NOVARTIS AG
Form 6-K
January 24, 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 January 24, 2014

(Commission File No. 1-15024)

Novartis AG

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MEDIA RELEASE • COMMUNIQUE AUX MEDIAS • MEDIENMITTEILUNG

Novartis to request re-examination of serelaxin (RLX030) in acute heart failure (AHF) for conditional marketing authorization in EU

- *Novartis to submit revised filing package for re-examination with request for conditional approval following CHMP negative opinion*

- *RLX030 is currently the only drug for which a reduction in mortality has been observed in patients with AHF in a major study; data shows RLX030 is generally well tolerated(1)*

- *Second phase III study RELAX-AHF-2 started enrolment in September 2013 with goal to replicate the key findings of RELAX-AHF(1)*

- *On February 13th Novartis will present RLX030 efficacy and safety data at the FDA s Cardiovascular and Renal Drugs Advisory Committee meeting to discuss potential US approval*

Basel, January 24, 2014 Novartis announced today it will shortly submit a revised filing package, including new data analyses, for re-examination for conditional approval of RLX030 (serelaxin) for acute heart failure by the Committee for Medicinal Products for Human Use (CHMP) following a negative opinion issued today. In accordance with CHMP process a revised opinion could be granted in Q2 2014.

The file for regulatory approval is continuing review by the Food and Drug Administration (FDA) in the United States where RLX030 was granted Breakthrough Therapy designation status in June 2013(2). Reviews are also underway with health authorities in 16 countries around the world.

With the results from RELAX-AHF showing significant mortality benefits with RLX030 in patients with AHF and recognizing that there had been no treatment breakthroughs in this area for 20 years, Novartis took a decision to file for regulatory approval, said David Epstein, Division Head of Novartis Pharmaceuticals. It has become apparent through the review process and in accordance with advice we ve received that the current evidence package may be more compatible with an application for conditional approval in the EU. We look forward to providing a revised package for review to the CHMP shortly.

In September 2013 the second phase III study RELAX-AHF-2 started recruitment of the over 6000 patients who are expected to be enrolled. The goal is to replicate the key findings of RELAX-AHF and the study will assess cardiovascular mortality as the primary endpoint. This would be one of the largest and most robust programs undertaken by a company for an AHF drug.

RLX030, a relaxin receptor agonist(3), is a form of a naturally occurring hormone (human relaxin 2) present in both men and women which rises in women during pregnancy to help the body cope with the additional cardiovascular demands(4),(5). RLX030 is thought to have multiple effects including relaxing the blood vessels, reducing fluid buildup and protecting the heart and vital organs from the cascade of damage that occurs during an

AHF episode(3),(6),(7),(8),(9). More than 1.5 million AHF episodes happen every year in Europe alone(10),(11), with 1 in 5 patients not surviving a year afterwards(12),(13),(14),(15),(16),(17).

About RELAX-AHF

RLX030 was studied in the phase III RELAX-AHF trial, which showed it had both short and longer-term effects, relieving symptoms and reducing the rate of heart failure worsening(1). In the trial patients who received RLX030 also had a 37% reduction in mortality at 6 months after an AHF episode compared to those who received conventional treatment(1). Data from clinical trials has shown that RLX030 was generally well tolerated(1),(18).

About acute heart failure

Heart failure is a debilitating and potentially life-threatening condition where the heart cannot pump enough blood around the body. More than 15 million people suffer from heart failure globally and this number is increasing(10),(19). The condition is often fatal when patients have one or repeated acute heart failure episodes(19). As an AHF episode approaches, patients become severely breathless and rapidly gain weight due to fluid build-up in the lungs and around the body. This is often compared to the sensation of drowning(20).

Patients experiencing an AHF episode need to be rushed to the emergency room for urgent treatment, making AHF the most common cause of hospitalization in patients over 65 years(10),(21). Currently 20 to 30% of patients die within 1 year after experiencing an AHF episode, and 3-4% do not survive the initial episode(12),(13),(14),(15),(16),(17). This means AHF causes more deaths than some advanced cancers, including breast and bowel cancer(22).

Disclaimer

The foregoing release contains forward-looking statements that can be identified by words such as to request, to submit, goal, will, potential, could, continuing review, expected, would, or similar terms, or by express or implied discussions regarding potential marketing approvals for RLX030 or the timing of any such approvals, or regarding potential future revenues from RLX030. 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 approved for sale in any market, or at any particular time. Nor can there be any guarantee that RLX030 will be commercially successful in the future. In particular, management s expectations regarding RLX030 could be affected by, among other things, the uncertainties inherent in research and development, including unexpected regulatory actions or delays or government regulation generally; unexpected clinical trial results and additional analysis of existing clinical data; 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 2012, the Group achieved net sales of USD 56.7 billion, while R&D throughout the Group amounted to approximately USD 9.3 billion (USD 9.1 billion excluding impairment and amortization charges). Novartis Group companies employ approximately 133,000 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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(2) Novartis press release FDA grants Breakthrough Therapy designation to Novartis serelaxin (RLX030) for acute heart failure issued on June 21, 2013

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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: January 24, 2014

By: /s/ MALCOLM B. CHEETHAM

Name: Malcolm B. Cheetham
Title: Head Group Financial Reporting and Accounting