NOVARTIS AG
Form 6-K
October 05, 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 September 25, 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

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Yes: o **No**: **x**

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Novartis' new heart failure medicine Entresto™ recommended by CHMP for EU approval

- *Positive opinion from EU review body puts Entresto on track to be approved for HFrEF patients across Europe likely by year end*

- *Entresto was studied in world's largest heart failure trial which was stopped early on strength of results that showed a 20% cut in cardiovascular deaths vs enalapril[1]*

- *Every day 10,000 Europeans are diagnosed with heart failure and 15 million already live with the condition, facing a high risk of death and poor quality of life[2,3]*

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

http://multimediacapsule.thomsonone.com/novartis/novartis-new-heart-failure-medicine-recommended-by-chmp-for-eu-approv

Basel, September 25, 2015 – Novartis announced today that the Committee for Medicinal Products for Human Use (CHMP) has adopted a positive opinion for Entresto™ (sacubitril/valsartan), marking an important milestone towards becoming available in the EU. Pending final approval by the European Commission (EC) Entresto, previously known as LCZ696, will be available for the treatment of adult patients with symptomatic chronic heart failure and reduced ejection fraction (HFrEF).

"With the poor prognosis heart failure patients face – only half will be alive 5 years from diagnosis - the CHMP's endorsement of Entresto brings hope for HFrEF patients in Europe," said David Epstein, Division Head, Novartis Pharmaceuticals. "Already we're hearing about the benefits US doctors and HFrEF patients are experiencing with Entresto and hope to receive a final green-light from the EC soon."

The CHMP's decision, which follows previous US and Swiss approvals, is based on results from the 8,442-patient PARADIGM-HF study in patients with HFrEF, 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 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 striking results in the PARADIGM-HF trial led me to believe that once approved LCZ696 could quickly replace what has been the bedrock treatment for more than 20 years, ACE-inhibitors” said Professor John McMurray of the University of Glasgow and one of two Principal Investigators. “Thousands of lives could be extended and hospital admissions prevented with LCZ696’s unique ability to boost natriuretic peptides, heart-helpful hormones, while simultaneously inhibiting the RAAS system.”

Heart failure is a highly debilitating, life-threatening condition in which the heart cannot pump enough blood around the body because the muscles of the heart become too weak or too stiff to work properly[3]. As a consequence patients face a high risk of death, repeated hospitalizations and symptoms such as breathlessness, fatigue and fluid retention that significantly impact quality of life. Even though millions live with heart failure most people fail to recognize the symptoms, meaning many are misdiagnosed or incorrectly attribute the signs to growing older.

About Entresto

Entresto exhibits the mechanism of action of an 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)[4].

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].

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Disclaimer

The foregoing release contains forward-looking statements that can be identified by words such as “recommended,” “positive opinion,” “on track,” “will,” “hope,” “soon,” “could,” or similar terms, or by express or implied discussions regarding potential marketing approvals 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 sale in any market, or at any particular time. Nor can there be any guarantee that Entresto will receive regulatory approval or be commercially successful in the future. 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; unexpected safety issues; unexpected manufacturing or quality 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-Neprilysin Inhibition versus Enalapril in Heart Failure, N Engl J Med 2014

2. López-Sendón J. The heart failure epidemic. Medicographia. 2011;33:363-369

3. Mosterd A, Hoes, A, Clinical epidemiology of heart failure, Heart 2007;93:1137-1146

4. Langenickel TH et al. Angiotensin receptor-neprilysin 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 25, 2015 By: /s/ PAUL PENEPENT
Name: Paul Penepent
Title: Head Group Financial Reporting and Accounting