

NOVARTIS AG
Form 6-K
August 25, 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 August 25, 2016

(Commission File No. 1-15024)

Novartis AG

(Name of Registrant)

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(Address of Principal Executive Offices)

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Novartis announces positive phase III results showing efficacy of BAF312 in patients with secondary progressive MS

The Phase III EXPAND study of BAF312 (siponimod) in secondary progressive multiple sclerosis (SPMS) met its primary endpoint of reducing the risk of three-month confirmed disability progression versus placebo. There are currently very limited treatment options for SPMS, a form of MS associated with gradual worsening of symptoms and accumulation of disability, independent of relapses. EXPAND is the largest study ever conducted in SPMS, and is part of Novartis' ongoing leadership and commitment to people with MS.

Basel, August 25, 2016 - Novartis today announced the Phase III EXPAND study, evaluating the efficacy and safety of oral, once-daily, BAF312 (siponimod) in secondary progressive multiple sclerosis (SPMS), met its primary endpoint of a reduction in the risk of disability progression, compared with placebo. The EXPAND study represents the largest randomized, controlled study in SPMS to date.[1]

"SPMS is a particularly disabling form of MS, and there is a need for effective treatment options to help delay disability progression in those living with the condition," said Vasant Narasimhan, Global Head of Drug Development and Chief Medical Officer for Novartis. "The positive EXPAND data are encouraging for a disease with such a high unmet need. We look forward to sharing the results at the upcomingECTRIMS congress, and thank all of the study participants and investigators."

Topline results of the EXPAND study, including primary and key secondary endpoints, will be presented as a late breaking oral abstract at the 32nd Congress of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS), September 17th, in London, UK. Novartis will complete full analyses of the data and evaluate next steps in consultation with health authorities.

About the EXPAND study

The EXPAND study is a randomized, double-blinded, placebo-controlled Phase III study, comparing the efficacy and safety of BAF312 versus placebo in people with secondary progressive multiple sclerosis (SPMS).[2] The EXPAND study is the largest randomized, controlled study in SPMS to date.[1] The study included 1,651 people with SPMS from 31 countries. Patients were randomized to receive either 2mg BAF312 or placebo in a 2:1 ratio respectively.[2]

The primary endpoint of the study was an improvement in the time to three-month confirmed disability progression, as measured by the expanded disability status scale (EDSS), versus placebo.[2] Secondary endpoints included delay in the time to six-month confirmed disability progression versus placebo, the time to confirmed worsening of at least 20% from baseline in the timed 25-foot walk test (T25FW), T2 lesion volume, annualized relapse rate (ARR), and the safety and tolerability of BAF312 in people with SPMS.[2]

About BAF312 (siponimod)

BAF312 (siponimod) is a selective modulator of specific types of the sphingosine-1-phosphate (S1P) receptor.[3] The S1P receptor is commonly found on the surface of specific cells residing in the central nervous system (CNS), that are responsible for causing CNS damage that drives loss of function in secondary progressive MS (SPMS).[3] BAF312 enters the brain and by binding to these specific receptors, may prevent the activation of these harmful cells, helping to reduce loss of physical and cognitive function associated with SPMS.[3]-[6]

About Multiple Sclerosis

Multiple sclerosis (MS) is a chronic disorder of the central nervous system (CNS) that disrupts the normal functioning of the brain, optic nerves and spinal cord through inflammation and tissue loss.[7] There are three types of MS: relapsing-remitting MS (RRMS), secondary progressive MS (SPMS) and primary progressive MS (PPMS). The evolution of MS results in an increasing loss of both physical and cognitive (e.g. memory) function.[8] This has a substantial negative impact on the approximately 2.3 million people worldwide affected by MS.[9]

About Novartis in Multiple Sclerosis

The Novartis multiple sclerosis (MS) portfolio includes Gilenya® (fingolimod, an S1P modulator), which is indicated for relapsing forms of MS and is also in development for pediatric MS. Extavia® (interferon beta-1b for subcutaneous injection) is approved in the US for the treatment of relapsing forms of MS. In Europe, Extavia is approved to treat people with relapsing remitting MS, secondary progressive MS (SPMS) with active disease and people who have had a single clinical event suggestive of MS.

In addition to BAF312 (siponimod) in development in SPMS, investigational compounds include ofatumumab (OMB157), a fully human monoclonal antibody in development for relapsing MS. Ofatumumab targets CD20, and is expected to begin phase III pivotal studies in the second half of 2016.

In the US, the Sandoz Division of Novartis markets Glatopa® (glatiramer acetate injection) 20mg/mL, the first generic version of Teva's Copaxone®* 20mg.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by words such as "currently," "ongoing," "commitment," "look forward," "upcoming," "will," "in development," "investigational," or similar terms, or by express or implied discussions regarding potential marketing approvals for BAF312, potential new indications or labeling for ofatumumab, or regarding potential future revenues from BAF312, ofatumumab, Gilenya, Extavia, Glatopa 20mg, or any of the other products and investigational compounds in the Novartis MS portfolio. 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 BAF312 will be submitted or approved for sale in any market, or at any particular time. Neither can there be any guarantee that ofatumumab 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 BAF312, ofatumumab, Gilenya, Extavia, Glatopa 20mg, or any of the other products and investigational compounds in the Novartis MS portfolio will be commercially successful in the future. In particular, management's expectations regarding BAF312, ofatumumab, Gilenya, Extavia, Glatopa 20mg, and the other products and investigational compounds in the Novartis MS portfolio 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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References

- [1] Kappos L et al. Baseline Subgroup Characteristics of EXPAND: A Phase 3 Study of Siponimod (BAF312) for the Treatment of Secondary Progressive Multiple Sclerosis (P3.084). *Neurology*. 2016; 86(16):suppl. P3.084
- [2] ClinicalTrials.gov. Exploring the Efficacy and Safety of Siponimod in Patients With Secondary Progressive Multiple Sclerosis (EXPAND). <https://clinicaltrials.gov/ct2/show/NCT01665144?term=BAF312+expand&rank=1> (link is external). Last accessed July 2016.
- [3] Gergely P et al. The selective sphingosine 1-phosphate receptor modulator BAF312 redirects lymphocyte distribution and has species-specific effects on heart rate. *Br J Pharmacol* 2012; 167(5): 1035-47.
- [4] Aslanis V, Faller T, Van de Kerkhof E, Schubart A, Wallström E, Beyerbach A. Siponimod (BAF312) (and/or its metabolites) penetrates into the CNS and distributes to white matter areas. *Mult Scler J* 2012; 18(10(suppl)): P792.
- [5] Brana C et al. Immunohistochemical detection of sphingosine-1-phosphate receptor 1 and 5 in human multiple sclerosis lesions. *Neuropathol Appl Neurobiol* 2014; 40(5): 564-78.
- [6] Tavares A, Barret B, Alagille D, et al. Brain distribution of MS565, an imaging analogue of siponimod (BAF312), in non-human primates. *Neurology* 2014; 82(10 (Suppl)): P1.168.
- [7] PubMed Health. Multiple Sclerosis. <http://www.ncbi.nlm.nih.gov/pubmedhealth/PMHT0024311/> (link is external). Last accessed July 2016.
- [8] National Multiple Sclerosis Society. Ms Symptoms. <http://www.nationalmssociety.org/Symptoms-Diagnosis/MS-Symptoms> (link is external). Last accessed July 2016.
- [9] Multiple Sclerosis International Federation. Atlas of MS 2013. <http://www.msif.org/wp-content/uploads/2014/09/Atlas-of-MS.pdf> (link is external). Last accessed July 2016.

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Media release (PDF): <http://hugin.info/134323/R/2037163/759025.pdf>

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 25, 2016 By: /s/ PAUL PENEPEPENT
Name: Paul Penepent
Head Group Financial
Title: Reporting and
Accounting