

NOVARTIS AG
Form 6-K
March 22, 2017

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 March 22, 2017

(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:

Form 20-F: Form 40-F:

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):

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Yes: **No:**

Novartis provides update on Phase III study of RLX030 (serelaxin) in patients with acute heart failure

- *Phase III RELAX-AHF-2 study did not meet primary endpoints of reduced cardiovascular death or worsening heart failure in patients with acute heart failure*
- *Novartis remains committed to improving and extending the lives of patients with cardiovascular disease and will continue to invest in ways to improve their outcomes*

Basel, March 22, 2017 - Novartis today announced results from the global Phase III RELAX-AHF-2 study investigating the efficacy, safety and tolerability of RLX030 (serelaxin) in patients with acute heart failure (AHF).

RELAX-AHF-2 did not meet its primary endpoints of reduction in cardiovascular death through Day 180 or reduced worsening heart failure through Day five when added to standard therapy in patients with AHF.

"We are disappointed this study did not confirm the efficacy of RLX030 in acute heart failure, especially given the urgent need for effective new treatments for this condition," said Vas Narasimhan, Global Head, Drug Development and Chief Medical Officer, Novartis. "We will continue to further analyze the data to better understand and learn from these results as well as evaluate next steps for the overall program. Novartis would like to thank the patients, investigators, and site personnel around the world for their unwavering support of this study. We remain committed to improving and extending the lives of patients with cardiovascular disease and will continue to invest in ways to improve their outcomes."

AHF is a life-threatening medical condition requiring urgent evaluation and treatment[1], and is the leading cause of hospitalization in those aged over 65 years[2],[3]. Risk of mortality after hospitalization for AHF is high[4]-[11] with approximately one in five patients not surviving a year afterwards[2],[12]-[14].

About RELAX-AHF-2

RELAX-AHF-2 (NCT01870778) is an event-driven, multicenter, randomized, double-blind, placebo-controlled, Phase III trial designed to evaluate the efficacy, safety and tolerability of RLX030 (serelaxin) when added to standard of care in patients with acute heart failure (AHF). The study has two primary endpoints; reduction of cardiovascular (CV) death through Day 180 and occurrence of worsening heart failure through Day five. The RELAX-AHF-2 study included 6,600 patients hospitalized for AHF and was initiated in October 2013.

About acute heart failure

AHF is a life-threatening condition requiring urgent treatment[1]. An AHF event may occur as a rapid deterioration of

existing heart failure (HF), or may be the first presentation of HF. The condition is progressive and can be fatal after patients have one or repeated AHF event(s)[4]. During an AHF event, patients become severely breathless and need to be rushed to the emergency room for urgent treatment, making AHF the most common cause of hospitalization in patients over 65 years[2],[3]. Risk of mortality after hospitalization for AHF is high[4]-[11] with approximately one in five patients not surviving a year afterwards[2],[12]-[14].

Despite significant progress in treating other heart conditions (including chronic HF) there have been no significant treatment breakthroughs that have improved mortality rates in AHF for decades.

About RLX030

RLX030, a relaxin receptor agonist[15], is a recombinant form of the naturally-occurring human relaxin-2 hormone. Human relaxin-2 is present in both men and women and elevated levels in pregnant women are thought to help the body cope with the additional CV demands during pregnancy[16],[17]

About the Novartis cardiovascular portfolio

Entresto® (sacubitril/valsartan) is the first and only approved medicine of its kind. Entresto has been given a Class I recommendation in United States and European Union clinical guidelines for treatment of heart failure with reduced ejection fraction (HFrEF)[18]. Approved indications may vary depending upon the individual country. Its unique mode of action reduces the strain on the failing heart by enhancing the protective neuro-hormonal systems (e.g. natriuretic peptide system) and simultaneously inhibiting the harmful effects of the overactive renin-angiotensin-aldosterone system (RAAS).

To better understand HF Novartis has established **FortiHFy**, the largest global clinical program in HF across the pharmaceutical industry. FortiHFy has more than 40 active or planned clinical studies designed to extend understanding of HF as well as to generate an array of additional data on symptom reduction, efficacy, quality of life benefits and real world evidence with Entresto.

In addition to CV research in HF, ACZ885 (canakinumab) is currently being investigated in patients with a previous heart attack and a high degree of vascular inflammation. The Phase III CANTOS trial is designed to determine if ACZ885 can reduce the risk of stroke, heart attack or death and is expected to read out in 2017.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by words such as "committed," "will," "next steps," "may," "can," "portfolio," "recommendation," "planned," "being investigated," "expected," or similar terms, or by express or implied discussions regarding potential marketing approvals for RLX030, potential new indications or labeling for Entresto and ACZ885, or regarding potential future revenues from RLX030, ACZ885 and 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 RLX030 will be submitted or approved for sale in any market, or at any particular time. Neither can there be any guarantee that ACZ885 or Entresto 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 RLX030, ACZ885 or Entresto will be commercially successful in the future. In particular, management's expectations regarding RLX030, ACZ885 and Entresto could be affected by, among other things, the uncertainties inherent in research and development, including clinical trial results and additional analysis of existing clinical data; 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; safety, quality or 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, cost-saving generic and biosimilar pharmaceuticals and eye care. Novartis has leading positions globally in each of these areas. In 2016, the Group achieved net sales of USD 48.5 billion, while R&D throughout the Group amounted to approximately USD 9.0 billion. Novartis Group companies employ approximately 118,000 full-time-equivalent associates. Novartis products are sold in approximately 155 countries around the world. For more information, please visit <http://www.novartis.com>.

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References

- [1] Ponikowski P, et al. 2016 ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure: The Task Force for the diagnosis and treatment of acute and chronic heart failure of the European Society of Cardiology (ESC). *Eur Heart J*. 2016; 37(27):2129-2200.
- [2] Mozaffarian D, Benjamin EJ, Go AS, et al. Heart Disease and Stroke Statistics-2016 Update: A report from the American Heart Association. *Circulation*. 2015; 133:e38-e360.
- [3] Weir LM, Pfuntner A, Maeda J, et al. HCUP facts and figures: statistics on hospital-based care in the United States, 2009. Rockville, MD: Agency for Healthcare Research and Quality, 2011.
- [4] Zannad F, et al. Heart failure burden and therapy. *Europace*. 2009; 11:v1-v9.
- [5] Mosterd A, Hoes AW. Clinical epidemiology of heart failure. *Heart*. 2007; 93:1137-46
- [6] Tavazzi L, et al. Nationwide survey on acute heart failure in cardiology ward services in Italy. *Eur Heart J*. 2006; 27:1207-15.
- [7] Garty M, et al. The management, early and one year outcome in hospitalized patients with heart failure: a national Heart Failure survey in Israel. *Isr Med Assoc J*. 2007; 9:227-33
- [8] Bui AL, et al. Epidemiology and risk profile of heart failure. *Nat Rev Cardiol* 2011; 8(1): 30-41.
- [9] Loehr LR, et al. Heart failure incidence and survival (from the Atherosclerosis Risk in Communities study). *Am J Cardiol*. 2008; 101:1016-1022.
- [10] Bueno H, et al. Trends in length of stay and short-term outcomes among Medicare patients hospitalized for heart failure: 1993-2008. *JAMA*. 2010; 303(21):2141-2147
- [11] Gheorghiade M, et al. Systolic blood pressure at admission, clinical characteristics, and outcomes in patients hospitalized with acute heart failure. *JAMA*. 2006; 296:2217-2226.
- [12] National heart failure audit: April 2010 - March 2011, NICOR and The British Society for Heart Failure, commissioned by the Healthcare Quality Improvement.
- [13] O'Connor M, et al. Causes of death and rehospitalization in patients hospitalized with worsening heart failure and reduced left ventricular ejection fraction: Results from efficacy of vasopressin antagonism in heart failure outcome study with tolvaptan (EVEREST) program. *American Heart Journal*. 2010; 159(5): 842-849.
- [14] Hunt S, et al. 2009 focused update incorporated into the ACC/AHA 2005 Guidelines for the Diagnosis and Management of Heart Failure in Adults: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines: developed in collaboration with the International Society for Heart and Lung Transplantation. *Circulation*. 2009; 119:e391-e479.
- [15] Du X, et al. Cardiovascular effects of relaxin: from basic service to clinical therapy. *Nat. Rev. Cardiol*. 2010; 7:48-58.

[16] Teichman S, et al. Relaxin, a pleiotropic vasodilator for the treatment of heart failure. *Heart Fail Rev.* 2009; 14:321-329.

[17] Teichman SL, et al. Relaxin: Review of biology and potential role in treating heart failure. *Curr Heart Fail Rep.* 2010; 7:75-82.

[18] Based on 2016 ESC HF Guidelines and 2016 ACC/AHA/HFSA Guideline Update.

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Attachments:

<http://www.globenewswire.com/NewsRoom/AttachmentNg/fc201c37-4ab7-4a36-ab06-852309952938>

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 22, 2017 By: /s/ PAUL PENEPEPENT
Name: Paul Penepent
Head Group Financial
Title: Reporting and
Accounting