

NOVARTIS AG  
Form 6-K  
September 16, 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 July 7, 2015  
(Commission File No. 1-15024)

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Novartis AG  
(Name of Registrant)

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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:

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Yes:  No:



Novartis' new heart failure medicine LCZ696, now called Entresto(TM), approved by FDA to reduce risk of cardiovascular death and heart failure hospitalization

• First in the world approval brings hope of longer life and fewer hospitalizations for millions of Americans with heart failure with reduced ejection fraction

• Entresto is the first and only treatment to show a significant mortality benefit in a head-to-head trial against ACE-inhibitor enalapril[1]

• Heart failure is a life-threatening condition affecting nearly 6 million Americans; about half have the reduced ejection fraction form[2]

• Approval comes six weeks ahead of FDA's priority review action date allowing Entresto to be available to US patients more quickly

**The digital press release with multimedia content can be accessed here:**

<http://multimediacapsule.thomsonone.com/novartis/novartis%E2%80%99-new-heart-failure-medicine-approved-by-fda>

**Basel, July 7, 2015** - Novartis announced today that the US Food and Drug Administration (FDA) has approved Entresto(TM) (sacubitril/valsartan) tablets, previously known as LCZ696, for the treatment of heart failure with reduced ejection fraction. Entresto will be available on prescription for patients whose condition is classified NYHA class II-IV, indicated to reduce the risk of cardiovascular death and heart failure hospitalization. It is usually administered in conjunction with other heart failure therapies, in place of an ACE inhibitor or other angiotensin receptor blocker.[1]

"Despite the uncertainty and high financial risk we designed the world's largest heart failure trial to compare Entresto to the previous gold standard. As a result millions of people diagnosed with reduced ejection fraction heart failure now have a much greater opportunity to live longer and stay out of hospital," said David Epstein, Division Head, Novartis Pharmaceuticals. "We recognize our responsibility to ensure Entresto reaches US patients and prescribers as soon as possible and will begin shipping in the US in the coming week."

The FDA's decision is based on results from the 8,442-patient PARADIGM-HF study which was stopped early when it was shown Entresto significantly reduced the risk of cardiovascular death versus ACE-inhibitor enalapril.[1] At the end of the study, patients with reduced ejection fraction who were given Entresto were more likely to be alive and less likely to have been hospitalized for heart failure

than those given enalapril. Analysis of safety data showed that Entresto had a similar tolerability profile to enalapril.

"The very meaningful survival advantage of Entresto seen in the PARADIGM-HF trial should persuade physicians to consider Entresto for all appropriate patients, in place of traditional ACE inhibitors or angiotensin receptor blockers," said Dr. Milton Packer, Professor and Chair for the Department of Clinical Sciences at University of Texas Southwestern Medical Center, Texas, USA. "Entresto is expected to change the management of patients with HFrEF for years to come."

Nearly 6 million people in the US suffer from heart failure and about half have the reduced ejection fraction form.[2] About 2.2 million of these patients have heart failure classified as NYHA II-IV, based on how much their symptoms limit their physical activity[3]. Heart failure is a debilitating, life-threatening condition in which the heart cannot pump enough blood around the body. Patients face a high risk of death, repeated hospitalizations and symptoms such as breathlessness, fatigue and fluid retention significantly impact quality of life.[4]

Entresto is currently undergoing review by Health Authorities around the world, including in Canada, Switzerland and the EU. Once approved by health authorities around the world, Entresto could achieve estimated peak sales in excess of \$5 billion for the reduced ejection fraction indication.

### **About Entresto**

Entresto is a first in class medicine (an ARNI, Angiotensin Receptor Neprilysin Inhibitor) that reduces the strain on the failing heart. A twice-a-day tablet, it acts to enhance the protective neurohormonal systems of the heart (NP system) while simultaneously suppressing the harmful system (the RAAS).[5]

Results from the 8,442 patient PARADIGM-HF study showed, versus enalapril, Entresto[1]:

- reduced the risk of death from cardiovascular causes by 20%
- reduced heart failure hospitalizations by 21%
- reduced the risk of all-cause mortality by 16%

Overall there was a 20% risk reduction on the primary endpoint, a composite measure of CV death or time to first heart failure hospitalization.

Fewer patients on Entresto discontinued study medication for any adverse event compared to those on enalapril. The Entresto group had more hypotension and non-serious angioedema but less renal impairment, hyperkalemia and cough

than the enalapril group.[1]

### **Disclaimer**

The foregoing release contains forward-looking statements that can be identified by words such as "hope," "will," "as soon as possible," "expected," or similar terms, or by express or implied discussions regarding potential additional marketing approvals or new indications or labeling for Entresto, or regarding potential future revenues from Entresto. 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 Entresto will be submitted or approved for any additional indications or labeling in any market, or at any particular time. Neither can there be any guarantee that Entresto will be submitted or approved for sale in any additional markets or at any particular time. Nor can there be any guarantee that Entresto will be commercially successful in the future, or will achieve any particular level of revenue. In particular, management's expectations regarding Entresto 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 and reimbursement issues; unexpected safety issues; 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 and cost-saving generic pharmaceuticals. Novartis is the only global company with leading positions in these areas. In 2014, the Group achieved net sales of USD 58.0 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 120,000 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>.

## References

- [1.] McMurray JJV et al. Angiotensin-Nepriylsin Inhibition versus Enalapril in Heart Failure, *N Engl J Med* 2014
- [2.] Mozaffarian D, et al. Heart Disease and Stroke Statistics - 2015 Update: A Report From the American Heart Association. *Circulation*. 2014
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- [5.] Langenickel TH et al. Angiotensin receptor-nepriylsin inhibition with LCZ696: a novel approach for the treatment of heart failure. *Drug Discovery Today: Therapeutic Strategies*.2012, Vol 9. No.4

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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: September 16, 2015 By: /s/ PAUL PENEPEPENT  
Name: Paul Penepent  
Head Group Financial  
Title: Reporting and  
Accounting

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