in cancer patients undergoing myelosuppressive chemotherapy (1.17 and 1.20 days for Zarxio and the reference product, respectively). The mean time to absolute neutrophil count recovery in cycle 1 was also similar (1.8 days ± 0.97 in ZARXIO arm vs 1.7 days ± 0.81 in reference product arm). No immunogenicity or antibodies against rhG-CSF were detected throughout the study.
Marketed as Zarzio® outside of the US, the Sandoz biosimilar filgrastim is available in more than 60 countries worldwide, has generated over 7.5 million patient-days of exposure and is the most widely used filgrastim in Europe.

Sandoz has a commitment to increasing patient access to high-quality biosimilars. Sandoz is the global market leader with over 50 percent volume share of biosimilars approved in North America, Europe, Japan and Australia. Sandoz currently markets three biosimilars (somatropin, filgrastim and epoetin alfa) outside the US; each of which occupies the #1 biosimilar position in its respective category. The Sandoz pipeline has several biosimilars across the various stages of development, including five programs in Phase III clinical trials/filing preparation – more than any other company in the industry.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

- Zarxio is contraindicated in patients with a history of serious allergic reactions to human granulocyte colony-stimulating factors such as filgrastim or pegfilgrastim.

WARNINGS AND PRECAUTIONS

- Splenic rupture, including fatal cases, has been reported following the administration of filgrastim products. Patients who report left upper abdominal or shoulder pain should be evaluated.
- Acute respiratory distress syndrome (ARDS) has been reported in patients receiving filgrastim products. Patients who develop fever and lung infiltrates or respiratory distress should be evaluated. Discontinue Zarxio in patients with ARDS.
- Serious allergic reactions, including anaphylaxis, have been reported in patients receiving filgrastim products. The majority of reported events occurred upon initial exposure. Provide symptomatic treatment for allergic reactions. Allergic reactions, including anaphylaxis, in patients receiving filgrastim products can recur within days after the discontinuation of initial anti-allergic treatment. Permanently discontinue Zarxio in patients with serious allergic reactions.
- Sickle cell crisis, in some cases fatal, has been reported with the use of filgrastim products in patients with sickle cell trait or sickle cell disease.
- Alveolar hemorrhage manifesting as pulmonary infiltrates and hemoptysis requiring hospitalization have been reported in healthy donors treated with filgrastim undergoing peripheral blood progenitor cell (PBPC) collection mobilization. Hemoptysis resolved with discontinuation of filgrastim. The use of Zarxio for PBPC mobilization in healthy donors is not an approved indication.
- Capillary leak syndrome (CLS) has been reported after G-CSF administration, including filgrastim products, and is characterized by hypotension, hypoalbuminemia, edema and hemoconcentration. Episodes vary in frequency, severity and may be life-threatening if treatment is delayed. Patients who develop symptoms of capillary leak syndrome should be closely monitored and receive appropriate treatment.

- Confirm the diagnosis of severe chronic neutropenia (SCN) before initiating Zarxio therapy. Myelodysplastic syndrome (MDS) and acute myelogenous leukemia (AML) have been reported to occur in the natural history of congenital neutropenia without cytokine therapy. Cytogenetic abnormalities, transformation to MDS, and AML have also been observed in patients treated with filgrastim for SCN. Abnormal cytogenetics and MDS have been associated with the eventual development of myeloid leukemia. The effect of filgrastim products on the development of abnormal cytogenetics and the effect of continued filgrastim administration in patients with abnormal cytogenetics or MDS are unknown. If a patient with SCN develops abnormal cytogenetics or myelodysplasia, the risks and benefits of continuing Zarxio should be carefully considered.
- Thrombocytopenia has been reported in patients receiving filgrastim products. Monitor platelet counts.
- Leukocytosis:
- Patients with Cancer Receiving Myelosuppressive Chemotherapy: White blood cell counts of 100,000/mm3 or greater were observed in approximately 2% of patients receiving filgrastim at dosages above 5 mcg/kg/day. In patients with cancer receiving ZARXIO as an adjunct to myelosuppressive chemotherapy, to avoid the potential risks of excessive leukocytosis, it is recommended that ZARXIO therapy be discontinued if the ANC surpasses 10,000/mm3 after the chemotherapy-induced ANC nadir has occurred. Monitor CBCs at least twice weekly during therapy.
- Peripheral Blood Progenitor Cell (PBPC) Collection and Therapy: During the period of administration of Zarxio for PBPC mobilization in patients with cancer, discontinue Zarxio if the leukocyte count rises to >100,000/mm3.
- Cutaneous vasculitis has been reported in patients treated with filgrastim products. In most cases, the severity of cutaneous vasculitis was moderate or severe. Most of the reports involved patients with SCN receiving long-term filgrastim therapy. Hold Zarxio therapy in patients with cutaneous vasculitis. Zarxio may be started at a reduced dose when the symptoms resolve and the ANC has decreased.
- The possibility that filgrastim acts as a growth factor for any tumor type, including myeloid malignancies and myelodysplasia, diseases for which filgrastim is not approved, cannot be excluded. The safety of filgrastim products in chronic myeloid leukemia (CML) and myelodysplasia has not been established. When Zarxio is used to mobilize PBPC, tumor cells may be released from the marrow and subsequently collected in the leukapheresis product. Available data is limited and inconclusive.
- The safety and efficacy of filgrastim products given simultaneously with cytotoxic chemotherapy have not been established. Do not use Zarxio in the period 24 hours before through 24 hours after the administration of cytotoxic chemotherapy. The safety and efficacy of filgrastim products have not been evaluated in patients receiving concurrent radiation therapy. Avoid the simultaneous use of Zarxio with chemotherapy and radiation therapy.
- Increased hematopoietic activity of the bone marrow in response to growth factor therapy has been associated with transient positive bone-imaging changes on nuclear imaging.

ADVERSE REACTIONS
Most common adverse reactions in patients:

- With nonmyeloid malignancies receiving myelosuppressive anti-cancer drugs (≥ 5% difference in incidence compared to placebo) are thrombocytopenia, nausea, pyrexia, chest pain, pain, fatigue, back pain, arthralgia, bone pain, pain in extremity, dizziness, cough, dyspnea, rash, blood lactate dehydrogenase increased and blood alkaline phosphatase increased
- With AML (≥ 2% difference in incidence) are epistaxis, back pain, pain in extremity, erythema, and rash maculo-papular
- With nonmyeloid malignancies undergoing myeloablative chemotherapy followed by BMT (≥ 5% difference in incidence) are rash and hypersensitivity
- Undergoing peripheral blood progenitor cell mobilization and collection (≥ 5% incidence) are bone pain, pyrexia, blood alkaline phosphatase increased and headache
- With severe chronic neutropenia (SCN) (≥ 5% difference in incidence) are arthralgia, bone pain, back pain, muscle spasms, musculoskeletal pain, pain in extremity, splenomegaly, anemia, upper respiratory tract infection, urinary tract infection, epistaxis, chest pain, diarrhea, hypoesthesia, and alopecia

Please click here for full Prescribing Information.

To report SUSPECTED ADVERSE REACTIONS, contact Sandoz Inc. at 1-800-525-8747 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

About Neutropenia
Neutropenia is a condition characterized by a low amount of neutrophils in your blood - one of the most common types of white blood cells - whose role is to protect the body from infections. Neutropenia occurs often following cancer treatments, as well as advanced HIV infections. Filgrastim is a naturally occurring protein produced commercially by recombinant DNA technology, which stimulates production of white blood cells.

Disclaimer
The foregoing release contains forward-looking statements that can be identified by words such as “paves way,” “look forward,” “potential,” “commitment,” or similar terms, or by express or implied discussions regarding potential future product approvals, or regarding potential revenues from Zarxio, or potential future products. You should not place undue reliance on these statements. Such forward-looking statements are based on the current beliefs and expectations of management regarding future events, and are subject to significant known and unknown risks and uncertainties. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those set forth in the forward-looking statements. There can be no guarantee that biosimilar filgrastim will be submitted for sale in any additional markets, or at any particular time. Nor can there be any guarantee that Zarxio, or any potential future products will be commercially successful in the future. In particular, management’s expectations regarding Zarxio, or such potential future products could be affected by, among other things, unexpected clinical trial results and additional analysis of existing clinical data; unexpected regulatory actions or delays or government regulation generally; competition in general, including potential approval of additional versions of biosimilar filgrastim; government, industry and general public pricing pressures; unexpected intellectual property litigation outcomes; unexpected manufacturing issues; general economic and industry conditions, and other risks and factors referred to in Novartis AG’s current Form 20-F on file with the US Securities and Exchange Commission. 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 Sandoz
Sandoz, a division of Novartis, is a global leader in generic pharmaceuticals, driving sustainable access to high-quality healthcare. Sandoz employs more than 26,000 people worldwide and supplies a broad range of affordable, primarily off-patent products to patients and customers around the globe.

The Sandoz global portfolio comprises approximately 1,100 molecules, which accounted for 2014 sales of USD 9.6 billion. Sandoz holds the global #1 position in biosimilars as well as in generic anti-infectives, ophthalmics and transplantation medicines. In addition, Sandoz holds leading global positions in key therapeutic areas ranging from generic injectables, dermatology and respiratory to cardiovascular, metabolism, central nervous system, pain and gastrointestinal. Sandoz develops, produces and markets finished dosage form (FDF) medicines as well as intermediary products including active pharmaceutical ingredients (APIs) and biotechnological substances. Nearly half of Sandoz's portfolio is in differentiated products – products that are scientifically more difficult to develop and manufacture than standard generics.

In addition to strong organic growth since consolidating its generics businesses under the Sandoz brand name in 2003, Sandoz has consistently driven growth in selected geographies and differentiated product areas through a series of targeted acquisitions, including Hexal (Germany), EBEWE Pharma (Austria), and Fougera Pharmaceuticals (US).

Sandoz is on Twitter. Sign up to follow @Sandoz_global at http://twitter.com/Sandoz_Global

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For further information:

Eric Althoff
Novartis Global Media Relations
+41-61-324-7999
+41-79-593-4202
eric.althoff@novartis.com

Sreejit Mohan
Sandoz Head Biopharma & OI Communications
+49 (0) 162 429 7971
sreejit.mohan@sandoz.com

Leslie Pott
Sandoz US Communications
+1-609-627-5287
+1-201-354-0279
leslie.pott@sandoz.com

Novartis Investor Relations

Central phone:	+41 61 324 7944	North America:	
Samir Shah	+41 61 324 7944	Richard Pulik	+1 212 830 2448
Pierre-Michel Bringer	+41 61 324 1065	Susan Donofrio	+1 862 778 9257
Thomas Hungerbuehler	+41 61 324 8425		
Isabella Zinck	+41 61 324 7188		

e-mail: investor.relations@novartis.com

Footnotes:

1. NEUPOGEN® is a registered trademark of Amgen.
2. ZARXIOTM is a trademark of Novartis AG.
3. ZARZIO® is a registered trademark of Novartis AG.

Media release (PDF): http://hugin.info/134323/R/1900097/675245.pdf