Novartis International AG
Novartis Global Communications
CH-4002 Basel
Switzerland

http://www.novartis.com

MEDIA RELEASE • COMMUNIQUE AUX MEDIAS • MEDIENMITTEILUNG

Novartis and Amgen announce FDA approval of Aimovig™ (erenumab), a novel treatment developed specifically for migraine prevention

- *Migraine is a severe neurologic disease that profoundly impacts millions of patients in the United States*
- *Aimovig is the first and only FDA-approved treatment to block the calcitonin gene-related peptide receptor (CGRP-R), which plays an important role in migraine*
- *Aimovig was consistently shown to reduce monthly migraine days, including in more difficult to treat populations, with many patients achieving at least a 50% reduction*

Basel, May 17, 2018 – Novartis today announced that the US Food and Drug Administration (FDA) has approved Aimovig™ (erenumab) for the preventive treatment of migraine in adults. Aimovig is a novel therapeutic approach as the first and only FDA-approved treatment specifically developed to prevent migraine by blocking the calcitonin gene-related peptide receptor (CGRP-R), which is believed to play a critical role in migraine. Aimovig 70 mg is self-administered once monthly via Amgen's device, the SureClick® autoinjector and does not require a loading dose. Some patients may benefit from a dosage of 140 mg once monthly.

"The FDA approval of Aimovig demonstrates Novartis commitment to bringing meaningful new medicines to patients with complex neurologic diseases, like migraine," said Paul Hudson, CEO Novartis Pharmaceuticals. "Aimovig is the first therapy of its kind targeting the CGRP receptor, and has demonstrated robust efficacy across the spectrum of migraine. We look forward to working closely with Amgen in the U.S. to bring this treatment to physicians and their patients, who could now gain days of their lives back each month."

In Phase II and III studies in chronic and episodic migraine, Aimovig resulted in significant reductions in monthly migraine days and use of acute migraine medications compared to placebo. These effects on monthly migraine days have been shown to be sustained for up to 15 months in an ongoing open-label extension study in episodic migraine (four to 14 headache days per month).

The efficacy, tolerability and safety of Aimovig has been assessed in more than 3,000 patients, including in a Phase IIIb study (LIBERTY) and an ongoing open-label extension of up to five years in duration. In LIBERTY, a dedicated study in difficult-to-treat populations – those with episodic migraine who have failed two to four prior treatments – patients taking Aimovig 140 mg had nearly three-fold higher odds of having their migraine days cut by half or more compared to placebo[1]. In clinical studies of Aimovig, the most common adverse reactions were injection site reactions and constipation.

"Having a treatment designed to specifically address the complex nature of migraine is an important and welcome step forward in headache medicine. Aimovig offers self-administration with proven efficacy across a spectrum of patients, including in those who have previously

tried other preventive therapies without success," said Stewart J. Tepper, MD, Professor of Neurology at the Geisel School of Medicine at Dartmouth Medical School. "Importantly, in clinical trials, Aimovig patients were able to start and stay on therapy – with a discontinuation rate of two percent due to adverse events – and experienced sustained migraine prevention."

Amgen and Novartis are committed to supporting the migraine community and to helping appropriate patients with affordable access to Aimovig. The Aimovig Ally™ product support program has been created to help patients navigate insurance coverage and identify potential access resources for those who are uninsured or underinsured.

The U.S. list price of Aimovig is $575 for once monthly 70 or 140 mg single-use prefilled SureClick® autoinjectors, or $6,900 annually. The price of Aimovig reflects the value it brings to patients and society, including the financial impact on sufferers, caregivers and employers, while also factoring in critical issues such as patient affordability, and fair and timely access.

Aimovig is expected to be available to patients in the U.S. within one week.

The European Medicines Agency (EMA) Marketing Authorization Application (MAA) for Aimovig is under review. Novartis expects approval in the EU in the coming months.

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 is believed to play a critical 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 LIBERTY
LIBERTY (NCT03096834) is a Phase IIIb, multicenter, randomized 12-week, double-blind, placebo-controlled study evaluating the safety and efficacy of Aimovig in patients with episodic migraine (defined in the trial as four to 14 migraine days per month at baseline) who have failed up to four prior preventive treatments for migraine[1]. In the study, 246 participants with episodic migraine who had two to four previous treatment failures were randomized to receive Aimovig 140 mg or placebo during the 12-week double-blind treatment phase. The primary endpoint was the percentage of patients with at least a 50% reduction of monthly migraine days from baseline over the last four weeks of the double-blind treatment phase of the study (weeks 9-12). The study includes an ongoing 52-week open-label extension study.

About Migraine
Migraine is a distinct neurological disease[2]. 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[3]. Migraine is associated with personal pain, disability and reduced quality of life, and financial cost to society[4]. 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[5]. It remains under-recognized and under-treated[4,6]. 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[7].

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 "potential," "could," "expected," "expects," "look forward," "believed," "ongoing," "commitment," "committed," "step forward," "investigational," "promising," "pipeline," 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
Novartis Global Media Relations
+41 61 324 7999 (direct)
+41 79 593 4202 (mobile)
eric.althoff@novartis.com

Angela Fiorin
Novartis Global Pharma Communications
+41 61 324 8631 (direct)
+41 79 752 6955 (mobile)
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		