NOVARTIS AG
Form 6-K
October 06, 2014

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 October 6, 2014

(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:

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

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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

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MEDIA RELEASE • COMMUNIQUE AUX MEDIAS • MEDIENMITTEILUNG

Novartis announces clinical collaboration to evaluate Bristol-Myers Squibb s novel immunotherapy in combination treatments for NSCLC

- *Phase I/II studies will evaluate Zykadia , INC280 and EGF816 in combination with Bristol-Myers Squibb s investigational immunotherapy Opdivo®*

- *Combination studies will evaluate compounds that have demonstrated evidence of targeting mutations associated with tumor growth in patients with NSCLC*

- *Collaboration highlights promising new treatment approach for patients and underscores Novartis commitment to patients and the lung cancer community*

Basel, October 6, 2014 Novartis announced today that it has entered into a clinical collaboration with Bristol-Myers Squibb Company (NYSE: BMY) to evaluate the safety, tolerability and preliminary efficacy of three molecularly targeted compounds in combination with Bristol-Myers Squibb s investigational PD-1 immune checkpoint inhibitor, Opdivo® (nivolumab), in Phase I/II trials of patients with non-small cell lung cancer (NSCLC).

Preclinical data suggests that combining molecularly targeted agents with immunotherapies such as nivolumab may have synergistic effects and lead to better outcomes for patients, said Alessandro Riva, MD, Global Head, Novartis Oncology Development and Medical Affairs. This collaboration enables us to study several key compounds, including our new highly-potent ALK inhibitor Zykadia, together with a promising, novel immunotherapy agent, paving the way for potential new treatment approaches for patients with NSCLC.

Both studies will be conducted by Novartis. One trial will evaluate the combination of Opdivo with Zykadia (ceritinib), an FDA-approved treatment for patients with anaplastic lymphoma kinase-positive (ALK+) metastatic NSCLC who have progressed on or are intolerant to crizotinib(1). A second study will investigate Opdivo with INC280, a potent and highly selective inhibitor of c-MET receptor tyrosine kinase, and separately with EGF816, a potent, third-generation EGFR tyrosine kinase inhibitor that is active against T790 mutations. INC280 and EGF816 are currently being investigated in various Phase I/II NSCLC trials. Additional details of the collaboration were not disclosed.

This collaboration with Bristol-Myers Squibb further advances Novartis development efforts in the field of immunotherapy. Earlier this year, Novartis acquired CoStim Pharmaceuticals Inc., adding late discovery stage immunotherapy programs focused on key oncogenic targets, including PD-1. Novartis is also actively investigating the potential of chimeric antigen receptor (CAR) T cell technologies in the treatment of various liquid and solid tumors through its alliance with the University of Pennsylvania.

About Zykadia

Zykadia (ceritinib) is indicated in the US for the treatment of patients with ALK+ metastatic NSCLC who have progressed on or are intolerant to crizotinib. This indication is approved under accelerated approval based on tumor response rate and duration of

response. An improvement in survival or disease-related symptoms has not been established. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

Outside of the US, Zykadia (ceritinib) is an investigational agent and has not been approved by regulatory authorities. Regulatory reviews are currently underway in the European Union and several countries within South America, Central America and Asia.

About INC280 and EGF816

Because these are investigational compounds, the safety and efficacy profiles of INC280 and EGF816 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 treatments. Because of the uncertainty of clinical trials, there is no guarantee that INC280 and EGF816 will ever be commercially available anywhere in the world.

Novartis licensed INC280 from Incyte Corporation and holds exclusive worldwide development and commercialization rights to the compound in all indications.

About Opdivo (nivolumab)

Cancer cells may exploit regulatory pathways, such as checkpoint pathways, to hide from the immune system and shield the tumor from immune attack. Opdivo is an investigational, fully-human PD-1 immune checkpoint inhibitor that binds to the checkpoint receptor PD-1 (programmed death-1) expressed on activated T-cells.

Bristol-Myers Squibb has a broad, global development program to study Opdivo in multiple tumor types consisting of more than 35 trials as monotherapy or in combination with other therapies in which more than 7,000 patients have been enrolled worldwide. Among these are several potentially registrational trials in NSCLC, melanoma, renal cell carcinoma (RCC), head and neck cancer, glioblastoma and non-Hodgkin lymphoma. In July, 2014, Opdivo received manufacturing and marketing approval in Japan for the treatment of patients with unresectable melanoma. Opdivo is also under review by the U.S. Food and Drug Administration and European Medicines Agency. Bristol-Myers Squibb has proposed the name Opdivo (pronounced op-dee-voh), which, if approved by health authorities, will serve as the trademark for nivolumab.

Zykadia Important Safety Information

Zykadia causes stomach and intestinal problems in most people, including diarrhea, nausea, vomiting, and stomach-area pain. These problems can sometimes be severe. Patients should follow their doctor s instructions about taking medicines to help these symptoms, and should call their doctor for advice if symptoms are severe or do not go away.

Zykadia may cause liver injury. Patients should have blood tests at least every month while taking Zykadia, and should talk to their doctor right away if they experience any of the following symptoms: tiredness (fatigue), itchy skin, yellow skin and eyes, nausea or vomiting, decreased appetite, pain on the right side of the stomach, urine turns dark or brown, bleeding or bruising more easily than normal.

Zykadia may cause severe or life-threatening swelling (inflammation) of the lungs during treatment that can lead to death. Symptoms may be similar to those symptoms from lung cancer. Patients should tell their doctor right away about any new or worsening symptoms, including trouble breathing or shortness of breath, fever, cough, with or without mucous, or chest pain.

Zykadia may cause very slow, very fast, or abnormal heartbeats. Doctors should check their patient s heart during treatment with Zykadia. Patients should tell their doctor right away if they feel new chest pain or discomfort, dizziness or lightheadedness, faint, or

have abnormal heartbeats, or if they start to take or have any changes in heart or blood pressure medicines.

People who have diabetes or glucose intolerance, or who take a corticosteroid medicine have an increased risk of high blood sugar with Zykadia. Patients should follow their doctor s instructions about blood sugar monitoring and call their doctor right away with any symptoms of high blood sugar, including increased thirst, increased hunger, headaches, trouble thinking or concentrating, urinating often, blurred vision, tiredness, or breath that smells like fruit.

Before patients take Zykadia, they should tell their doctor about all medical conditions, including liver problems; diabetes or high blood sugar; heart problems, including a condition called long QT syndrome; are pregnant, think they may be pregnant, or plan to become pregnant; are breastfeeding or plan to breastfeed.

Zykadia may harm unborn babies. Women who are able to become pregnant must use an effective method of birth control during treatment with Zykadia and for at least 2 weeks after stopping Zykadia. It is not known if Zykadia passes into breast milk. Patients and their doctor should decide whether to take Zykadia or breastfeed, but should not do both.

Patients should tell their doctor about medicines they take, including prescription medicines, over-the-counter medicines, vitamins and herbal supplements.

The most common side effects of Zykadia include diarrhea, nausea, vomiting, abdominal pain, tiredness (fatigue), decreased appetite and constipation.

Patients should tell their doctor of any side effect that bothers them or does not go away. These are not all of the possible side effects of Zykadia. For more information, patients should ask their doctor or pharmacist.

Patients should take Zykadia exactly as their health care provider tells them. Patients should not change their dose or stop taking Zykadia unless their health care provider advises them to. Zykadia should be taken once a day on an empty stomach. Patients should not eat for 2 hours before and 2 hours after taking Zykadia. If a dose of Zykadia is missed, they should take it as soon as they remember. If their next dose is due within the next 12 hours, they should skip the missed dose and take the next dose at their regular time. Patients should not drink grapefruit juice or eat grapefruit during treatment with Zykadia, as it may make the amount of Zykadia in their blood increase to a harmful level.

Please see full Prescribing Information for Zykadia.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by words such as to evaluate, will, investigational, promising, commitment, suggests, may, potential, being investigated, investigating, underway, yet, being studied, potentially, Breakthr similar terms, or by express or implied discussions regarding potential marketing authorizations for Zykadia, INC280, EGF816, or other investigational compounds in the Novartis Oncology pipeline, potential new indications or labeling for Zykadia, or potential future revenues from such products and compounds. 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 Zykadia, INC280, EGF816 or any other product in the Novartis Oncology pipeline will be submitted or approved for sale in any market or at any particular time. Neither can there

be any guarantee that Zykadia will be submitted or approved for any additional indications or labeling in any market, or at any particular time. Nor can there be any guarantee that such products and compounds will be commercially successful in the future. In particular, management s expectations regarding such products and compounds could be affected by, among other things, the uncertainties inherent in research and development, including unexpected clinical trial results and additional analysis of existing clinical data; unexpected regulatory actions or delays or government regulation generally; the company s ability to obtain or maintain proprietary intellectual property protection; general economic and industry conditions; global trends toward health care cost containment, including ongoing pricing pressures; unexpected manufacturing issues, 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.

Opdivo® is a registered trademark of Bristol-Myers Squibb Company.

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, over-the-counter and animal health products. Novartis is the only global company with leading positions in these areas. In 2013, the Group achieved net sales of USD 57.9 billion, while R&D throughout the Group amounted to approximately USD 9.9 billion (USD 9.6 billion excluding impairment and amortization charges). Novartis Group companies employ approximately 135,000 full-time-equivalent associates and sell products in more than 150 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) Zykadia (ceritinib) Prescribing Information. East Hanover, New Jersey, USA: Novartis Pharmaceuticals Corporation; April 2014.

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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:	October 6, 2014	By:	/s/ MALCOLM B. CHEETHAM
		Name:	Malcolm B. Cheetham
		Title:	Head Group Financial Reporting and Accounting