NOVARTIS AG
Form 6-K
June 01, 2018

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 June 1, 2018

(Commission File No. 1-15024)

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Novartis AG

(Name of Registrant)

Lichtstrasse 35

4056 Basel

Switzerland

(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:

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Yes: **No**:

Novartis International AG
Novartis Global Communications
CH-4002 Basel
Switzerland

http://www.novartis.com

MEDIA RELEASE • COMMUNIQUE AUX MEDIAS • MEDIENMITTEILUNG

Novartis receives positive CHMP opinion for Aimovig® (erenumab) for the prevention of migraine

- If approved, Aimovig®(erenumab) is expected to be the first and only available therapy designed specifically for migraine prevention in the EU

- *Positive opinion based on robust data package demonstrating Aimovig's consistent, sustained efficacy and placebo-like safety profile*

- *Aimovig, self-administered once every four weeks, via an auto-injector pen, has shown significant benefits in a broad spectrum of migraine patients, including those who are difficult to treat*

Basel, June 1, 2018 – Novartis today announced the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has recommended approval for Aimovig® (erenumab) for the prevention of migraine in adults who have at least four migraine days per month. The World Health Organization (WHO) has listed migraine as one of the top ten causes of years lived with disability worldwide[1]. Aimovig is the first treatment of its kind specifically developed to prevent migraine by blocking the calcitonin gene-related peptide receptor (CGRP-R), which plays a critical role in migraine. If approved, Aimovig will be self-administered once every four weeks via an auto-injector pen.

"We are excited to be one step closer to bringing the first targeted migraine prevention therapy to patients in Europe," said Paul Hudson, Chief Executive Officer at Novartis Pharma. "If approved, patients suffering from migraine will no longer have to rely on preventive treatments repurposed from other diseases that are often associated with poor tolerability and lack of efficacy. With Aimovig, physicians may soon provide these patients with an option for a safe, effective and well-tolerated migraine prevention treatment."

The CHMP positive opinion is based on a robust data package, including four Phase II and III clinical studies of more than 2,600 patients experiencing four or more migraine days per month. Aimovig demonstrated clinically meaningful and statistically significant benefits versus placebo in reducing the number of migraine days per month across the spectrum of migraine, giving patients more migraine free days of their lives back. In the clinical program, half of patients with episodic migraine (4-14 monthly migraine days) taking Aimovig had their number of migraine days cut by half or more, a significantly higher percentage compared to placebo (STRIVE: 43.3% and 50% Aimovig 70mg and 140mg respectively; placebo: 26.6%, p<.001). Patients with chronic migraine (15 or more monthly migraine days) achieved a similar, statistically significant response (40% and 41% Aimovig 70mg and 140mg respectively, placebo: 23%, p<.001)[2,3].

The safety, efficacy and tolerability of Aimovig have now been assessed in clinical studies involving more than 3,000 patients. This number includes the CHMP data package and further studies such as LIBERTY, a dedicated study in difficult-to-treat populations – those with episodic migraine who have failed two to four prior treatments. In LIBERTY, patients taking Aimovig 140 mg had significantly higher likelihood of having their migraine days cut by half or more compared to placebo[3]. Across all studies, the safety and tolerability profile of Aimovig

was comparable to placebo, including in a dedicated study assessing cardiovascular safety in patients with stable (exercise-induced) angina[3-7].

The European Commission will review the CHMP opinion and usually delivers its final decision within three months. The decision will be applicable to all 28 European Union member states plus Iceland, Norway and Liechtenstein. Aimovig received FDA approval on May 17, 2018 and additional regulatory filings are underway with other health authorities worldwide. Novartis has created a patient access program for Aimovig, as part of the company's commitment to provide patients with safe and timely access in accordance with local health authority regulations and applicable laws in cases where the product is not or not yet available.

Novartis and Amgen are co-commercializing Aimovig in the U.S. Amgen has exclusive commercialization rights to the drug in Japan and Novartis has exclusive rights to commercialize in the rest of the world.

About Aimovig® (erenumab)

Aimovig is the only FDA-approved treatment specifically developed to prevent migraine by blocking the calcitonin gene related peptide receptor (CGRP-R), which plays an important role in migraine. Aimovig has been studied in several large, global, randomized, double-blind, placebo-controlled studies to assess its safety and efficacy in migraine prevention. More than 3,000 patients have participated in our overall clinical trial program across the four placebo-controlled Phase II and Phase III clinical studies and their open-label extensions.

About Migraine

Migraine is a distinct neurological disease[8]. It involves recurrent attacks of moderate to severe head pain that is typically pulsating, often unilateral and associated with nausea, vomiting and sensitivity to light, sound and odors[9]. Migraine is associated with personal pain, disability and reduced quality of life, and financial cost to society[10]. It has a profound and limiting impact on an individual's abilities to carry out everyday tasks and was reported by the World Health Organization to be one of the top 10 causes of years lived with disability for men and women[1]. It remains under-recognized and under-treated[10,11]. Existing preventive therapies have been repurposed from other indications and are often associated with poor tolerability and lack of efficacy, with high discontinuation rates among patients[12].

About Novartis and Amgen Neuroscience Collaboration

In August 2015, Novartis entered into a global collaboration with Amgen to develop and commercialize pioneering treatments in the field of migraine and Alzheimer's disease. The collaboration focuses on investigational Amgen drugs in the migraine field, including Aimovig (approved by the FDA in May 2018 for the preventive treatment of migraine in adults) and AMG 301 (currently in Phase II development). In April 2017, the collaboration was expanded to include co-commercialization of Aimovig in the U.S. For the migraine program, Amgen retains exclusive

commercialization rights in Japan, and Novartis has exclusive commercialization rights in Europe, Canada and rest of world. Also, the companies are collaborating in the development and commercialization of a beta-secretase 1 (BACE) inhibitor program in Alzheimer’s disease. The oral therapy CNP520 (currently in Phase III for Alzheimer’s disease) is the lead molecule and further compounds from both companies' pre- clinical BACE inhibitor programs may be considered as follow-on molecules.

Novartis in Neuroscience

Novartis has a strong ongoing commitment to neuroscience and to bringing innovative treatments to patients suffering from neurological conditions where there is a high unmet need. We are committed to supporting patients and physicians in multiple disease areas, including Multiple Sclerosis (MS), Alzheimer's disease, Parkinson's disease, Epilepsy and

Attention Deficit Hyperactivity Disorder, and have a promising pipeline in MS, Alzheimer's disease, migraine and specialty neurology (e.g., neuropathic pain).

Disclaimer

This press release contains 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 “positive opinion,” “recommended,” “recommendation,” “potential,” “could,” “expected,” “will,” “underway,” “ongoing,” “commitment “committed,” “investigational,” “promising,” “pipeline,” “may,” “goal,” or similar terms, or by express or implied discussions regarding potential marketing approvals, new indications or labeling for Aimovig or the other investigational or approved products described in this press release, or regarding potential future revenues from such products or the collaboration with Amgen. 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 Aimovig or the other investigational or approved products described in this press release will be submitted or approved for sale or for any additional indications or labeling in any market, or at any particular time. Neither can there be any guarantee that the collaboration with Amgen will achieve any or all of its intended goals and objectives, or be commercially successful. Nor can there be any guarantee that Aimovig or the other investigational or approved products described in this press release will be commercially successful in the future. In particular, our expectations regarding such products, and the collaboration with Amgen, 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; regulatory actions or delays or government regulation generally; global trends toward health care cost containment, including government, payor and general public pricing and reimbursement pressures; our ability to obtain or maintain proprietary intellectual property protection; the particular prescribing preferences of physicians and patients; general political and economic conditions; safety, quality or manufacturing issues; potential or actual data security and data privacy breaches, or disruptions of our information technology systems, 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 2017, the Group achieved net sales of USD 49.1 billion, while R&D throughout the Group amounted to approximately USD 9.0 billion. Novartis Group companies employ approximately 124,000 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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Novartis Media Relations

Central media line: +41 61 324 2200
E-mail: media.relations@novartis.com

Eric Althoff	Angela Fiorin
Novartis Global Media Relations	Novartis Global Pharma Communications
+41 61 324 7999 (direct)	+41 61 324 8631 (direct)
+41 79 593 4202 (mobile)	+41 79 752 6955 (mobile)
eric.althoff@novartis.com	angela.fiorin@novartis.com

Novartis Investor Relations

Central investor relations line: +41 61 324 7944
E-mail: investor.relations@novartis.com

Central		North America	
Samir Shah	+41 61 324 7944	Richard Pulik	+1 212 830 2448
Pierre-Michel Bringer	+41 61 324 1065	Cory Twining	+1 212 830 2417
Thomas Hungerbuehler	+41 61 324 8425		
Isabella Zinck	+41 61 324 7188		

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: June 1, 2018 By: /s/ PAUL PENEPENT
Name: Paul Penepent
Title: Head Group Financial Reporting and Accounting