NOVARTIS AG
Form 6-K
November 01, 2016

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 November 1, 2016

(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**:

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MEDIA RELEASE • COMMUNIQUE AUX MEDIAS • MEDIENMITTEILUNG

Novartis LEE011 (ribociclib) granted FDA Priority Review for first-line treatment of HR+/HER2- advanced breast cancer

- *Priority Review based on Phase III MONALEESA-2 trial, which showed LEE011 plus letrozole, as initial treatment for advanced breast cancer, significantly extended progression-free survival compared to letrozole alone*[1]

- *Underscores potential of LEE011 plus letrozole as a new treatment option for advanced breast cancer; may lead to faster access for US patients*

- *A marketing authorization application for LEE011 plus letrozole has also been accepted for review by the European Medicines Agency (EMA)*

Basel, November 1, 2016 – Novartis announced today that the US Food and Drug Administration (FDA) accepted the company's New Drug Application (NDA) for filing and granted Priority Review for LEE011 (ribociclib) as first-line treatment of postmenopausal women with hormone-receptor positive, human epidermal growth factor receptor-2 negative (HR+/HER2-) advanced or metastatic breast cancer in combination with letrozole. The NDA is based on a comprehensive clinical package, including results of the Phase III MONALEESA-2 trial. The trial, which was presented at the European Society for Medical Oncology (ESMO) 2016 Congress and published simultaneously in the *New England Journal of Medicine,* showed LEE011 plus letrozole reduced the risk of progression or death by 44% (HR = 0.556, 95% CI: 0.429-0.720; *P* = 0.00000329) over letrozole alone, significantly extending progression-free survival (PFS) across all patient subgroups[1]. The company also announced that the EMA has accepted for review the marketing authorization application for LEE011 plus letrozole in the same patient population.

“These regulatory milestones, along with the FDA Breakthrough Therapy designation granted in August, underscore the need for new treatment options for women living with HR+/HER2- advanced breast cancer,” said Bruno Strigini, CEO, Novartis Oncology. “Priority Review allows a shorter review period compared with FDA standard review in the US, helping us to potentially bring LEE011 plus letrozole to patients more quickly. We also are working diligently with the EMA and other Health Authorities to bring this treatment to patients around the world as fast as possible.”

FDA Priority Review designation requires the agency to take action on an application within six months of its filing date compared to ten months under standard review[2]. FDA grants Priority Review to applications for new drug candidates that treat serious conditions, such as advanced breast cancer for which there is currently no cure, and if approved, would provide a significant improvement in treatment safety or efficacy[2].

About LEE011 (ribociclib)

LEE011 (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 in a cell, can enable cancer cells to grow and divide too quickly. Targeting CDK4/6 with enhanced precision may play a role in ensuring cancer cells do not grow uncontrollably.

LEE011 is not approved for any indication in any market at this time. LEE011 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 LEE011 through the robust MONALEESA (Mammary ONcology Assessment of LEE011's Efficacy and SAfety) clinical trial program, which includes MONALEESA-2, MONALEESA-3, and MONALEESA-7. These trials are evaluating LEE011 in multiple endocrine therapy combinations across a broad range of patients, including men and premenopausal women.

MONALEESA-2 is a Phase III randomized, double blind, placebo controlled, multicenter global registration trial to evaluate the safety and efficacy of LEE011 in combination with letrozole compared to letrozole alone in postmenopausal women with HR+/HER2- advanced breast cancer who received no prior therapy for their advanced breast cancer[1].

The trial randomized 668 patients in a 1:1 ratio stratified by the presence of liver and/or lung metastases at 223 clinical trial sites globally[1]. Patients received LEE011 600 mg/daily (three weeks on and one week off), or placebo, in combination with letrozole 2.5 mg/daily.

The primary endpoint of the trial was PFS[1]. Secondary endpoints included: overall survival, overall response rate, clinical benefit rate, health-related quality of life, safety and tolerability[1].

The MONALEESA-3 trial is evaluating LEE011 in combination with fulvestrant compared to fulvestrant alone in men and post-menopausal women with HR+/HER2- advanced breast cancer who have received no or a maximum of one prior endocrine therapy.

The MONALEESA-7 trial is investigating LEE011 in combination with endocrine therapy and goserelin compared to endocrine therapy and goserelin alone in pre-menopausal women with HR+/HER2- advanced breast cancer who have not previously received endocrine therapy. Both MONALEESA-3 and MONALEESA-7 are fully enrolled.

About Advanced Breast Cancer

Up to one-third of patients with early-stage breast cancer will subsequently develop metastatic disease[3]. Metastatic breast cancer is the most serious form of the disease and occurs when the cancer has spread to other parts of the body, such as the brain, bones or liver[4]. Advanced breast cancer comprises metastatic breast cancer (stage 4) and locally advanced breast cancer (stage 3)[4]. Survival rates for women living with advanced breast cancer are lower than those for women with earlier stage disease. The 5-year relative survival rate for stage 3 breast cancer is approximately 72%, while metastatic (stage 4) breast cancer has a 5-year relative survival rate of approximately 22%[5].

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[6]. 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[6].

Disclaimer

The foregoing release contains forward-looking statements that can be identified by words such as “Priority Review,” “potential,” “may,” "Breakthrough Therapy designation," “potentially,” “would,” "continuing," “evaluating,” “investigating,” "will," “pipelines,” or similar terms, or by express or implied discussions regarding potential marketing approvals for

LEE011, or regarding potential future revenues from LEE011 or 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 LEE011 will be submitted or approved for sale in any market, or at any particular time. Nor can there be any guarantee that LEE011 or any other product in the Novartis breast cancer pipeline will be commercially successful in the future. In particular, management's expectations regarding LEE011 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 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; competition in general; global trends toward health care cost containment, including ongoing pricing pressures; unexpected manufacturing, safety or quality 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, eye care and cost-saving generic pharmaceuticals. Novartis is the only global company with leading positions in these areas. In 2015, the Group achieved net sales of USD 49.4 billion, while R&D throughout the Group amounted to approximately USD 8.9 billion (USD 8.7 billion excluding impairment and amortization charges). Novartis Group companies employ approximately 118,000 full-time-equivalent associates. Novartis products are available in more than 180 countries around the world. For more information, please visit http://www.novartis.com.

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References

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6. Novartis Data on File

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Media release (PDF): http://hugin.info/134323/R/2053164/768466.pdf

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: November 1, 2016 By: /s/ PAUL PENEPENT
Name: Paul Penepent
Title: Head Group Financial Reporting and Accounting