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:

Form 20-F: Form 40-F:

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Indicate by check mark whether the registrant by furnishing the information contained in this form is also thereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934.

Yes: **No**:

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MEDIA RELEASE • COMMUNIQUE AUX MEDIAS • MEDIENMITTEILUNG

Novartis announces analysis published in The Lancet showing ACZ885 reduced lung cancer mortality by 77% in the CANTOS study with further studies planned

- *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*
- *CANTOS is the first Phase III clinical trial to support a long-established hypothesis from pre-clinical models that inhibition of IL-1ß impacts cancer incidence and mortality*
- *CANTOS cardiovascular study which met primary endpoint as published in The New England Journal of Medicine, validating anti-inflammatory agent impacts cardiovascular risk reduction*
- *Novartis plans to discuss lung cancer hypothesis with regulatory authorities and begin evaluation in additional Phase III confirmatory studies*

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

Basel, August 27, 2017 - Earlier today, Novartis revealed primary data from the Canakinumab Anti-inflammatory Thrombosis Outcomes Study (CANTOS), a Phase III study evaluating the role of ACZ885, an interleukin-1ß antibody, in people with a prior heart attack and inflammatory atherosclerosis as measured by high-sensitivity C-reactive protein (hsCRP), a known marker of inflammation, at levels of >=2mg/L. An additional pre-planned analysis showed that ACZ885 reduced the rate of lung cancer incidence and mortality among study participants. Effects were dose-dependent with a relative risk reduction of 67% finding for lung cancer (HR 0.33 [95% CI: 0.18-0.59]) and 77% for lung cancer mortality (HR 0.23 [95% CI: 0.10-0.54]) observed among patients receiving the 300mg dose of ACZ885 every three months1. As part of the study design, all cases of cancers were reviewed by an independent panel of oncologists unaware of study drug allocation. Details of the lung cancer analysis were presented today, alongside the cardiovascular outcomes data, at the European Society of Cardiology (ESC) Congress and published simultaneously in *The Lancet1,2*. The details of the cardiovascular findings were also presented at ESC and simultaneously published in *The New England Journal of Medicine3*.

"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 Paul Ridker, MD, CANTOS Study Chairman and Director of the Center for Cardiovascular Disease Prevention at Brigham and Women's Hospital. "From a cardiologist perspective, these findings represent a novel approach to the treatment of heart disease with the potential to also help patients with certain cancers."

"By targeting the IL-1ß pathway, CANTOS study findings provide further insights into the role of inflammation in lung cancer and medical researchers additional data to conduct trials to prove this important hypothesis," said Howard A. "Skip" Burris, MD, President of Clinical Operations and Chief Medical Officer, Sarah Cannon Research Institute (Nashville, TN) and Chair of the CANTOS Cancer Adjudication Committee.

"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 cardiovascular data to regulatory authorities for approval and initiating additional phase III studies in lung cancer."

IL-1ß is a key cytokine in the inflammatory pathway known to drive the continued progression of inflammatory atherosclerosis. By inhibiting the tumor micro-environment mediated by interleukin-1ß, the CANTOS study data analysis explored whether ACZ885, a monoclonal antibody that targets and inhibits the action of IL-1ß, could have an impact on the occurrence and progression of 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. Trial participants with a prior history of atherosclerosis, a hsCRP level of >=2mg/L, and who were free of previously-diagnosed cancer, received either placebo or one of three doses of ACZ885 (50mg, 150mg, and 300mg subcutaneously every 3 months). All participants received current standard of care therapies, with 91% of participants taking lipid-lowering statins. During a median follow up of 3.7 years, as compared to placebo, ACZ885 resulted in dose dependent reduction in hsCRP of 26 to 41% and a dose-dependent reduction in IL-6 of 25 to 43% (p=<0.0001). For all cancer related mortality (n=196 across treatment), ACZ885 resulted in a significant reduction compared to placebo at the 300mg dose (HR 0.49: [95% CI: 0.31-0.75] p=0.0009). Incident lung cancer (n=129 across treatment) was reduced at the 300mg dose versus placebo (HR 0.33 [95% CI: 0.18-0.59]; p=<0.0001) and the 150mg dose versus placebo (HR 0.61 [95% CI: 0.39-0.97]; p=0.034). Lung cancer mortality was significantly less common at the 300mg dose versus placebo (HR 0.23 [95% CI: 0.10-0.54] p=0.0002)[1].

The overall rates of adverse events (AEs), serious AEs, and discontinuations due to AEs were similar to placebo across all ACZ885 doses. In the six year-long study, 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 in 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].

Over the last decade, the development of immuno-oncology agents have become a primary therapeutic category in fighting certain types of cancers and have improved the outcome for patients, especially those living with lung cancer. Novartis is exploring a number of immunotherapy approaches including priming or educating the immune system so that it can recognize cancer as a threat, attempting to unleash immune cells that have already been primed, and investigating ways to make the tumor more accessible to immune cells. This scientific research is helping the medical community to understand how cancer is responding to therapy - including which patients may benefit from treatments.

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.
In agreement with the US Food and Drug Administration in 2010, incident cancers were adjudicated by a blinded independent oncology monitoring committee. Data on incident cancers, including cancer deaths, were collected as serious adverse events and analyzed in a prospective fashion. History of cancer was an exclusion criteria to study enrollment (baseline CT scans were not conducted) and diagnosis of cancer led to a discontinuation of treatment with ACZ885 as per protocol.

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.

Novartis Commitment to Lung Cancer
Worldwide, lung cancer causes more deaths than colon, breast and prostate cancer combined, and an estimated 1.8 million new cases of lung cancer are diagnosed each year[4,5]. Novartis Oncology's research in innovative therapies has helped transform treatment approaches for patients living with mutation-driven types of lung cancer. The company continues its commitment to the global lung cancer community through ongoing studies, as well as the exploration of investigational targeted and immuno-oncology agents in non-small cell lung cancer.

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," "planned," "expect," "anticipate," "look forward," "believe," "commitment," "investigational," "pipeline," "launch," "exciting," "perhaps," "may," "could," "exploring," "attempting," "investigating," 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.

Novartis is on Twitter. Sign up to follow @Novartis at http://twitter.com/novartis and @NovartisCancer at http://twitter.com/novartiscancer.

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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