NOVARTIS AG
Form 6-K
December 14, 2016

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 December 12, 2016

(Commission File No. 1-15024)

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Novartis AG

(Name of Registrant)

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(Address of Principal Executive Offices)

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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:

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):

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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 provides update on pegpleranib Phase III clinical trial program in patients with neovascular age-related macular degeneration (nAMD or wet AMD)

- *Two pivotal Phase III studies did not show additional improvement in best corrected visual acuity (BCVA) for pegpleranib and Lucentis (ranibizumab) combination treatment over standard of care Lucentis monotherapy[1,2]*

- *Recent Lucentis EU approval in new choroidal neovascularization (CNV) indication demonstrates Novartis' strong commitment to innovate and grow Lucentis (ranibizumab) as standard of care in diseases of the retina – Lucentis is the only treatment available for a wide range of CNV conditions*

- *Novartis continues to discover and develop next generation of treatment for neovascular age-related macular degeneration (nAMD) patients with RTH258*

Basel, December 12, 2016 – Novartis today announced initial topline results from two pivotal Phase III clinical studies evaluating the safety and efficacy of pegpleranib in combination with Lucentis® (ranibizumab) for the treatment of neovascular age-related macular degeneration (nAMD). Studies OPH1002 and OPH1003, sponsored by Ophthotech Corporation, did not meet the primary endpoint of superiority for the pegpleranib and ranibizumab combination therapy, measured as best corrected visual acuity (BCVA) in terms of additional letter gains over ranibizumab monotherapy. At month 12, patients in the pegpleranib and ranibizumab combination treatment groups showed a 10.74 letter BCVA improvement in study OPH1002[1] and a 9.91 letter BCVA improvement in study OPH1003[2]. Patients treated with ranibizumab alone showed a 9.82 letter BCVA improvement in the OPH1002[1] study and a 10.36 letter BCVA improvement in the OPH1003[2] study.

“We are fully committed to innovate and grow Lucentis as standard of care in diseases of the retina and to continue our research in this area. The key message from the data is that the proven efficacy of Lucentis monotherapy was not improved by the addition of pegpleranib", said Vasant Narasimhan, Global Head, Drug Development and Chief Medical Officer, Novartis. “Together with Ophthotech we continue to analyze the data. We are confident that underlying data will provide further understanding and guidance on how best to help patients with this disease. Novartis continues researching new treatment options for patients with nAMD, and we are looking forward to the phase III results of our next generation treatment RTH258.”

Data from the OPH1002 and OPH1003 studies, including secondary and exploratory efficacy endpoints, will be presented at a future medical meeting.

About the OPH1002 and OPH1003 studies

The OPH1002 and OPH1003 studies are both randomized, double blind, Phase III clinical trial studies designed to evaluate the safety and efficacy of pegpleranib 1.5mg in combination with ranibizumab versus ranibizumab monotherapy in people with subfoveal neovascular age-related macular degeneration (nAMD)[1,2]. A total of 1,248 patients over the age of 50 were enrolled across both studies (621 patients in the OPH1002 study and 627 patients in the

OPH1003 study)[6] and were randomized to receive either pegpleranib in combination with ranibizumab or ranibizumab alone each month up to the 12 month primary endpoint of the study[1,2].

The primary efficacy endpoint in both studies was defined as mean change in best corrected visual acuity (BCVA) from baseline at 12 months. A number of secondary and exploratory efficacy endpoints are currently being analyzed across both studies[1,2].

About nAMD

Age-related macular degeneration (AMD) is a common and degenerative eye condition caused by damage to the macula[3], and is globally ranked as the third most common cause of blindness[7]. The disease is a leading cause of vision loss in people aged over 50 years[3] and impacts an estimated 20 to 25 million people worldwide[4]. It is the primary cause of blindness in industrialized countries[7]. Neovascular age-related macular degeneration (nAMD or wet AMD) occurs when abnormal blood vessels form underneath the macula and cause damage to the cells, particularly if they leak blood and fluid into the eye[8]. Without treatment, vision deteriorates within days[8].

About pegpleranib

Pegpleranib is a 32-mer pegylated DNA aptamer that selectively binds to PDGF-BB and PDGF-AB homo and hetero-dimers, respectively, thereby disrupting the interaction with their cognate tyrosine kinase receptors (PDGF-BB with PDGFR- , PDGFR - and PDGFR- ; PDGF-AB with PDGFR- and PDGFR-). These receptors are commonly expressed on cells of mesenchymal origin such as pericytes[9-13]. In a preclinical model, pegpleranib potently stripped neovascular pericytes from the underlying endothelial cells[14]. Pericyte stripping from a neovascular complex may leave the underlying endothelial cells in an unprotected and vulnerable state, thereby increasing their sensitivity to the effects of VEGF blockade[9-10,12,15-17]. Pegpleranib is currently being investigated in Phase III clinical trials for the treatment of neovascular age-related macular degeneration (nAMD or wet AMD)[1,2,5].

About the Ophthotech and Novartis license and commercialization agreement

In May 2014, Novartis signed a license and commercialization agreement with Ophthotech Corporation (Ophthotech) and holds the exclusive rights to pegpleranib outside the United States. Ophthotech holds the rights to pegpleranib in the United States.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by words such as “commitment,” “continues,” “next generation,” “continue,” “confident,” “will,” “committed,” “looking forward,” “being analyzed,” “being inv or similar terms, or by express or implied discussions regarding potential marketing approvals for RTH258, potential marketing approvals for pegpleranib, alone or in combination with Lucentis, potential new indications or labeling for Lucentis, alone or in combination with pegpleranib, or regarding potential future revenues from RTH258, pegpleranib, Lucentis, or the combination of pegpleranib and Lucentis. 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 RTH258 will be submitted or approved for sale in any market, or at any particular time. Neither can there be any guarantee that pegpleranib, alone or in combination with Lucentis, will be submitted or approved for sale in any market, or at any particular time. Nor can there be any guarantee that Lucentis, alone or in combination with pegpleranib, will be submitted or approved for any additional indications or labeling in any market, or at any particular time. Neither can there be any guarantee that RTH258, pegpleranib, Lucentis, or the combination of pegpleranib and Lucentis will be commercially successful in the future. In particular, management’s expectations regarding RTH258, pegpleranib, Lucentis, and the combination of pegpleranib

and Lucentis 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 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, eye care and cost-saving generic pharmaceuticals. Novartis is the only global company with leading positions in these areas. In 2015, the Group achieved net sales of USD 49.4 billion, while R&D throughout the Group amounted to approximately USD 8.9 billion (USD 8.7 billion excluding impairment and amortization charges). Novartis Group companies employ approximately 118,000 full-time-equivalent associates. Novartis products are available in more than 180 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: December 12, 2016 By: /s/ PAUL PENEPENT
Name: Paul Penepent
Head Group Financial
Title: Reporting and
Accounting