NOVARTIS AG
Form 6-K
November 28, 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 November 28, 2014

(Commission File No. 1-15024)

Novartis AG

(Name of Registrant)

Lichtstrasse 35

4056 Basel

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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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 heart failure medicine LCZ696 granted accelerated assessment by CHMP in Europe(1)

- *Decision by EU review body could speed access to LCZ696 for HFrEF patients in the EU*

- *LCZ696 is the first investigational cardiovascular drug to be granted accelerated assessment, shortening the formal review clock by 60 days(2)*

- *Approximately 15 million people in the EU live with heart failure, facing a high risk of death and poor quality of life, despite currently available medicines(3)*

Basel, November 28, 2014 Novartis announced today that the Committee for Medicinal Products for Human Use (CHMP) has granted accelerated assessment to LCZ696, an investigational medicine for patients with heart failure with reduced ejection fraction (HFrEF). The expedited review procedure is granted infrequently by the EMA and has never been awarded in the cardiovascular area until now. The designation allows the CHMP to grant an opinion at day 150 versus a normal 210 day procedure, meaning a decision on EU approval is expected within 2015.

Novartis is committed to extending and improving more lives sooner with LCZ696, and this decision by the CHMP we hope will greatly support our effort to do so in Europe, said David Epstein, Division Head, Novartis Pharmaceuticals.

Novartis requested accelerated assessment of LCZ696 in accordance with the European Medicines Agency regulations that it may be justified for medicinal products of major interest from the point of view of public health and in particular from the view point of therapeutic innovation .

Novartis expects to submit the file for marketing authorization in the European Union in early 2015. The submission is planned to be based on results from the landmark PARADIGM-HF study, the largest ever conducted in heart failure, which showed LCZ696 was superior to ACE-inhibitor enalapril on key endpoints, including significantly reducing the risk of CV death or heart failure hospitalization.

In the US LCZ696 has been granted Fast Track designation by the FDA and a rolling submission is expected to be complete by the end of 2014.

About LCZ696 in heart failure

LCZ696, a twice a day medicine being investigated for heart failure, 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 only block the harmful effects and mortality remains very high with up to 50% of patients dying within 5 years of a diagnosis of heart failure(4),(5),(6).

LCZ696 is an ARNI (Angiotensin Receptor Neprilysin Inhibitor) and has a unique mode of action which is thought to reduce the strain on the failing heart. It harnesses the body s natural defenses against heart failure, simultaneously acting to enhance the levels of

natriuretic and other endogenous vasoactive peptides, while also inhibiting the renin-angiotensin-aldosterone system (RAAS).

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 life.

It is a significant and growing public health concern with a high unmet need for new treatments. Every year, the total cost of heart failure (HFrEF and HFpEF) to the worldwide economy is $108 billion(7), and hospitalizations comprise 60-70% of treatment costs(8),(9).

Disclaimer

The foregoing release contains forward-looking statements that can be identified by words such as accelerated assessment, could, investigational, expedited review procedure, expected, committed, will, may, expects, planned, Fast Track, being investigated, terms, or by express or implied discussions regarding potential marketing approvals for LCZ696, or the timing of any such approvals, 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 submitted or approved for sale 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, 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 133,000 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) European Medicines Agency. Meeting highlights from the Committee for Medicinal Products for Human Use (CHMP) 17-20 November 2014. http://www.ema.europa.eu/docs/en_GB/document_library/Annex_to_CHMP_highlights/2014/11/WC500177877.pdf

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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:	November 28, 2014	By:	/s/ MALCOLM B. CHEETHAM
		Name:	Malcolm B. Cheetham
		Title:	Head Group Financial Reporting and Accounting