NOVARTIS AG
Form 6-K
March 31, 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 March 31, 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:

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MEDIA RELEASE • COMMUNIQUE AUX MEDIAS • MEDIENMITTEILUNG

PARADIGM-HF trial of Novartis LCZ696 for chronic heart failure closes early based on strength of interim results

- *Data Monitoring Committee (DMC) unanimously recommends early closure confirming combined primary endpoint met - LCZ696 delayed cardiovascular death and reduced heart failure hospitalizations vs. enalapril*

- *PARADIGM-HF is the largest ever trial of a heart failure treatment, robustly designed to assess LCZ696 in patients with chronic heart failure with reduced ejection fraction(1)*,(2)

- *Over 20 million people across the US and EU live with chronic heart failure, facing a high risk of death and poor quality of life, despite currently available medicines(3),(4),(5)*

Basel, March 31, 2014 Novartis announced today that the Data Monitoring Committee (DMC) unanimously recommended early closure of the PARADIGM-HF study, indicating patients with chronic heart failure with reduced ejection fraction (HF-REF) who received LCZ696 lived longer without being hospitalized for heart failure than those who received standard care with ACE-inhibitor enalapril. Based on the compelling efficacy and primary endpoint having been met, the trial will now close early. This follows two previous interim analyses that showed the safety profile of LCZ696 was acceptable.

Novartis recognizes the huge global need for treatments that extend and improve the lives of people with heart failure and we believe LCZ696 s unique mechanism of action could be transformative, said Tim Wright, Global Head of Development, Novartis Pharmaceuticals. This result is a demonstration of our commitment to developing innovative medicines that have an impact on the most important outcomes like cardiovascular mortality.

The results of PARADIGM-HF will be submitted to a major medical conference for presentation and Novartis will now initiate discussions with global health authorities regarding approval for marketing.

The results of PARADIGM-HF are truly impressive said Dr. Milton Packer, Professor and Chair for the Department of Clinical Sciences at University of Texas Southwestern Medical Center, Texas, USA and one of the two Principal Investigators. The finding that treatment with

LCZ696 was superior to currently recommended doses of enalapril has profound implications for the care of patients with chronic heart failure. We now have compelling evidence that supports LCZ696 as a new cornerstone in the management of chronic heart failure.

LCZ696, a twice a day pill for heart failure, is a first in class medicine that acts in multiple ways on the neurohormonal systems of the heart, blocking receptors exerting harmful effects while simultaneously promoting protective mechanisms(2),(6),(7). Known as an ARNI (Angiotensin Receptor Neprilysin Inhibitor) LCZ696 is thought to reduce the strain on the failing heart, promoting the ability of the heart muscle to recover(2),(7).

LCZ696 is the second treatment being developed by Novartis for patients with heart failure, along with RLX030 (serelaxin) for acute heart failure(8).

About the PARADIGM-HF study

PARADIGM-HF is a randomized, double-blind, Phase III outcome study evaluating the efficacy and safety profile of LCZ696 versus enalapril (a widely used ACE inhibitor) in 8,436 patients with heart failure with reduced ejection fraction (HF-REF)(1),(2). The primary outcome is a composite of time to first occurrence of either cardiovascular death or heart failure hospitalization, and the trial is also designed to be able to detect a significant difference in cardiovascular death(1),(2). The study was initiated in December 2009 and currently is the largest clinical trial in heart failure ever undertaken(1),(2).

About chronic heart failure

Chronic heart failure is a progressive, debilitating disease where the heart is unable to pump enough blood throughout the body. Symptoms such as breathlessness, fatigue and fluid retention can appear slowly and worsen over time, significantly impacting quality of life(4),(9). Approximately half of patients have the reduced ejection fraction form of the disease (HF-REF)(10).

Heart failure is a significant and growing public health concern with more 20 million people living with the disease across Europe and the US alone(3),(4),(5). It continues to be associated with high morbidity and mortality, frequent hospitalization and poor quality of life, despite currently available medicines(11),(12). Heart failure presents a major and growing health-economic burden that currently exceeds $45 billion worldwide(13),(14),(15),(16). As such, there is a high unmet need for new treatments that reduce cardiovascular mortality and the frequency of hospitalization.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by words such as recommends, indicating, risk, recommended, believe, could, commitment, will, implications, supports, thought, designed, growing, continues, or similar terms, or by expre 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 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 and diagnostic tools, 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 136,000 full-time-equivalent associates and operate in more than 140 countries around the world.

For more information, please visit http://www.novartis.com.

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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:	March 31, 2014	By:	/s/ MALCOLM B. CHEETHAM
		Name:	Malcolm B. Cheetham
		Title:	Head Group Financial Reporting and Accounting