NOVARTIS AG
Form 6-K
February 13, 2015

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 February 13, 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

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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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Novartis' heart failure medicine LCZ696 granted FDA priority review

- Decision could speed access to LCZ696 for HFrEF patients in the US, reducing total review time from 12 to 8 months
- Filing is based on results from the landmark PARADIGM-HF study1
- Nearly six million people live with heart failure in the US, and despite current therapies, up to 50% of patients die within five years of diagnosis2,3

Basel, February 13, 2015– Novartis announced today that the US Food and Drug Administration (FDA) has granted priority review designation to LCZ696, an investigational medicine for the treatment of heart failure with reduced ejection fraction (HFrEF). The designation accelerates the review of therapies that offer a significant improvement in the safety or effectiveness of the treatment, prevention or diagnosis of a serious condition4. For LCZ696 this reduces the total review time from 12 to 8 months, meaning the FDA could make a decision on approval in August 2015.

"LCZ696 is a demonstration of our commitment to developing innovative medicines that improve important heart failure related outcomes such as cardiovascular mortality, hospitalization and quality of life," said David Epstein, Division Head, Novartis Pharmaceuticals. "The FDA's decision reflects the significant need to extend and improve life for HFrEF patients and Novartis is working to ensure LCZ696 can become available in the US as soon as possible."

The New Drug Application (NDA) was submitted under the agency's Fast Track program and is based on results from the landmark PARADIGM-HF study, the largest ever conducted in heart failure1, which showed LCZ696 was superior to ACE-inhibitor enalapril on key endpoints, including significantly reducing the risk of CV death or heart failure hospitalization. Patients' reports of how well they felt were significantly better with LCZ696 than enalapril, whilst maintaining an acceptable safety profile.

In the EU the Committee for Medicinal Products for Human Use (CHMP) has granted accelerated assessment to LCZ696.

About LCZ696 in heart failure
LCZ696, a twice a day medicine being investigated for heart failure, has a unique mode of action which is thought to reduce the strain on the failing heart1. It acts to enhance the protective neurohormonal systems of the heart (NP system) while simultaneously suppressing the harmful system (the RAAS). Currently available medicines for HFrEF primarily block the harmful effects and mortality remains very high with up to 50% of patients dying within 5 years of a diagnosis of heart failure3,5,6.

Heart failure is a debilitating and life-threatening disease in which the heart cannot pump enough blood around the body. Symptoms such as breathlessness, fatigue and fluid retention can appear slowly and worsen over time,

significantly impacting quality of life7.

It is a significant and growing public health concern with a high unmet need for new treatments. Every year, HF costs the world economy $108 billion, and hospitalizations comprise 60-70% of direct treatment costs8,9,10.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by words such as “priority review,” “could,” “investigational,” “commitment,” “can,” “being investigated,” “thought,” “growing,” or similar terms, or by exp implied discussions regarding potential marketing approvals for LCZ696, or regarding potential future revenues from LCZ696. 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 LCZ696 will be approved for sale in any market, or submitted for approval in any additional markets, or at any particular time. Neither can there be any guarantee that LCZ696 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 LCZ696 will be commercially successful in the future. In particular, management’s expectations regarding LCZ696 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.

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 over-the-counter products. Novartis is the only global company with leading positions in these areas. In 2014, the Group achieved net sales of USD 58 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 130,000 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.

Novartis is on Twitter. Sign up to follow @Novartis at http://twitter.com/novartis.

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Media release (PDF): http://hugin.info/134323/R/1894530/671653.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: February 13, 2015 By: /s/ MALCOLM B. CHEETHAM

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