NOVARTIS AG
Form 6-K
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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 August 27, 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:

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Yes: **No**:

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MEDIA RELEASE • COMMUNIQUE AUX MEDIAS • MEDIENMITTEILUNG

Novartis Phase III CANTOS study demonstrates that targeting inflammation with ACZ885 reduces cardiovascular risk

- *Study showed a significant 15% reduction of major adverse cardiovascular events (MACE) in people with a prior heart attack and inflammatory atherosclerosis who were treated with 150mg of ACZ885, in addition to standard of care including lipid-lowering therapy*
- *Effect driven by 24% relative reduction in risk of heart attack; a non-significant 10% reduction in risk of cardiovascular death was observed*
- *Sub-group of study participants whose inflammation was reduced below the median hsCRP saw a 27% relative risk reduction on primary MACE end-point*
- *Additionally, a review of blinded, pre-planned oncology safety analyses revealed a 77% reduction in lung cancer mortality and 67% reduction in lung cancer cases in patients treated with 300mg of ACZ885*
- *Novartis plans to discuss the CANTOS study findings with health authorities and to submit the cardiovascular data for regulatory approval*

The digital press release with multimedia content can be accessed here:Basel, August 27, 2017 - Novartis today revealed primary data from CANTOS, a Phase III study evaluating quarterly injections of ACZ885 (canakinumab) in people with a prior heart attack and inflammatory atherosclerosis as measured by high-sensitivity C-reactive protein (hsCRP) levels of >=2mg/L, a known marker of inflammation. Trial participants received either placebo or one of three doses of ACZ885 in combination with current standard of care therapies, with 91% of them taking lipid-lowering statins. The study showed that ACZ885 led to a statistically significant 15% reduction in the risk of major adverse cardiovascular events (MACE), a composite of non-fatal heart attack, non-fatal stroke and cardiovascular death, compared to placebo (p-value 0.021). 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 sub groups. The study met the primary endpoint in cardiovascular risk reduction with the 150mg dose of ACZ885; the 300mg dNovartis International AG (Reseller: InPublic - PNR API) - 1602355ose showed similar benefits and the 50mg dose was less

efficacious. The study findings in cardiovascular risk reduction were presented today at the European Society of Cardiology (ESC) Congress and published simultaneously in *The New England Journal of Medicine*. The details of the additional CANTOS lung cancer findings were also presented at ESC and simultaneously published in *The Lancet*.

"The results of CANTOS are exciting because we now have clear evidence that in addition to lowering cholesterol, targeting inflammation reduces patients' risk of cardiovascular disease, and perhaps even lung cancer," said Dr. Paul Ridker, MD, CANTOS Study Chairman and Director of the Center for Cardiovascular Disease Prevention at Brigham and Women's Hospital. "On behalf of the entire study team, I would like to thank all of the clinical trial site physicians and healthcare providers, and of course the thousands of patients who participated in this trial over the years, for their passion and dedication to advancing this important research."

"These data are a significant milestone because they show that selectively targeting inflammation with ACZ885 reduces cardiovascular risk and that ACZ885 may also be an important immuno-oncology therapy targeting IL-1ß for lung cancer," said Vas Narasimhan, Global Head, Drug Development and Chief Medical Officer, Novartis. "We look forward to submitting the CANTOS data to regulatory authorities for approval in cardiovascular and initiating additional phase III studies in lung cancer."

With more than 10,000 patients enrolled in the study over the last six years, CANTOS was one of the largest and longest-running clinical trials in Novartis' history. Additional positive benefit observed in the CANTOS study was a reduction in the number of patients requiring unplanned revascularization for worsening chest pains (unstable angina), a component of the four-point MACE key secondary endpoint. Treatment with 150mg of ACZ885 resulted in a:

- **17%** reduction in the relative risk of a composite of non-fatal heart attack, non-fatal stroke, cardiovascular death and hospitalization for unstable angina requiring unplanned revascularizations ($p < 0.005$)
- **36**% reduction in the relative risk of hospitalization for unstable angina requiring unplanned revascularization, as a component of this composite ($p < 0.021$)
- **32%** reduction in the relative risk of any coronary revascularization ($p < 0.001$) which was an exploratory endpoint

Time to all-cause mortality was also assessed as a secondary endpoint in the study, with 150mg dose of ACZ885 demonstrating an 8% reduction which did not reach statistical significance. The other key secondary endpoint - new onset of diabetes - was neutral.

A sub-group responder analysis showed that the 50% of patients who achieved an hsCRP value of less than the median at three months after the first injection experienced a 27% relative risk reduction on the primary MACE end-point.

The overall rates of adverse events (AEs), serious AEs, and discontinuations due to AEs were similar to placebo across all ACZ885 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 (ACZ885 150mg vs placebo, respectively). At the 300mg dose, serious infections were reported in 11.7% vs 10.2% and malignancies were reported in 6.7% vs 7.1% of participants (ACZ885 300mg vs placebo, respectively). Fatal infections occurred in about one per 1,000 patients on placebo. Although rare, this occurrence was higher in the combined ACZ885 group than placebo. On the other hand, cancer deaths were cut in half by ACZ885 such that there was a non-significant reduction in death from any cause.[1]

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 ACZ885 (also known as canakinumab) 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 ACZ885 vs placebo. The primary endpoint of the study was time to first occurrence of major adverse CV event (MACE), a composite of CV death, non-fatal MI, and non-fatal stroke. 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 median follow-up time was 3.7 years. The study ran for approximately six years.

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 alone.[4],[5] 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 death, non-fatal myocardial infarction, and non-fatal stroke.[2] 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/L.[6] 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)
ACZ885 (canakinumab) is a selective, high-affinity, fully human monoclonal antibody that inhibits IL-1ß, a key cytokine in the inflammatory pathway known to drive the continued progression of inflammatory atherosclerosis. ACZ885 works by blocking the action of IL-1ß for a sustained period of time, therefore inhibiting inflammation that is caused by its over-production. ACZ885 is the first and only investigational treatment which has shown that selectively targeting inflammation significantly reduces cardiovascular risk.

Disclaimer
This press release contains forward-looking statements, including "forward-looking statements" within the meaning of the United States Private Securities Litigation Reform Act of 1995. Forward-looking statements can generally be identified by words such as "potential," "can," "will," "plans," "expect," "anticipate," "look forward," "believe," "committed," "investigational," "pipeline," "launch," "may," "exciting," "perhaps," "look forward to," or similar terms, or by express or implied discussions regarding potential marketing approvals, new indications or labeling for ACZ885, or regarding potential future revenues from ACZ885. You should not place undue reliance on these statements. Such forward-looking statements are based on our 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 ACZ885 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 ACZ885 will be commercially successful in the future, or that efforts to achieve commercial success for ACZ885 in any new indications would not have a negative impact on the product's sales in existing indications. In particular, our expectations regarding ACZ885 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, as well as the planned clinical trials of ACZ885 in lung cancer, and the length of time such planned clinical trials may take; regulatory actions or delays or government regulation generally; our ability to obtain proprietary intellectual property protection or to maintain it for an amount of time sufficient to enable ACZ885 to become a commercial success in any new indications that may be approved; the particular prescribing preferences of physicians and patients, including uncertainties as to whether physicians and patients would adopt ACZ885 into their treatment regimens in any new indications that might be approved; global trends toward health care cost containment, including government, payor and general public pricing and reimbursement pressures, and potential conflicts between the appropriate pricing of ACZ885 in the indications for which the product is currently sold, and potential appropriate pricing of the product in any new indications that might be approved; 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 119,000 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: August 28, 2017 By: /s/ PAUL PENEPENT
Name: Paul Penepent
Title: Head Group Financial Reporting and Accounting