NOVARTIS AG
Form 6-K
March 14, 2017

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 14, 2017

(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: Form 40-F:

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: **No**:

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: **No**:

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: **No**:

Novartis Kisqali® (ribociclib, LEE011) receives FDA approval as first-line treatment for HR+/HER2- metastatic breast cancer in combination with any aromatase inhibitor

- *Approved based on a first-line Phase III trial that met its primary endpoint of progression-free survival (PFS) at interim analysis due to superior efficacy compared to letrozole alone[1]*
- *At this interim analysis, Kisqali plus letrozole reduced risk of disease progression or death by 44% over letrozole alone, and demonstrated tumor burden reduction with a 53% overall response rate[1]*
- *Kisqali plus letrozole showed treatment benefit across all patient subgroups regardless of disease burden or tumor location[1]*
- *At a subsequent analysis with additional follow-up and progression events, a median PFS of 25.3 months for Kisqali plus letrozole and 16.0 months for letrozole alone was observed[2]*

Basel, March 13, 2017 - The US Food and Drug Administration (FDA) has approved Kisqali® (ribociclib, formerly known as LEE011) in combination with an aromatase inhibitor as initial endocrine-based therapy for treatment of postmenopausal women with hormone receptor positive, human epidermal growth factor receptor-2 negative (HR+/HER2-) advanced or metastatic breast cancer.

Kisqali is a CDK4/6 inhibitor approved based on a first-line Phase III trial that met its primary endpoint early, demonstrating statistically significant improvement in progression-free survival (PFS) compared to letrozole alone at the first pre-planned interim analysis[1]. Kisqali was reviewed and approved under the FDA Breakthrough Therapy designation and Priority Review programs.

"Kisqali is emblematic of the innovation that Novartis continues to bring forward for people with HR+/HER2- metastatic breast cancer," said Bruno Strigini, CEO, Novartis Oncology. "We at Novartis are proud of the comprehensive clinical program for Kisqali that has led to today's approval and the new hope this medicine represents for patients and their families."

The FDA approval is based on the superior efficacy and demonstrated safety of Kisqali plus letrozole versus letrozole alone in the pivotal Phase III MONALEESA-2 trial. The trial, which enrolled 668 postmenopausal women with HR+/HER2- advanced or metastatic breast cancer who received no prior systemic therapy for their advanced breast cancer, showed that Kisqali plus an aromatase inhibitor, letrozole, reduced the risk of progression or death by 44 percent over letrozole alone (median PFS not reached (95% CI: 19.3 months-not reached) vs. 14.7 months (95% CI: 13.0-16.5 months); HR=0.556 (95% CI: 0.429-0.720); $p<0.0001$)[1].

More than half of patients taking Kisqali plus letrozole remained alive and progression free at the time of interim analysis, therefore median PFS could not be determined[1]. At a subsequent analysis with additional 11-month follow-up and progression events, a median PFS of 25.3 months for Kisqali plus letrozole and 16.0 months for letrozole alone was observed[2]. Overall survival data is not yet mature and will be available at a later date.

"In the MONALEESA-2 trial, ribociclib plus letrozole reduced the risk of disease progression or death by 44 percent over letrozole alone, and more than half of patients (53%) with measurable disease taking ribociclib plus letrozole experienced a tumor burden reduction of at least 30 percent. This is a significant result for women with this serious form of breast cancer," said Gabriel N. Hortobagyi, MD, Professor of Medicine, Department of Breast Medical Oncology, The University of Texas MD Anderson Cancer Center and MONALEESA-2 Principal Investigator. "These results affirm that combination therapy with a CDK4/6 inhibitor like ribociclib and an aromatase inhibitor should be a new standard of care for initial treatment of HR+ advanced breast cancer."

Kisqali is taken with or without food as a once-daily oral dose of 600 mg (three 200 mg tablets) for three weeks, followed by one week off treatment. Kisqali is taken in combination with four weeks of any aromatase inhibitor[1].

Breast cancer is the second most common cancer in American women[3]. The American Cancer Society estimates more than 250,000 women will be diagnosed with invasive breast cancer in 2017[3]. Up to one-third of patients with early-stage breast cancer will subsequently develop metastatic disease[4].

Novartis is committed to providing patients with access to medicines, as well as resources and support to address a range of needs. The Kisqali patient support program is available to help guide eligible patients through the various aspects of getting started on treatment, from providing educational information to helping them understand their insurance coverage and identify potential financial assistance options. For more information, patients and healthcare professionals can call 1-800-282-7630.

The full prescribing information for Kisqali can be found at https://www.pharma.us.novartis.com/sites/www.pharma.us.novartis.com/files/kisqali.pdf.

About Kisqali® (ribociclib)

Kisqali (ribociclib) is a selective cyclin-dependent kinase inhibitor, a class of drugs that help slow the progression of cancer by inhibiting two proteins called cyclin-dependent kinase 4 and 6 (CDK4/6). These proteins, when over-activated, can enable cancer cells to grow and divide too quickly. Targeting CDK4/6 with enhanced precision may play a role in ensuring that cancer cells do not continue to replicate uncontrollably.

Kisqali was developed by the Novartis Institutes for BioMedical Research (NIBR) under a research collaboration with Astex Pharmaceuticals.

About the MONALEESA Clinical Trial Program

Novartis is continuing to assess Kisqali through the robust MONALEESA clinical trial program, which includes two additional Phase III trials, MONALEESA-3 and MONALEESA-7, that are evaluating Kisqali in multiple endocrine therapy combinations across a broad range of patients, including premenopausal women. MONALEESA-3 is evaluating Kisqali in combination with fulvestrant compared to fulvestrant alone in postmenopausal women with HR+/HER2- advanced breast cancer who have received no or a maximum of one prior endocrine therapy. MONALEESA-7 is investigating Kisqali in combination with endocrine therapy and goserelin compared to endocrine therapy and goserelin alone in premenopausal women with HR+/HER2- advanced breast cancer who have not previously received endocrine therapy.

About Novartis in Advanced Breast Cancer

For more than 25 years, Novartis has been at the forefront of driving scientific advancements for breast cancer patients and improving clinical practice in collaboration with the global community. With one of the most diverse breast cancer pipelines and the largest number of breast cancer compounds in development, Novartis leads the industry in discovery of new therapies and combinations, especially in HR+ advanced breast cancer, the most common form of the disease.

Kisqali® (ribociclib) Important Safety Information

Kisqali® (ribociclib) can cause a heart problem known as QT prolongation. This condition can cause an abnormal heartbeat and may lead to death. Patients should tell their healthcare provider right away if they have a change in their heartbeat (a fast or irregular heartbeat), or if they feel dizzy or faint. Kisqali can cause serious liver problems. Patients should tell their healthcare provider right away if they get any of the following signs and symptoms of liver problems: yellowing of the skin or the whites of the eyes (jaundice), dark or brown (tea-colored) urine, feeling very tired, loss of appetite, pain on the upper right side of the stomach area (abdomen), and bleeding or bruising more easily than normal. Low white blood cell counts are very common when taking Kisqali and may result in infections that may be severe. Patients should tell their healthcare provider right away if they have signs and symptoms of low white blood cell counts or infections such as fever and chills. Before taking Kisqali, patients should tell their healthcare provider if they are pregnant, or plan to become pregnant as Kisqali can harm an unborn baby. Females who are able to become pregnant and who take Kisqali should use effective birth control during treatment and for at least 3 weeks after the last dose of Kisqali. Do not breastfeed during treatment with Kisqali and for at least 3 weeks after the last dose of Kisqali. Patients should tell their healthcare provider about all of the medicines they take, including prescription and over-the-counter medicines, vitamins, and herbal supplements since they may interact with Kisqali. Patients should avoid pomegranate or pomegranate juice, and grapefruit or grapefruit juice while taking Kisqali. The most common side effects (incidence >=20%) of Kisqali when used with letrozole include white blood cell count decreases, nausea, tiredness, diarrhea, hair thinning or hair loss, vomiting, constipation, headache, and back pain. The most common grade 3/4 side effects in the Kisqali + letrozole arm (incidence >2%) were low neutrophils, low leukocytes, abnormal liver function tests, low lymphocytes, and vomiting. Abnormalities were observed in hematology and clinical chemistry laboratory tests.

Please see the Full Prescribing Information for Kisqali, available at https://www.pharma.us.novartis.com/sites/www.pharma.us.novartis.com/files/kisqali.pdf.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by words such as "Breakthrough Therapy designation," "Priority Review," "hope," "should," "estimates," "will," "committed," "may," "continuing to assess," "evaluating," "investigating," "pipelines," "in development," or similar terms, or by express or implied discussions regarding potential new indications or labeling for Kisqali or any of the other products in the Novartis breast cancer pipeline, regarding potential marketing approvals for Kisqali or any of the other products in the Novartis breast cancer pipeline, or regarding potential future revenues from Kisqali and the other products in the Novartis breast cancer pipeline. 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 Kisqali or any of the other products in the Novartis breast cancer pipeline will be submitted or approved for any additional indications or labeling in any market, or at any particular time. Neither can there be any guarantee that Kisqali will be submitted or approved for sale in any additional markets, or at any particular time. Nor can there be any guarantee that any of the other products in the Novartis breast cancer pipeline will be submitted or approved for sale in any market, or at any particular time. Neither can there be any guarantee that Kisqali or any of the other products in the Novartis breast cancer pipeline will be commercially successful in the future. In particular, management's expectations regarding Kisqali and the other products in the

Novartis breast cancer pipeline could be affected by, among other things, the uncertainties inherent in research and development, including clinical trial results and additional analysis of existing clinical data; 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 healthcare cost containment, including ongoing pricing pressures; safety, quality or 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.

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, cost-saving generic and biosimilar pharmaceuticals and eye care. Novartis has leading positions globally in each of these areas. In 2016, the Group achieved net sales of USD 48.5 billion, while R&D throughout the Group amounted to approximately USD 9.0 billion. Novartis Group companies employ approximately 118,000 full-time-equivalent associates. Novartis products are sold in approximately 155 countries around the world. For more information, please visit http://www.novartis.com.

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For Novartis multimedia content, please visit www.novartis.com/news/media-library

For questions about the site or required registration, please contact media.relations@novartis.com

References

[1] Kisqali (ribociclib) Prescribing information. East Hanover, New Jersey, USA: Novartis Pharmaceuticals Corporation; March 2016.

[2] Novartis Data on File

[3] American Cancer Society. How Common Is Breast Cancer? Available at https://www.cancer.org/cancer/breast-cancer/about/how-common-is-breast-cancer.html. Accessed January 23, 2017.

[4] O'Shaughnessy J. Extending survival with chemotherapy in metastatic breast cancer. The Oncologist. 2005;10(Suppl 3):20-29.

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Novartis Media Relations

Central media line: +41 61 324 2200

E-mail: media.relations@novartis.com

Eric Althoff Julie Masow

Novartis Global Media Relations | Novartis Oncology Media Relations

+41 61 324 7999 (direct) | +1 862 778 7220 (direct)

+41 79 593 4202 (mobile) | +1 862 579 8456 (mobile)

eric.althoff@novartis.com | julie.masow@novartis.com

Novartis Investor Relations

Central investor relations line: +41 61 324 7944

E-mail: investor.relations@novartis.com

Central		North America	
Samir Shah	+41 61 324 7944	Richard Pulik	+1 212 830 2448
Pierre-Michel Bringer	+41 61 324 1065		
Thomas Hungerbuehler	+41 61 324 8425		
Isabella Zinck	+41 61 324 7188		

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: March 14, 2017 By: /s/ PAUL PENEPENT
Name: Paul Penepent
Title: Head Group Financial Reporting and Accounting