

NOVARTIS AG  
Form 6-K  
November 18, 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 17, 2014**

**(Commission File No. 1-15024)**

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(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:

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**Nine new analyses show Novartis LCZ696 could change course of heart failure for patients(1),(2)**

- *New data from PARADIGM-HF shows LCZ696 cut incidence of sudden deaths, emergency room visits, hospitalizations, worsening symptoms and need for more intense treatment in HFrEF patients versus enalapril(1)*
- *Patients and doctors assessments of disease severity were also significantly better with LCZ696 than enalapril(1)*
- *Effects on certain heart biomarkers indicate that compared to enalapril, LCZ696 reduced cardiac stress and damage(1)*
- *Heart failure is highly debilitating and life-threatening - up to half of patients who die from cardiovascular causes will die suddenly when their heart stops pumping, before medical intervention is possible(2),(3)*

**Basel, November 17, 2014** New data on Novartis investigational medicine, LCZ696, for patients with heart failure with reduced ejection fraction (HFrEF) shows it has the potential to change the course of the disease for patients(1),(2). In August 2014 Novartis presented topline results from the landmark PARADIGM-HF study showing LCZ696 was superior to ACE inhibitor enalapril on key endpoints, including significantly reducing the risk of CV death or heart failure hospitalization(4).

The new analyses being presented for the first time at the American Heart Association Scientific Sessions 2014, with a paper being simultaneously published in *Circulation*, show that versus enalapril, LCZ696 significantly(1),(2):

- reduced the risk of dying suddenly by 20%(2) in HFrEF patients 45% of CV deaths and 36% of all cause deaths are sudden(2)
- reduced first and subsequent HFrEF hospitalizations by 21% and 23% respectively(1)
- reduced hospitalizations for a cardiovascular reason or for any reason both by 16%(1)
- reduced the need for more intense treatment at home by 16%(1)

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- reduced emergency room visits because of rapid symptom worsening by 30%(1)

When hospitalized, LCZ696 and enalapril patients remained under care for approximately the same time, but those on LCZ696 had 18% fewer stays in intensive care and were 31% less likely to need IV drugs to help their heart pump. Patients' reports of how well they felt and doctors' assessments of disease severity were also significantly better with LCZ696 than enalapril(1).

These results provide strong evidence that we may be able to do more than reduce risk of death or hospitalization with LCZ696 versus enalapril. This therapy offers hope to millions of people living with HFrEF that they can also reduce or slow the decline in their heart function, potentially altering the progression of their disease, said David Epstein, Division Head, Novartis Pharmaceuticals.

Analysis of cardiac biomarkers (NTpro-BNP and troponin), substances that indicate the progression of cardiac disease and risk, showed levels were consistently lower with LCZ696 than enalapril, reflecting reduced heart stress and subsequent damage(1),(2).

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).

Novartis plans to complete the file for marketing authorization with the US FDA by the end of 2014 and in the European Union in early 2015.

#### **About the PARADIGM-HF study**

PARADIGM-HF is a randomized, double-blind, phase III study that evaluated the efficacy and safety profile of LCZ696 versus enalapril (a widely studied ACE inhibitor) in 8,442 patients with HFrEF(7). The baseline characteristics showed the patients enrolled were typical HFrEF patients with NYHA Class II-IV heart failure(8). PARADIGM-HF was specifically designed to see if LCZ696 could decrease CV mortality by at least 15% vs. enalapril(5). Patients received LCZ696 or enalapril in addition to current best treatment regimen. The primary endpoint was a composite of time to first occurrence of either cardiovascular death or heart failure hospitalization, and it is the largest heart failure study ever done(5),(8).

#### **About LCZ696 in heart failure**

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(4),(9). 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(10).

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(10), and hospitalizations comprise 60-70% of treatment costs(11),(12).

#### **Disclaimer**

The foregoing release contains forward-looking statements that can be identified by words such as could, will, investigational, potential, may, hope, potentially, being investigated, plans, thought, growing, or similar terms, or by express or implied discussions regarding potential

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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, 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>.

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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 17, 2014

By: /s/ MALCOLM B. CHEETHAM

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