NOVARTIS AG
Form 6-K
October 23, 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 October 23, 2014

(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: x Form 40-F: o

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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: o **No**: x

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MEDIA RELEASE • COMMUNIQUE AUX MEDIAS • MEDIENMITTEILUNG

Novartis AIN457 (secukinumab) meets primary endpoint in two Phase III studies in ankylosing spondylitis, a debilitating joint condition of the spine

- *Secukinumab is the first selective IL-17A inhibitor to meet primary endpoint in two pivotal Phase III studies showing improvement in active ankylosing spondylitis (AS) patients symptoms versus placebo*

- *AS is a painful, progressively debilitating condition associated with inflammation of the spine, causing irreversible consequences that significantly reduce patients mobility and quality of life(1),(2)*

- *Up to 40% of patients have an inadequate or no response to standard of care anti-TNF (tumor-necrosis-factor) medicines, currently the only biologic therapies available for patients with AS(1)*

- *The secukinumab results in AS follow positive topline data in psoriatic arthritis (PsA) announced in September; joint regulatory filing of secukinumab in AS and PsA planned for 2015*

Basel, October 23, 2014 Novartis today announced that AIN457 (secukinumab) met primary and key secondary endpoints in two pivotal Phase III studies (MEASURE 1 and MEASURE 2) in patients with ankylosing spondylitis (AS). Key endpoints included improvements in signs and symptoms of the disease versus placebo and associated improvements in physical function and quality of life. Secukinumab is an investigational medicine that works by stopping the action of interleukin-17A (IL-17A)(3), a protein that is central to the development of inflammatory diseases(4), including AS. MEASURE 1 and MEASURE 2 enrolled a combined total of approximately 600 patients. Detailed results of the studies will be presented at an upcoming medical congress.

We are thrilled to see positive results with secukinumab in AS, a gravely debilitating condition with a significant remaining unmet need as up to 40% of patients do not respond to anti-TNF therapies, said Vasant Narasimhan, Global Head of Development, Novartis Pharmaceuticals. With these results in AS and the recently announced positive results in psoriatic arthritis, we now have data from four Phase III trials of secukinumab in spondyloarthropathies which we look forward to presenting at a congress later this year.

AS is a common type of spondyloarthropathy (SpA), a family of long-term diseases impacting joints (inflammatory diseases), which includes other conditions such as psoriatic arthritis (PsA)(5). Occurring in up to 1% of the general population typically young men and women aged 25 or older AS is a painful, debilitating condition primarily associated with swelling, in severe cases fusion of the spine (bones growing together), and irreversible bone formation (new bones growing)(6),(7). It can cause persistent back pain, stiffness, fatigue and curvature of the spine that result in patients becoming progressively disabled and unable to work(1),(2). People with AS have very few therapeutic options available to them. In case of non-response to non-steroidal anti-inflammatory

drugs (NSAIDs), anti-TNF medicines are the only currently available biologic treatment alternative but are not effective for all patients, representing a substantial unmet need(1).

Joint regulatory applications for secukinumab in AS and PsA are planned for 2015. This follows the secukinumab global regulatory applications for moderate-to-severe plaque psoriasis which were filed in October 2013 with regulatory decisions anticipated in late 2014 or early 2015.

MEASURE 1 and MEASURE 2 are randomized, placebo-controlled, multicenter studies designed to demonstrate efficacy of secukinumab in AS compared to placebo and to assess safety, tolerability and long-term effectiveness. The Assessment of Spondyloarthritis International Society criterion (ASAS 20) was the primary endpoint. Secukinumab showed an acceptable safety profile in both studies which was consistent with that observed in the large psoriasis clinical trial program, involving approximately 4,000 patients(8).

About ankylosing spondylitis (AS)

Ankylosing spondylitis (AS) is a common type of spondyloarthropathy (SpA), a family of long-term diseases of joints (inflammatory disease)(5). Up to 70% of patients with severe AS can develop spinal fusion (bones grow together), significantly reducing mobility and quality of life(2),(9),(10). AS occurs in up to 1% of the general population and typically affects young men and women aged 25 or older(6),(7). Certain genetic factors increase a person s risk of developing AS by more than 50%(11).

About secukinumab (AIN457) and interleukin-17A (IL-17A)

Secukinumab (AIN457) is a fully human monoclonal antibody that selectively neutralizes the action of IL-17A(3). Secukinumab is the first medicine selectively targeting IL-17A with positive Phase III results for the treatment of AS. IL-17A, a protein that stimulates inflammation, is central to the development of psoriasis and other inflammatory arthritic diseases, including AS(4).

In addition to AS, secukinumab is also in clinical trials for the treatment of psoriasis arthritis (PsA) and rheumatoid arthritis (RA). Global regulatory applications for secukinumab in AS and PsA are planned for 2015. This follows the secukinumab global regulatory applications for moderate-to-severe plaque psoriasis which were filed in October 2013 with approvals anticipated in late 2014 or early 2015.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by words such as investigational, will, upcoming, look forward, planned, anticipated, or similar terms, or by express or implied discussions regarding potential marketing authorizations for AIN457, or regarding potential future revenues from AIN457. 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 AIN457 will be approved for

sale in any market where it has been submitted. Neither can there be any guarantee that AIN457 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 AIN457 will be commercially successful in the future. In particular, management s expectations regarding AIN457 could be affected by, among other things, the uncertainties inherent in research and development, including unexpected clinical trial results and additional analysis of existing clinical data; unexpected 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; 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 2013, the Group achieved net sales of USD 57.9 billion, while R&D throughout the Group amounted to approximately USD 9.9 billion (USD 9.6 billion excluding impairment and amortization charges). Novartis Group companies employ approximately 136,000 full-time-equivalent associates and operate in more than 140 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.

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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: October 23, 2014

By: /s/ MALCOLM B. CHEETHAM

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