NOVARTIS AG
Form 6-K
November 14, 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 November 13, 2017

(Commission File No. 1-15024)

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Novartis AG

(Name of Registrant)

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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: Form 40-F:

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Yes: **No**:

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MEDIA RELEASE • COMMUNIQUE AUX MEDIAS • MEDIENMITTEILUNG

Novartis canakinumab (ACZ885) reduced cardiovascular risk by 25% in subgroup of CANTOS Phase III trial participants

- Subgroup of patients had a 25% reduction in major adverse cardiovascular events when treated with canakinumab in a new analysis of Phase III CANTOS trial presented at the American Heart Association Scientific Sessions 2017[1]
- *The analysis showed a 31% reduction in cardiovascular death and a 31% reduction in all-cause mortality in patients whose inflammation – as measured by hsCRP – decreased below 2mg/L three months after initiating canakinumab[1]*
- *hsCRP (high-sensitivity C-reactive protein) is a simple, inexpensive and widely available biomarker test for residual inflammatory risk*[2]
- *Results suggest that in the future, physicians may be able to identify patients who can achieve the greatest cardiovascular benefit from long-term canakinumab treatment*
- *Analysis showed that the estimated number of patients needed to treat (NNT) for the subgroup was 16; the NNT for the CANTOS cohort as a whole was 24*[1]

Basel, November 13, 2017 – Novartis today announced results from a new analysis of the Phase III CANTOS study presented by Dr. Paul Ridker at the American Heart Association (AHA) Scientific Sessions 2017 and published simultaneously in *The Lancet*[1]. The pre-planned secondary analysis of an exploratory endpoint showed that people with a prior heart attack who achieved hsCRP levels below 2mg/L at three months after the first dose of canakinumab had a 25% reduction in major adverse cardiovascular events (MACE) versus placebo (HRadj=0.75, 95% CI 0.66-0.85,

p<0.0001)1. These patients also had a significant reduction of 31% in the rate of cardiovascular (CV) death (HRadj=0.69, 95% CI 0.56-0.85, p=0.0004) and all-cause death (HRadj=0.69, 95% CI 0.58-0.81, p<0.0001)1. There was no significant reduction in these endpoints observed among those treated with canakinumab who achieved hsCRP levels equal to or above 2mg/L1. This analysis indicates that on-treatment hsCRP testing may offer a quick and reliable way to identify the patients most likely to achieve the greatest benefits from long-term canakinumab treatment1,2. It also demonstrates that treating inflammation in addition to lowering cholesterol may significantly reduce the risk of recurrent CV events1.

“This CANTOS analysis suggests that the initial biologic response to canakinumab may provide a simple method to identify which patients are most likely to obtain long-term benefits,” said Dr. Paul Ridker, MD, CANTOS Study Chairman and Director of the Center for Cardiovascular Disease Prevention at Brigham and Women's Hospital. “Importantly, these data also support the value of targeting inflammation when treating patients who have had a heart attack in the past, reinforcing that ‘lower is better’ when it comes to levels of inflammation.”

“This outcome is an exciting new development in the field of personalized cardiovascular medicine,” said Vas Narasimhan, Global Head, Drug Development and Chief Medical Officer, Novartis. “In addition to offering targeted cardiovascular benefits for patients, personalized treatment approaches can also be more cost-efficient for the overall healthcare system. We hope we can bring this innovative treatment to patients in the near future.”

The analysis also evaluated the number of patients needed to treat (NNT). NNT is an epidemiological measure used to communicate the effectiveness of a health-care intervention in which the lower the NNT, the more effective the intervention. The estimated NNT of the subgroup of patients was 16, indicating that 16 patients treated with canakinumab whose hsCRP values dropped below 2mg/L would need to be treated for five years to prevent one death, heart attack, stroke or coronary revascularization1. The NNT for the CANTOS cohort as a whole was 241.

Canakinumab has been shown to have major effects on inflammation, which is associated with atherothrombosis, the main cause of acute coronary syndromes and CV death1,3. People with elevated inflammatory biomarkers, such as hsCRP (high-sensitivity C-reactive protein), are at an increased risk of CV events3. The hsCRP test is a simple, inexpensive and widely available blood biomarker test that may also be used for residual inflammatory risk2. This subgroup analysis by Dr. Paul Ridker included patients whose level of hsCRP at three months was 2mg/L or greater, as well as those whose level was less than 2mg/L, which is a commonly used clinical cut point for hsCRP measuring residual inflammatory risk1,4. The analysis supports that patients who achieve an hsCRP level of less than 2mg/L by the third month on treatment may receive the greatest benefit from long-term treatment with canakinumab1. The safety profile of canakinumab in the subgroup of patients whose hsCRP levels dropped below 2mg/L was consistent with the overall study population. The overall rates of adverse events (AEs), serious AEs, and discontinuations due to AEs in CANTOS were similar to placebo across all canakinumab doses. There was no relationship between on-treatment hsCRP levels and adverse events1.

With more than 10,000 patients enrolled in the study over six years, CANTOS was one of the largest and longest-running clinical trials in Novartis history. As previously announced, initial data from the CANTOS study showed that quarterly treatment with 150mg canakinumab resulted in a statistically significant 15% reduction in MACE - a composite of CV death, non- fatal myocardial infarction, and stroke - in people with a prior heart attack and inflammatory atherosclerosis5. Pending final regulatory discussions, Novartis plans to file CANTOS CV data for regulatory approval in Q4 2017.

About CANTOS (NCT01327846)

The Canakinumab Anti-inflammatory Thrombosis Outcomes Study (CANTOS) (NCT01327846) is a randomized, double-blind, placebo-controlled, event-driven Phase III study designed to evaluate the efficacy, safety and tolerability of quarterly subcutaneous injections of canakinumab (also known as ACZ885) in combination with standard of care in the prevention of recurrent cardiovascular (CV) events among 10,061 people with a prior myocardial infarction (MI) and with a high-sensitivity C-reactive protein (hsCRP) level of ≥2mg/L. The study evaluated three different doses of canakinumab vs placebo. The primary endpoint of the study was time to first occurrence of major adverse CV events (MACE), a composite of CV death, non-fatal MI, and non-fatal stroke. Initial results showed that canakinumab met

the primary endpoint and led to a statistically significant 15% reduction in the risk of MACE, compared to placebo (p-value 0.021)5. This benefit was sustained throughout the duration of the study (median follow up 3.7 years) and was largely consistent across key pre-specified baseline subgroups5. Secondary endpoints included time to first occurrence of the composite CV endpoint consisting of CV death, non-fatal MI, non-fatal stroke and hospitalization for unstable angina requiring unplanned revascularization; time to

new onset type 2 diabetes among people with pre-diabetes at randomization; time to occurrence of non-fatal MI, non-fatal stroke or all-cause mortality; and time to all-cause mortality. The study ran for approximately six years. The overall rates of adverse events (AEs), serious AEs, and discontinuations due to AEs were similar to placebo across all canakinumab doses. During the average follow-up time of 3.7 years, serious infections were reported in 11.3% vs 10.2% and malignancies were reported in 6.4% vs 7.1% of participants (canakinumab 150mg vs placebo, respectively)5. Fatal infections were rare and occurred in about one per 1,000 patients on placebo5.

In a pre-specified secondary analysis designed to address the relationship of hsCRP reduction to event reduction in CANTOS the researchers evaluated the effects of canakinumab on rates of MACE, CV mortality, and all-cause mortality according to on- treatment levels of hsCRP. The researchers used multivariable modeling to adjust for baseline factors associated with achieved hsCRP and multiple sensitivity analyses to address the magnitude of residual confounding.

About heart attack and inflammatory atherosclerosis

Heart attack occurs in about 580,000 people every year in the five largest European Union countries and 750,000 people in the United States alone6,7. Despite optimal standard treatment, patients who have had a prior heart attack live with a higher ongoing risk of secondary major adverse cardiovascular events (MACE), a composite of cardiovascular (CV) death, non-fatal myocardial infarction, and non-fatal stroke7. It has been shown that in about four in 10 people, this risk is directly related to the increased inflammation associated with inflammatory atherosclerosis as measured by a high-sensitivity C-reactive protein (hsCRP) biomarker level of ≥2mg/L8. The recurrent MACE in people with inflammatory atherosclerosis are associated with increased morbidity, mortality and reduced quality of life and currently represent a major economic burden on patients and healthcare systems around the world.

About ACZ885 (canakinumab)

Canakinumab (ACZ885) is a selective, high-affinity, fully human monoclonal antibody that inhibits IL-1 , a key cytokine in the inflammatory pathway known to drive the continued progression of inflammatory atherosclerosis9-13. Canakinumab works by blocking the action of IL-1 for a sustained period of time, therefore inhibiting inflammation that is caused by its over-production14,15. Canakinumab is the first and only investigational treatment which has shown that selectively targeting inflammation significantly reduces cardiovascular risk.

Disclaimer

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current beliefs and expectations 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 the investigational or approved products described in this press release will be submitted or approved for sale or for any additional indications or labeling in any market, or at any particular time. Nor can there be any guarantee that such products will be commercially successful in the future. In particular, our expectations regarding such products 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; our ability to obtain or maintain proprietary intellectual property protection; the particular prescribing preferences of physicians and patients; global trends

toward health care cost containment, including government, payor and general public pricing and reimbursement pressures; general economic and industry conditions, including the effects of the persistently weak economic and financial environment in many countries; 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 121,000 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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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 13, 2017 By: /s/ PAUL PENEPENT
Name: Paul Penepent
Head Group Financial
Title: Reporting and
Accounting